POLICY ROUNDTABLES

Intellectual Property Rights

2004

Introduction

The OECD Competition Committee debated intellectual property rights in June 2004. This document includes an executive summary and the documents from the meeting: an analytical note by Mr. Jeremy West of the OECD, written submissions from Argentina, Canada, Chinese Taipei, France, Japan, Korea, Mexico, New Zealand, Norway, Switzerland, Turkey, the United Kingdom, and the United States, as well as an aide-memoire of the discussion.

Overview

Competition policy and intellectual property (IP) policy are interdependent and affect each other in important ways**.** Competition agencies should not become involved in the IP-granting process itself, but they can undertake a variety of measures to promote a greater consideration of competition issues by IP agencies**.**

When evaluating licensing arrangements, it is advisable for competition authorities to determine whether the parties' relationships are vertical or horizontal**.** When evaluating grant-back obligations, it is advisable for competition authorities to distinguish between severable and non-severable improvements**.** Patent pools, like most licensing arrangements, are usually beneficial to competition. They may, however, occasionally reduce or eliminate it. When evaluating patent pools, it is advisable for competition authorities to determine whether the pooled technologies are complementary and essential**.**

The nature of the biotechnology industry creates unusual challenges for IP agencies, which have been criticised for issuing biotechnology patents too freely. Too many patents, in turn, may lead to the unnecessary creation of market power and a slowdown in innovation. The nature of the biotechnology industry also presents competition agencies with substantial challenges and implies that an extra measure of caution may be warranted when contemplating intervention.

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FOREWORD

This document comprises proceedings in the original languages of a Roundtable on Intellectual Property Rights which was held by the Competition Committee in June 2004.

It is published under the responsibility of the Secretary General of the OECD to bring information on this topic to the attention of a wider audience.

This compilation is one of a series of publications entitled “Competition Policy Roundtables”.

PRÉFACE

Ce document rassemble la documentation dans la langue d’originale dans laquelle elle a été soumise, relative à une table ronde sur les droits de propriété intellectuelle, qui s’est tenue en juin 2004 dans le cadre du Comité de la concurrence.

Il est publié sous la responsabilité du Secrétaire général de l’OCDE, afin de porter à la connaissance d’un large public les éléments d’information qui ont été réunis à cette occasion.

Cette compilation fait partie de la série intitulée « Les tables rondes sur la politique de la concurrence ».

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EXECUTIVE SUMMARY

by the Secretariat

Considering the discussion at the roundtable, the delegate submissions and the background paper, a number of key points emerge:

(1) Competition policy and intellectual property (IP) policy are interdependent and affect each other in important ways.

Overzealous enforcement of competition laws against IP owners can damage the incentives to innovate that IP systems are designed to foster. On the other hand, when IP is excessively easy to obtain, it may lead to market power, to the detriment of competition and consumers. Therefore, in an "easy patentability" environment, for example, competition agencies and courts tend to compensate by using competition laws to limit the negative effects of over-patenting. Because competition law is a relatively blunt instrument for that purpose, however, it would be preferable to fix the problems from within the patent system rather than from outside it.

(2) *Competition agencies should not become involved in the IP-granting process itself, but nevertheless they can undertake a variety of measures to promote a greater consideration of competition issues by IP agencies during their IP approval procedures.*

For several reasons, such as a lack of relevant technical expertise and limited resources, it does not appear to be prudent for competition authorities to assume responsibilities related to the initial review of IP applications. Instead, delegates came up with a variety of ways for competition authorities to try to improve IP agencies' awareness of competition issues so that the latter agencies can begin to take any necessary steps to improve the IP approval process themselves. Among the ideas that have already been successfully implemented in some jurisdictions are opening interdisciplinary dialogs with patent agencies to foster greater mutual understanding of each other's fields, commissioning expert reports that study a nation's patenting system to determine whether and how it is causing any undue competition problems, and holding seminars or hearings in which academics, public and private sector practitioners, and industry participants come together to discuss the overlap between IP and competition policies. Whatever IP-related initiatives competition agencies may take, they should strive to limit the anticompetitive aspects of IPR while respecting its necessity.

(3) Competition agencies should consider publishing a set of guidelines describing how they will analyse licensing agreements and other conduct involving intellectual property.

Issuing guidelines will help businesses to structure their IP arrangements so that they are consistent with competition laws. In addition, competition agencies themselves will benefit from the exercise of determining what their approach will be to various types of licensing conduct and other uses of IP. For example, the European Commission recently issued new guidelines on patents and licensing that explain the Commission's approach, create "safe harbours" in which businesses can be assured that they are acting within the law, and aim to create a good balance between protecting incentives to innovate and protecting competition. Similarly, the Korean Fair Trade Commission has enacted guidelines for reviewing the exercise of IP rights that include a "black list" of behaviour that can harm competition, as well as a "white list" of exempted practices that may be shown to have either a benign or a positive effect on competition.

(4) When evaluating licensing arrangements, it is advisable for competition authorities to determine whether the parties' relationships are vertical or horizontal**.**

In other words, it is helpful to identify whether agreements are between competitors or between non-competitors because that information will inform the policy decision that needs to be made. Obviously, agreements between competitors are more likely to cause competitive problems and should therefore be subjected to greater scrutiny. Authorities in some jurisdictions expressly distinguish horizontal from vertical licensing agreements, as reflected in the European Commission's new guidelines, whereas other authorities, such as the Japan Fair Trade Commission, take the structural nature of the relationship into account as part of a broader rule of reason approach.

(5) When evaluating grant-back obligations, it is advisable for competition authorities to distinguish between severable and non-severable improvements.

A grant-back obligation is a provision in a licensing arrangement that requires the licensee to grant a license on any improvements it patents related to the original invention back to the licensor. Grant-backs may encourage efficient licensing by serving as a form of financing for cash-poor licensees who are willing to share some of the fruits of their research with licensors in lieu of an up-front payment. Some grant-back arrangements, however, are more likely to damage incentives to innovate and/or cause competitive problems than others, depending on whether they encompass severable improvements and whether they are exclusive. Severable improvements can be used by licensees without infringing the original invention, whereas non-severable improvements cannot be used without infringing the original invention. Because licensors already have a measure of authority over non-severable improvements, even exclusive grant-backs of non-severable innovations are relatively less likely to cause competition concerns. In contrast, grant-backs of severable improvements may damage incentives for follow-on innovation because they are not otherwise legally dependent on the licensor. They may also serve as a means of prolonging the licensor's market power by nullifying or reducing the threat of what would otherwise become rival products. Therefore, these types of grant-backs should be subjected to relatively more scrutiny, particularly if they are exclusive.

(6) Patent pools, like most licensing arrangements, are usually beneficial to competition. They may, however, occasionally reduce or eliminate it. When evaluating patent pools, it is advisable for competition authorities to determine whether the pooled technologies are complementary and essential.

The discussion reflected general agreement that patent pools have strong pro-competitive potential, particularly in the biotechnology industry. Patent pools are formed when two or more parties get together and arrange to have their patents licensed as a package. They make it easier to exploit technology by removing IP barriers, promote the integration of complementary technologies, and reduce the transaction costs of obtaining multiple licenses. They are also viewed as a cheaper and faster way to resolve some disputes than litigation is. Nevertheless, patent pools are uncommon in the biotechnology industry so far and when they do arise, they also bring some competition concerns with them. Patent pools that include only complementary and essential patents are especially less likely to cause competitive problems than other kinds of pools. If, on the other hand, a pool includes patents that are substitutes for each other, then there is a risk that the pool is actually a device for jointly selling what would otherwise be competing technologies. Moreover, if a pool includes patents that are not essential (*i.e.*, patents that have substitutes outside the pool), then it may foreclose third-party technologies because pool licensees will have already been granted access to the technology included in the pool.

(7) An "anticommons" problem does not seem to be a problem at present in the biotechnology industry, but the conditions that could cause one to develop do exist.

An anticommons is a situation that is often mentioned in academic literature as a cause for concern for IP and competition policymakers. It arises when so many patents have been awarded that the difficulty of identifying which licenses are needed, and of negotiating and paying for those licenses, is so great that further innovation is discouraged or even halted. There is, however, little evidence to suggest that the biotechnology industry currently has an anticommons problem, according to several sources such as the 2002 hearings held on competition and IP policy by the U.S. antitrust authorities and an expert report by the Swiss Federal Institute of Intellectual Property on research and patenting in biotechnology. Nevertheless, the biotech industry does have several characteristics that make it fertile ground for an anticommons, such as a proliferation of patents held by a large number of market participants and an occasional tendency by companies to accumulate IP for defensive purposes.

(8) There is some disagreement about whether unilateral refusals to license IP should ever be deemed anti-competitive and, if so, how to remedy them.

In several jurisdictions, it is possible for a unilateral refusal to license IP to violate competition laws, and there are procedures for using compulsory licensing as a remedy in such cases. Typically, in those jurisdictions, the competition agency performs a dominance test and if it is met, then the agency examines whether that dominance is being used via an IP right to create conditions that might reduce competition. For example, a recent decision by the European Court of Justice allows compulsory licensing remedies when unilateral refusals to license IP prevent the emergence of a new product, are unjustified, and exclude any competition in a secondary market. Compulsory licensing can be a fast and effective means of forcing competition into a market, but it has certain disadvantages and burdens that affect innovation, competition agencies and courts. In contrast, there are very few examples of liability stemming from unilateral refusals to license IP in other countries such as the U.S., where the recent *Trinko* decision suggests that there can be no antitrust liability for such conduct and thus, no mandatory licensing, either. Of course, it is sometimes the case that refusals to license IP simply do not harm competition. For example, in its *Punto-Flex* case, the Mexican competition authority found that a unilateral refusal to license had actually increased competition, so no action was taken against the IP holder.

(9) Most OECD countries recognise some version of a generally accepted principle that using a patented invention for purely experimental purposes is not patent infringement.

The experimental use exemption is especially important in the biotechnology industry because research tools, upon which other inventions and potential inventions are dependent, make up a large proportion of the patents awarded. Furthermore, the exemption may ease the effects of any eventual anticommons by clearing a path through patent thickets for at least some follow-on research. In addition, the experimental use exemption can increase competition in countries where it is interpreted liberally, as it can allow companies to work with patented technologies to determine whether they might have other useful applications, or to ensure that generic drugs are available as soon as a patent expires. If applied too readily, however, the exemption may discourage innovation by depriving inventors of the full measure of reward from their inventions.

(10) The nature of the biotechnology industry creates unusual challenges for IP agencies, which have been criticised for issuing biotechnology patents too freely. Too many patents, in turn, may lead to the unnecessary creation of market power and a slowdown in innovation.

The biotechnology industry is characterised by rapid growth, complexity, comparative youth, and a tendency for its participants to attach a high degree of importance to IP. In combination, these characteristics have created an industry that collectively submits a large and quickly growing number of difficult, highly technical patent applications, which makes it harder for patent examiners to pare down broad claims and weed out all of the application that do not meet statutory patentability criteria. Approving patent applications that should have been limited or rejected could, in some cases, reduce

competition by providing patent protection to undeserving technologies. It could also retard innovation by making it more difficult for inventors to do their work without infringing or paying for someone else's technology.

(11) The nature of the biotechnology industry also presents competition agencies with substantial challenges and implies that an extra measure of caution may be warranted when contemplating intervention.

The discussion revealed that a number of agencies consider themselves under-equipped to analyse this technologically advanced and quickly changing industry. While some agencies have begun to take steps to recruit personnel with expertise geared toward IP and/or biotechnology, others do not have sufficient funding to do so. In either case, considering how few competition cases have been brought in the biotechnology industry at this relatively early stage, participants recognised that it is sensible for them to proceed carefully in this field, so as to ensure that their actions do not have the unintended effect of discouraging innovation. The industry's rapid development has also led to situations in which enforcement officials have found that by the time they are ready to take action, the relevant companies have changed their behaviour or their ownership.

SYNTHÈSE

par le Secrétariat

De la discussion en table ronde, des contributions des délégués et du document de référence, il ressort un certain nombre de points clés :

(1) La politique de la concurrence et la politique relative à la propriété intellectuelle (PI) sont interdépendantes et s'influencent l'une l'autre de façon importante.

Un excès de zèle dans l'application des lois sur la concurrence aux détenteurs de PI peut nuire aux incitations à innover que les systèmes de PI sont censés favoriser. Par contre, lorsque les droits de propriété intellectuelle sont excessivement faciles à obtenir, cela peut conduire à un pouvoir de marché, préjudiciable à la concurrence et aux consommateurs. Par conséquent, dans un environnement où l'obtention de brevets est aisée, par exemple, les autorités de la concurrence et les tribunaux ont tendance à compenser en utilisant la législation sur la concurrence pour limiter les effets négatifs d'un brevetage excessif. Cependant, parce que la loi sur la concurrence est un instrument relativement grossier à cet égard, il serait préférable de régler les problèmes à l'intérieur du système de brevets plutôt que de l'extérieur.

(2) Les autorités de la concurrence ne devraient pas s'occuper du processus d'octroi de DPI, mais néanmoins elles peuvent prendre diverses mesures visant à promouvoir une meilleure prise en compte des questions de concurrence par les autorités responsables de la PI au cours des procédures d'approbation de la PI.

Pour plusieurs raisons, telles qu'un manque de connaissances techniques spécialisées dans le domaine et des ressources limitées, il ne semble pas prudent que les autorités de la concurrence assument des responsabilités liées à l'examen initial des demandes en matière de PI. En revanche, les délégués proposent une série de moyens par lesquels les autorités de la concurrence devraient tenter de mieux sensibiliser aux questions de concurrence les organismes en charge de la PI, de façon à ce que ces organismes puissent commencer à prendre eux-mêmes les mesures nécessaires pour améliorer le processus d'approbation en matière de PI. Parmi les idées qui ont déjà été mises en oeuvre avec succès dans certaines juridictions, citons l'ouverture d'un dialogue multidisciplinaire avec des offices de brevets afin de favoriser une meilleure compréhension mutuelle des domaines de chacun, la commande de rapports d'experts qui étudient le régime de brevets d'une nation pour déterminer s'il pose éventuellement des problèmes par rapport à la concurrence, et la tenue de séminaires ou d'auditions où des universitaires, des praticiens du secteur public et du secteur privé ainsi que des participants de l'industrie se réunissent pour discuter du chevauchement entre politique de la concurrence et politique relative à la PI. Quelles que soient les initiatives en rapport avec la PI que puissent prendre les autorités de la concurrence, elles devraient s'efforcer de limiter les aspects anticoncurrentiels des DPI, tout en respectant la nécessité de ces droits.

(3) Les autorités de la concurrence devraient envisager de publier une série de lignes directrices décrivant comment elles vont analyser les accords de licence et autres comportements impliquant la propriété intellectuelle.

La publication de lignes directrices aidera les entreprises à structurer leurs dispositions en matière de PI de façon à ce qu'elles soient compatibles avec les lois sur la concurrence. En outre, les autorités de la

concurrence elles-mêmes bénéficieront de l'exercice consistant à déterminer quelle sera leur approche des divers types de comportement en matière d'octroi de licences et autres utilisations de la PI. Par exemple, la Commission européenne a publié récemment de nouvelles directives sur les brevets et licences qui expliquent la démarche de la Commission, créent des « zones de sécurité » où les entreprises peuvent être assurées qu'elles agissent dans le cadre de la loi, et visent à établir un bon équilibre entre la protection des incitations à innover et la protection de la concurrence. De la même manière, la Fair Trade Commission de la Corée a mis en oeuvre des lignes directrices pour examiner l'exercice des DPI, qui comprennent une « liste noire » de comportements susceptibles de nuire à la concurrence, ainsi qu'une « liste blanche » de pratiques exemptées qui peuvent se révéler avoir soit un effet bénin, soit un effet positif sur la concurrence.

(4) Lors de l'évaluation des accords de licence, il est souhaitable que les autorités de la concurrence déterminent si les relations des parties sont verticales ou horizontales.

Autrement dit, il est utile de savoir si les accords sont conclus entre concurrents ou entre non concurrents, parce que cette information servira de base à la décision qu'il convient de prendre. A l'évidence, les accords entre concurrents risquent davantage de poser des problèmes concurrentiels et devraient donc être soumis à un contrôle plus strict. Dans certaines juridictions, les autorités distinguent expressément les accords de licence horizontaux des accords verticaux, comme on le voit dans les nouvelles directives de la Commission européenne, tandis que d'autres autorités, telles que la Fair Trade Commission du Japon, tiennent compte de la nature structurelle de la relation dans le cadre d'une démarche plus large de bon sens.

(5) Lors de l'évaluation des obligations de cession en retour, il est souhaitable que les autorités de la concurrence distinguent les perfectionnements séparables de ceux qui ne le sont pas.

Dans un accord de licence, une obligation de cession en retour est une disposition qui exige de l'acquéreur de la licence (licencié) qu'il rétrocède à l'inventeur une licence sur tout perfectionnement lié à l'invention initiale qu'il fait breveter. Les cessions en retour peuvent encourager l'efficience en matière de concession de licences, en servant en quelque sorte de financement pour les acquéreurs de licences qui ont peu de trésorerie et qui sont prêts à partager certains fruits de leur recherche avec leur concédant au lieu de lui verser immédiatement une somme forfaitaire. Cependant, certains accords de cession en retour risquent davantage que d'autres de porter atteinte aux incitations à innover et/ou de poser des problèmes de concurrence, selon qu'ils englobent ou non des perfectionnements séparables et qu'ils sont ou non exclusifs. Des perfectionnements séparables peuvent être utilisés par les licenciés sans qu'il soit porté atteinte à l'invention originale, ce qui n'est pas le cas des perfectionnements non séparables. Parce que les concédants ont déjà un certain pouvoir sur les perfectionnements non séparables, même les cessions en retour exclusives d'innovations non séparables risquent relativement moins de causer des soucis en matière de concurrence. Par contre, les cessions en retour de perfectionnements séparables peuvent être préjudiciables à des innovations complémentaires, parce qu'en l'absence de cession en retour, le concédant n'aurait juridiquement aucun droit sur ceux-ci. Elles peuvent aussi servir de moyen de prolonger le pouvoir de marché du concédant en annulant ou en réduisant la menace de ce qui deviendrait sinon des produits rivaux. C'est pourquoi ces types de cessions en retour devraient être soumis à plus de contrôle, surtout s'ils sont exclusifs.

(6) Les communautés de brevets, comme la plupart des accords de licence, sont habituellement profitables à la concurrence. Occasionnellement, toutefois, ils peuvent réduire ou éliminer la concurrence. Lors de l'évaluation des communautés de brevets, il est souhaitable que les autorités de la concurrence déterminent si les technologies mises en commun sont complémentaires et essentielles.

Les débats reflètent l'opinion générale selon laquelle les communautés de brevets ont un fort potentiel pro-concurrentiel, notamment dans le secteur des biotechnologies. Les communautés de brevets sont

constituées de deux ou plusieurs parties qui se regroupent et s'arrangent pour que leurs brevets fassent l'objet d'un contrat de licence global. Il leur devient plus facile d'exploiter la technologie en supprimant les obstacles liés à la PI, de promouvoir l'intégration de technologies complémentaires et de réduire les coûts de transaction liés à l'obtention de licences multiples. C'est aussi une façon moins onéreuse et plus rapide de résoudre certains différends que de passer par une procédure judiciaire. Néanmoins, les communautés de brevets ne sont pas très répandues actuellement dans le secteur des biotechnologies, et lorsqu'il s'en forme, elles apportent aussi avec elles quelques préoccupations relatives à la concurrence. Les communautés qui ne comprennent que des brevets complémentaires et essentiels sont surtout moins susceptibles de poser des problèmes de concurrence que d'autres types de mises en commun. Si par contre une communauté inclut des brevets qui peuvent se substituer les uns aux autres, alors il y a un risque que la communauté soit en réalité un subterfuge pour vendre conjointement ce qui serait sinon des technologies concurrentes. De plus, si une communauté comprend des brevets qui ne sont pas essentiels (c'est-à-dire qui ont des substituts en dehors du pool), alors cela peut évincer des technologies de tierces parties parce que les acquéreurs du pool se seront déjà vus consentir l'accès à la technologie incluse dans la communauté.

(7) L'"anti-commun" ne semble pas être un problème actuellement dans le secteur des biotechnologies, mais les conditions existent pour qu'il en devienne un.

Un "anti-commun" est une situation qui est souvent mentionnée dans les écrits spécialisés en tant que source de préoccupation pour les responsables des politiques de la concurrence et de la PI. Elle apparaît lorsque de si nombreux brevets ont été octroyés que la difficulté d'identifier quelles licences sont nécessaires, de négocier et de payer des redevances pour ces licences est si grande que la poursuite de l'innovation est découragée ou même stoppée. On a toutefois peu de preuves qui donnent à penser que le secteur des biotechnologies souffre actuellement d'un tel problème, selon plusieurs sources telles que les auditions organisées en 2002 sur la politique de la concurrence et de la PI par les autorités américaines de la concurrence et un rapport d'expert de l'Institut fédéral suisse de la propriété intellectuelle sur la recherche et les brevets en biotechnologies. Néanmoins, la biotechnologies présentent plusieurs caractéristiques qui en font un terrain fertile pour l'anti-commun, telles qu'une prolifération de brevets détenus par un grand nombre de participants au marché et une tendance occasionnelle des entreprises à accumuler de la PI à des fins défensives.

(8) Il y a un certain désaccord sur le fait de savoir s'il convient de considérer ou non comme anticoncurrentiels les refus unilatéraux de licence en matière de PI. Dans l'affirmative, comment faudrait-il y remédier ?

Dans plusieurs juridictions, il est possible qu'un refus unilatéral d'octroyer une licence en matière de PI viole les lois sur la concurrence, et il existe des procédures pour y remédier en recourant à la cession de licences obligatoires. En général, dans ces ressorts juridictionnels, l'autorité de la concurrence procède à un test de position dominante et, s'il est positif, elle examine si cette position dominante est utilisée par le biais d'un DPI pour créer des conditions susceptibles de réduire la concurrence. Par exemple, une récente décision de la Cour européenne de justice autorise le recours aux licences obligatoires lorsque des refus unilatéraux d'octroyer des licences en matière de PI empêchent l'émergence d'un nouveau produit, sont injustifiés et excluent toute concurrence sur un marché secondaire. Les licences obligatoires peuvent être un moyen rapide et efficace de faire entrer de force la concurrence sur un marché, mais elles présentent certains inconvénients et charges qui pèsent sur l'innovation, l'autorité de la concurrence et les tribunaux. Par contre, il y a très peu d'exemples de responsabilité provenant de refus unilatéraux de licence de PI dans d'autres pays, tels que les Etats-Unis où la récente décision *Trinko* suggère qu'il ne peut y avoir aucune responsabilité au titre de la législation antitrust pour une telle conduite et donc aucune licence obligatoire non plus. Certes, il arrive parfois que des refus de licence ne portent pas atteinte à la concurrence. Par exemple, dans l'affaire *Punto-Flex,* l'autorité mexicaine de la concurrence a jugé qu'un refus unilatéral

d'octroi de licence avait en fait accru la concurrence, de sorte qu'aucune mesure n'a été prise à l'encontre du détenteur de la PI.

(9) La plupart des pays de l'OCDE reconnaissent une version quelconque d'un principe généralement accepté selon lequel le fait d'utiliser une invention brevetée à des fins purement expérimentales ne porte pas atteinte au droit des brevets.

L'exemption pour usage expérimental est particulièrement importante dans le secteur des biotechnologies parce que les outils de la recherche, dont dépendent d'autres inventions et des inventions potentielles, constituent une grande partie des brevets accordés. En outre, l'exemption peut atténuer les effets de tout « anti-commun » éventuel en ouvrant un chemin dans le maquis des brevets, au moins pour certaines recherches dans le prolongement de l'invention initiale. En outre, l'exemption pour usage expérimental peut accroître la concurrence dans les pays où elle est interprétée de façon libérale, car elle peut permettre à des entreprises de travailler avec des technologies brevetées afin de déterminer si elles pourraient avoir d'autres applications utiles, ou de s'assurer que des médicaments génériques sont disponibles dès qu'un brevet arrive à expiration. Cependant, si elle est appliquée trop facilement, l'exemption risque de décourager l'innovation dans la mesure où elle ne permet pas aux inventeurs de profiter pleinement des retombées de leurs inventions.

(10) La nature de l'industrie des biotechnologies crée des défis inhabituels pour les organismes en charge de la PI qui ont été critiqués pour avoir octroyé trop librement des brevets en biotechnologies. Un trop grand nombre de brevets risque à son tour de conduire à la création non nécessaire d'un pouvoir de marché et à un ralentissement de l'innovation.

Le secteur des biotechnologies se caractérise par sa croissance rapide, sa complexité, sa jeunesse, comparativement à d'autres, et par une tendance qu'ont ses participants à attacher un degré élevé d'importance à la PI. La combinaison de ces traits caractéristiques a créé une industrie qui soumet collectivement un grand nombre, et un nombre en croissance rapide, de demandes de brevets difficiles, hautement techniques, de sorte que les examinateurs de brevets ont plus de mal à réduire les revendications larges et à éliminer de la demande tout ce qui ne répond pas aux critères statutaires de brevetabilité. L'approbation de demandes de brevet qui auraient dû être limitées ou rejetées pourrait, dans certains cas, réduire la concurrence en assurant la protection de brevets à des technologies qui ne le méritent pas. Elle pourrait aussi retarder l'innovation en rendant la tâche plus difficile aux inventeurs qui doivent faire leur travail sans porter atteinte à la technologie de quelqu'un d'autre, à moins d'en payer le prix.

(11) La nature des biotechnologies lance aussi aux autorités de la concurrence des défis substantiels et implique qu'il faille peut-être redoubler de prudence lorsqu'on envisage une intervention.

Il est apparu au cours de la discussion qu'un certain nombre d'organismes se considèrent sous-équipés pour analyser cette branche technologiquement avancée et en changement rapide. Tandis que certaines autorités ont commencé à prendre des mesures pour recruter du personnel hautement spécialisé dans la PI et/ou la biotechnologie, d'autres n'ont pas suffisamment d'argent pour le faire. Dans un cas comme dans l'autre, considérant le petit nombre d'affaires relatives à la concurrence qui ont été traitées apparues dans le secteur des biotechnologies jusqu'à présent, les participants reconnaissent qu'il est raisonnable d'avancer prudemment dans ce domaine, pour être sûrs que leurs actions n'ont pas pour effet non intentionnel de décourager l'innovation. Le développement rapide de cette branche a aussi amené des situations dans lesquelles les autorités chargées de faire respecter la loi ont découvert que, d'ici à ce qu'elles soient prêtes à prendre des mesures, les entreprises concernées auront changé de comportement ou de propriétaire.

BACKGROUND NOTE

1. Introduction

The science of biotechnology has been pushing the frontiers of both human knowledge and intellectual property ("IP") for three decades. As scientists developed techniques for isolating and creating genetic material[1] and began to apply them commercially, a new industry grew and so did its appetite for patent protection. The United States Supreme Court's 1980 ruling that genetically modified organisms could be patented provided much of the confidence and incentive that was needed for biotechnology innovators to build their industry.[2] Although the wisdom of granting patents on DNA is still debated, the policy of other OECD countries to allow such patents has been fairly well settled for some time, as well. The door was therefore opened for biotechnological innovation to create a flood of IP, and it did.

The number of patent applications from the biotechnology industry has grown faster than the number of patent applications from other industries over the past several years. Thousands of biotechnology patents are issued world wide every year, contributing to the development of new products, services, and tools in agriculture, pharmaceuticals, and industrial products and processes.[3] Today, the completion of the human genome[4] and the increasingly sophisticated use of human embryonic stem cells, for example, have raised the ambitions of biotechnology firms to lofty levels. They are pursuing technology that will enable them to do things such as create special cells that teach the body's immune system how to destroy cancer cells, or regenerate damaged and diseased organs.[5] The inventors who are developing these and other biotechnological innovations rely on IP rights to protect and validate their work. They also rely on IP licenses to gain access to needed tools and technologies. Empirical studies on the role of patents have, by and large, affirmed their importance in encouraging innovation in the biotechnology industry.

However, in addition to some important inventions, the rising tide of biotechnology patents has brought concerns that they are being granted too freely and too broadly. Too many patents that cover too much ground will not only harm competition, but will also stifle innovation by making further research riskier, more difficult or more expensive. At the same time, certain licensing techniques that are used in the biotechnology industry, such as grant-backs and reach-through royalties, can aggravate those problems. Recognising the growing importance of the industry and the new questions it is raising about the IP/competition interface, the Competition Committee decided in October 2003 to hold a roundtable addressing issues at the crossroads of IP and competition policy in the biotechnology field. This roundtable updates, in a more industry-specific fashion, the Committee's 1998 roundtable on Competition Policy and Intellectual Property Rights.

The key points of this paper are:

- Some observers have raised concerns that patentability standards are enforced too loosely by patent offices with respect to the biotechnology industry, and that even the technically valid patents sometimes have claims that are worded too broadly. Yet policy changes with respect to patentability and allowable patent breadth can have both positive and negative effects on innovation and competition.

- It is true that the biotechnology industry's comparative youth, complexity, and continuing rapid expansion tend to make it more difficult for patent examiners to pare down broad patent claims and weed out every application that does not meet statutory patentability criteria. Approving patent applications that should have been limited or rejected could, in some circumstances, reduce competition and incentives for innovation. In addition, the industry's dependence on patented, upstream research tools raises the possibility of patent gridlocks that impede technological progress. It has also contributed to some licensing practices (such as reach-through agreements and grant-back provisions) that could harm competition.

- A common term for a patent gridlock is an "anticommons." An anticommons is a situation in which so many patents have been awarded that the difficulty of identifying which licenses are needed, and of negotiating and paying for those licenses is so great that further innovation is discouraged or even halted. The evidence to date suggests that the biotechnology industry, though vulnerable, still has not developed an anticommons.

- Member jurisdictions have adopted different versions of a generally accepted principle that using a patented invention for purely experimental purposes is not behaviour that is subject to patent infringement liability. The experimental use exemption is important not only because it may ease the effects of any eventual anticommons, but because it can also lead to greater competition, depending on how liberally it is interpreted. At the same time, the experimental use exemption must be used judiciously because it may discourage innovation if applied too readily.

- In considering the competition effects of IP policies such as patentability and patent breadth standards and the experimental use exemption, competition agencies must address the question of how far into the IP policy realm it is appropriate for them to go. Whether they limit their IP-related activity to applying competition law in cases involving IP or they get directly involved in the formulation and application of IP policy, agencies should strive to limit the anticompetitive aspects of IPR while respecting its necessity. It appears that the wisest course of action for an agency wishing to influence IP policy is either to challenge the validity of invalid or overbroad patents through litigation or by requesting patent re-examinations, or to open a dialogue with the IP agency and take an advisory role (or both).

- Turning to licensing conduct, patent pools have been identified as another possible solution to any eventual biotechnological anticommons. Patent pools are formed when two or more parties get together and arrange to have their patents licensed as a package. Yet patent pools, at least so far, are uncommon in the industry and even if they were to arise, they would bring certain competition concerns with them. Those concerns include reducing competition in the pool participants' horizontal market (if they compete), facilitating collusion in downstream markets, foreclosing competing technologies, and reducing innovation incentives. The European Commission and U.S. antitrust agencies have developed largely similar criteria for analysing patent pools. These criteria focus on whether the pooled technologies are substitutes or complements, but also take into account other considerations designed to filter out arrangements that are likely to reduce competition.

- One licensing arrangement that has been gaining popularity in the biotechnology industry is reach-through licensing. Reach-through licensing agreements assess royalties based on the revenue generated by a downstream product, regardless of whether it is made using the licensed technology. Although this practice can facilitate efficient licensing by solving valuation and financing problems that are common in the industry, it also has the potential to cause foreclosure effects.

- Another arrangement used in the biotechnology industry is grant-back licensing. Grant-backs require licensees to give the licensor rights to any follow-on technology that the licensees patent. Like reach-throughs, grant-backs may encourage efficient licensing by serving as a form of financing for cash-poor licensees. However, they may also serve to extend or prolong a licensor's market power. Extra scrutiny by competition agencies is warranted when the licensor has a dominant position and the grant-back calls for an exclusive license to, or a total assignment of, follow-on rights.

- Agencies may encounter situations in which a unilateral refusal to license raises competition concerns in biotechnology markets, especially given the industry's dependence on upstream research tools. A very recent decision by the European Court of Justice demonstrates its willingness to impose compulsory licensing remedies when unilateral refusals to license IP prevent the emergence of a new product, are "unjustified," and exclude any competition in a "secondary" market. Exactly what conditions will satisfy those terms is not clear, though. Compulsory licensing can be an effective means of injecting competition into a market, but it has certain disadvantages and burdens that affect innovation, competition agencies and courts.

- Another type of unilateral, IP-related behaviour that agencies may encounter is patent hoarding. Firms may hoard patents because they are trying to build a wall of IP around themselves in an effort to acquire or protect a dominant position. Firms might also hoard patents because they want to use them as leverage when negotiating with companies whose patents they might be infringing. Patent hoarding is inefficient in the sense that it expends resources on creating or acquiring inventions that are not used productively. In some circumstances, it may also deter entry, but different jurisdictions have different views on whether patent hoarding could be considered unlawful. Interestingly, patent hoarding is more likely to occur when patentability standards are more relaxed, which may make it an attractive candidate for discussions that could take place between competition and IP agencies.

Part II of this paper provides a very brief recapitulation of the tensions and common goals at the intersection of IP and competition policy. Part III is an introduction to biotechnology and the features that distinguish it from other industries for purposes of IP and competition policy. Part IV addresses the ways in which patentability and patent breadth affect competition in the biotechnology industry. Part V then outlines some steps that competition agencies might take to influence the formulation and application of patent policy. Finally, Part VI turns to IP-related conduct and some of the attendant competition policy enforcement issues that arise in that context.

2. The intellectual property and competition policy interface in brief

The exploitation of intellectual property rights ("IPR") challenges some traditional assumptions about the benefits of competitive markets. Competition policy generally aims to secure the benefits that flow to consumers from marginal cost pricing by promoting competition. IP laws, on the other hand, aim to bring about the benefits that accrue from new products and creations by protecting innovators from some forms of competition, which sets up the apparent conflict between the two policy regimes.

Both IP policy and competition policy aim to encourage innovation, but both will discourage it if pursued too strongly or too weakly. On the IP side, if it is too easy to obtain patents, for example, potential inventors might be discouraged from innovating, on balance, because there are so many parties with so many patents that it is too difficult and expensive to determine which licenses are needed and to pay for them. On the competition side, if law enforcement is pursued so strongly that rivals are allowed to make unencumbered use of a company's innovation, then there will be little incentive to innovate in the first place.

A basic balance has therefore been achieved by rewarding inventors with some temporary protection from free riders, after which competition is facilitated by permitting the invention to be copied and sold by anyone. That basic balance does not ensure, however, that the two policies are always as well-aligned as they could be.

Box 1. IP Basics.

A patent gives its holder the exclusive right to make, use, and sell an invention for a limited time (usually 20 years) within the country where its application was filed. In return, the applicant must disclose the invention in the text of the application. Patents are supposed to be granted only for inventions that are novel, non-obvious, and useful (having an industrial application). In addition, the patent application must include a specification of the invention with instructions that are adequate to enable a skilled person to produce or perform the invention. In other words, the specification must be "enabling." The invention itself is defined in the "claims," which are part of the specification. The patent's scope of protection can be determined by reading the claims.

There are other types of exclusive IPRs, *i.e.*, copyrights and trademarks, but patents provide a broader protection that goes beyond the specific expression of an invention to the concept of the invention itself. That is one of the reasons why patents are the IP of choice in the biotechnology field.[6]

It is hardly controversial today for competition agencies to take actions occasionally that affect IPRs. To reduce uncertainty regarding the IP system and competition law enforcement, the circumstances under which agencies will act should be identified and publicised to the business community. Some jurisdictions, such as the European Union, Japan, and the United States have issued guidelines which serve that purpose with respect to licensing agreements.[7] However, agencies may also need to confront the decision whether to look beyond competition law itself and get involved more directly with IP processes and IP policy. Competition agencies might address, for example, issues such as whether patents were obtained despite noncompliance with an IP statute, or even what the IP law should be in the first place.

The challenge for competition authorities, regardless of how far they venture into the IP sphere, is how to minimize the anticompetitive effects of IPR while respecting its existence and the societal goals it is meant to promote. Virtually all competition laws contain exemptions or exceptions designed to ensure that they do not negate rights explicitly granted by patent laws. Agencies that limit IPRs to promote competition may inadvertently decrease the incentive to innovate, thereby doing much greater damage than the behaviour they were trying to address.

> An antitrust policy that reduced prices by 5 percent today at the expense of reducing by 1 percent the annual rate at which innovation lowers the costs of production would be a calamity. In the long run a continuous rate of change, compounded, swamps static losses.[8]

Consequently, as in merger policy, IP is an area where competition agencies must make difficult trade-offs involving uncertain future effects.

A fundamental premise must be that IPR does not necessarily create or increase market power. Many patents have been issued for inventions that never had a market, let alone market power. Furthermore, even when there is demand for an invention, a patent still cannot protect it against competition from non-infringing products, some of which may be superior in price and/or quality. Thus it is not surprising that most patents do not, in fact, bestow market power.[9] That fact has led some competition agencies to state expressly that they do not assume intellectual property creates market power.[10] Yet competition and patent law and policy still have more than ample opportunity to collide.

3. Relevant features of the biotechnology industry

3.1 Definition

A very simple definition of biotechnology is "applied biology." More specifically, it could be defined as the use of living organisms to make or enhance a therapeutic substance, a new organism, or a means of identifying and developing other products. That definition would encompass traditional methods used for plant and animal breeding and fermentation. Some people use the term to refer only to newer areas of genetic science. In this context, biotechnology might be defined as a collection of technologies that capitalise on the attributes of cells, such as their manufacturing capabilities, and use biological molecules, such as DNA and proteins, to do useful things.

3.2 Innovations aimed at improving human health

Therapeutic applications. In the biotechnology industry's early years in the 1970s and 1980s, DNA sequence patents tended to cover tangible matter that was used to make curative products. These patents were treated in roughly the same manner as patents on chemical compounds and did not encounter substantial resistance so long as they were sufficiently distinguished from naturally occurring matter.[11]

Some major biotechnology firms continue to search for DNA sequences that encode therapeutic proteins in the hope of turning them into pharmaceuticals. There is a great deal more that is valuable in genomic information, however, besides those types of proteins.[12] For example, genes can be used as diagnostic tools that signal the presence of a disease.

Research applications. Today, the study of genes and their functions, or "genomics," and the application of computer databases and algorithms to manage biological information, or "bioinformatics," have become highly important facilitators for the biomedical R&D process (as opposed to being ultimate, end-user products themselves). They are used in a variety of ways to accelerate the process of identifying, developing and enhancing therapeutic products. For example, genomic information and bioinformatics may be used to identify disease pathways or genes that show promise as drug targets.

3.3 Agricultural innovations

The character of agricultural biotechnology patents varies depending on the national system and the restrictions it places on biological patents. In some countries, it is possible to obtain a patent on a gene and its application in a plant. It is also possible to obtain a patent on a plant itself, or on processes and inventions having to do with plants or plant genes. An example of a biotechnological innovation in agriculture is genetically modified plants that are resistant to disease.

3.4 Distinguishing characteristics of biotechnology for purposes of IP and competition policy

None of the traits discussed below pertain only to the biotechnology industry, but their combined presence raises distinct IP policy and competition issues.

Youth. The biotechnology industry is relatively young, which has important implications for the scope of patent claims in the field. It is common for groundbreaking inventions that create new markets to receive broadly worded patents for a number of reasons. First, the main constraint on the scope of patent claims is the prior art in the relevant field.[13] Newer industries obviously tend to have less prior art than more established industries. Second, no one may know enough about a young field of research at the time of filing to realise that a patent claim is broad. More perniciously, the company filing the patent application may realise that it is overly broad, but patent examiners may not.

Complexity. The biotechnology industry is relatively complex in comparison with most other sectors. Furthermore, the complexity is believed to be growing, both in terms of the number of claims in patent applications and the level of difficulty in interpreting them.[14] The increasing complexity may be making it more difficult for patent examiners to keep up with the evolving technology.[15]

Rapid expansion. The overall industry is developing very rapidly and the number of DNA patents has been increasing accordingly. To gain some perspective on this growth, consider the following statistics:

- Nearly half of the world's soybean crops are now genetically engineered.[16]

- In 1990, OECD nations granted a total of roughly 1900 biotechnology patents. In 2001, the United States alone granted more than 5000 DNA patents, and Japan added another 1223.[17]

- From 1995 to 2001 the European Union experienced an average annual growth rate in biotechnology venture capital investment of 30 percent.

- The growth rate in the United States followed closely behind at 27 percent.[18]

It is possible that the growth of patent applications is straining the resources of patent agencies and therefore contributing to a deterioration in patent quality.

Applications. The majority of biotechnology research is geared toward application in the health care industry. Most of the biotechnology companies who do that work are small, focus heavily on research, and do little or no marketing. Instead, they aim to form partnerships with larger companies, often pharmaceuticals manufacturers, who handle marketing. The second largest application of biotechnology research is agricultural, involving genetically modified organisms and foods, for example. The structure in this tier of the biotechnology industry is quite different, with very large, global agribusinesses doing most of the research and holding most of the patents.

- Almost two-thirds of the more than 300 biotechnology enterprises that exist in France are involved in the health care sector.[19]

- A recent survey in the United States showed that almost three-quarters of firms engaged in biotechnology work indicated that human health applications are their primary area of biotechnology-related activity.[20]

Patents are especially important. Patents play a bigger role in spurring biotechnological innovation than they do in most other types of innovation.[21] This makes biotechnology an exception to a rather substantial body of empirical economic work that raises doubts about whether patents promote innovation significantly.[22]

A confluence of factors may help to explain the relative importance of patents in the biotechnology industry. One relevant factor is that the firms tend to be small. For example, firms with fewer than 50 employees are prevalent in Canada's biotechnology sector, accounting for almost three in four firms that innovate in the field.[23] In the United States, a recent study showed that 57 percent of firms active in the biotechnology sector have 50 employees or fewer.[24] These small companies naturally tend to have a thinner pipeline of technologies than larger firms.

Another contributing factor is that it takes a relatively long time to develop products in the biotechnology sector.[25] That, in combination with the thin pipelines, means that small biotechnology companies often have to endure many years with no sales revenue before they come up with a winning

(*i.e.*, profitable) idea. Patents validate and protect their research while it is being developed. That, in turn, may help the firms to secure investment funding and remunerative partnerships that enable them to continue working during their lean years.[26] Having a patent portfolio can enable biotechnology start-ups to secure the funding they need to bring their work to fruition and become viable competitors.

Research tools. The biotechnology industry is in a stage of development where it is generating more information than it can presently use. New genetic entities are being discovered and even created on a daily basis by scientists who are mapping the genomes of various organisms or building new kinds of cells. Sequencing the genome of a single human cell generates tens of thousands of new entities (*e.g.*, yeast containing fragments of the human genome). Even a relatively simple bacterial cell brings forth hundreds of such new entities when it is sequenced.[27] In other words, the sequencing of the human genome merely provides a starting point for further genomics projects. An extraordinary amount of work must still be done to convert that information into practical applications.[28] The task of blindly wading through the reams of new data without some assistance or guidance might occupy generations of scientists.

Consequently, some biotechnology companies focus less on patenting downstream products and more on patenting upstream research aids, or "research tools." These research tools are not broadly marketable, but many of them help follow-on innovators to sift through the data more intelligently and thus to find and develop downstream innovations faster.

Research tool inventors have an understandable desire to capture some of the profit that their inventions help to make possible. Yet it can be quite difficult to place a value on research tool licenses. Until downstream inventors use them, no one can be sure whether the tools will help to identify or develop any financially successful downstream products. Even if a tool does wind up facilitating a winning product, at the time of licensing there is no way of knowing exactly how much of a contribution it will make. This problem has led upstream biotechnology innovators to adopt creative patent claiming and licensing techniques that raise thorny issues for patent and competition agencies alike. Two of these techniques – reach-through licensing agreements and grant-backs – are discussed below in Part VI.B.

Interdependency. A related point is that much of the work in biotechnology is dependent on proprietary technology owned by other firms. In fact, it is often dependent on numerous patented inventions controlled by many different companies. That makes biotechnology ripe for a "patent thicket" or "anticommons" problem, in which further innovation may be stunted simply because there is already too much IP. That phenomenon is discussed in Part IV.B. Interdependency between inventions also highlights the need to balance the incentives an IP system creates for the first inventor with those for follow-on inventors, and may make it more likely than in other industries that unduly broad patents discourage innovation.

4. Patent quality, patent scope, and fears of an anticommons in the biotechnology industry

The biotechnology industry is relatively new, complex, and rapidly evolving. Concerns about patent quality have been raised in such industries, meaning that patents may sometimes be granted for technologies that do not meet statutory criteria of novelty, non-obviousness, and utility. Some commentators have also claimed that the scope of patent claims in these industries is excessive, meaning that even though the inventions themselves are probably eligible for patent protection, the patent claims associated with them are worded too broadly or ambiguously.[29] This section of the paper addresses how patent quality and scope may affect innovation and competition in the biotechnology industry. It then addresses whether quality and scope problems have led to an anticommons and discusses a possible means of ameliorating it.

4.1 How Ease of Patentability and Patent Scope Affect Innovation and Competition

Ideally, a patent right (and the market power it might create) should be granted only if, and only to the extent that, it is necessary to encourage the innovation covered by the right. This "but for" question does not provide practical operational standards, but it is the right question to be asked in principle.[30] The statutory criteria of non-obviousness, novelty, and utility can be seen as a proxy for the "but for" test.

It is a curious feature of patentability and patent breadth that each of them can simultaneously exercise positive and negative effects on innovation and competition. These inconsistencies are a potential source of frustration for policymakers, who may find that adjusting the available policy levers for patentability and patent breadth leads to unpredictable results.

Because many of the positive and negative effects of patentability and patent breadth are similar, this paper discusses the two subjects together. Beginning with the positive effects, the easier it is to obtain a patent in general, and the broader that patent is allowed to be, the greater a potential innovator's expected reward for a contemplated innovation tends to be. Obviously, the higher the expected reward, the more likely the inventor is to undertake the innovation.

Moreover, to the extent that easy patentability and broad patent scope cause competitors to make greater investments in R&D so that they might invent around the patents, easy standards may actually lead to more innovation and thus affect both competition and consumer welfare positively. Alternatively, competitors may opt to concede the patent holder's market but invest in an entirely new market instead, leading to innovation that might not have occurred but for the patent in the first market.

Turning to the negative effects, it is equally clear that the easier it is to obtain patents and the broader they are, the more of them will tend to be issued and the more comprehensive they will be (up to a saturation point). That, in turn, makes it more likely that entering a market will trigger an infringement lawsuit. Thus, the easier patent standards are, the more likely it is that products that ought to be able to compete will infringe instead. Infringement litigation is expensive and time-consuming. Easy standards of patentability and patent scope therefore increase the risk of entering a market and tend to reduce competition accordingly.

In thinking about the potential competitive harm of easy patent standards, it is important to bear in mind that patent protection goes beyond the precise words that were chosen to describe an invention. Instead, patents envelope the idea or concept behind what is expressed in the claims, to the extent that they are actually deducible from the wording of the claims. Patents therefore grant exclusive rights not only on a particular invention, but also on others that are deemed to be functionally equivalent.

Greater ease and breadth of patentability also raise the difficulty, cost, and risk of incremental innovation by making infringement a more common concern. That tends to reduce investment in follow-on innovation for two reasons. First, the patent holder, satisfied with the strength of its patent position, may sense no need to invest in further innovation itself. Second, follow-on innovators are more likely to need a license to the original patent before they can reap any benefit from their work.[31] Identifying which ones are needed and paying for them requires valuable resources. Those resources are wasted when unwarranted or overly broad patents are issued due to a loose patent policy. In fact, an easy patent policy could lead, at least theoretically, to a situation in which so many interdependent inputs are patented that the money and time required to identify and to procure all of the necessary licenses discourages or even stops further innovation in a field of research.[32] The biotechnology field, with its tendency to create and rely on research tool patents, is especially vulnerable to this hazard.

Furthermore, if patent policy is so relaxed that it leads to unwarranted and overly broad patents, consumers will in some instances be deprived of the benefits of competition without receiving the full measure of offsetting value that a patentable invention is supposed to provide. Indeed, biotechnology firms have indicated that they sometimes avoid areas of research that they would have otherwise entered if those areas appear to be covered even by questionable patents.[33] Alternatively, they may eliminate the risk by paying for a license. If the patent should not have been granted in the first place, though, the license fee distorts both the incentive to innovate and the ultimate cost of any follow-on invention.

Box 2. Are overly broad patents affecting biotechnological innovation?

Some very broad biotechnology patents certainly have been approved, but they do not seem to have had much of an effect on technology transfer or innovation in the biotechnology industry. In some cases, the patent holders have made their IP easily available for reasonable fees. In other cases, courts have invalidated the overbroad patents. Moreover, it has become more difficult to obtain broad biotechnology patents, at least in the United States. Three examples illustrate these points.

In 1980, Stanford University obtained a patent on the gene-splicing method known as the Cohen-Boyer technique.[34] The patent's claims went beyond the technique itself, covering any recombinant organisms created with the technique, even though such organisms and their possible uses were not specifically identified. The technique was used widely to create a range of new biotechnology products, and strictly speaking, every one of them was subject to Stanford's patent. The validity of the patent was never legally challenged, however, because it was licensed widely and reasonably.[35]

Twenty years later Human Genome Sciences (HGS) obtained a patent for a gene whose function was initially unknown. The application stated that the gene was useful as a research reagent or as material for diagnostics. Other scientists subsequently discovered that HGS's patented DNA sequence actually coded for the CCR5 receptor, which is used by the HIV virus to infect a cell. This development caused widespread fear that HGS's patent would block AIDS research. So far, that fear seems to be unwarranted. HGS has issued several licenses for research into new HIV drugs and does not plan to prevent academics from conducting research on CCR5 without a license.[36]

Also in 2000, the University of Rochester obtained a patent on a method for selectively inhibiting an enzyme called COX-2 with "a non-steroidal compound." Its application, however, did not disclose such a compound, provide any way to identify one, or indicate that the university even knew of such a compound. Nevertheless, when the patent issued, the university immediately used it in an infringement suit against several large pharmaceutical companies who make drugs that use non-steroidal compounds to inhibit COX-2. That decision backfired dramatically. In February 2004, an appellate court ruled not only that there was no infringement, but that the university's failure to identify a compound required by its method rendered the patent invalid for lack of description.[37]

These are only examples, rather than systematic empirical findings, but they suggest that overbroad patents are not having a strong impact on innovation – at least not yet. Furthermore, the European, Japanese, and American patent agencies have collaborated on studies regarding permissible patent scope and requisite support for the claims. The studies show, for example, that patent applications on partial gene sequences with inadequate disclosure of utility or function will not be granted patent protection.[38] The United States has also made it more difficult to patent genetic material without accompanying knowledge of a specific, substantial, and credible use for a given gene and its proteins.[39]

To make matters worse, when governments grant patents too easily, follow-on inventors are more likely to find themselves in need of complementary licenses from a multitude of IP owners. In cases where those IP owners have market power, they will tend to charge higher aggregate licensing fees than they would if they acted as a single entity. This phenomenon is called "royalty stacking." It is really nothing more than the familiar problem of successive vertical monopolies leading to higher prices and lower output than if a single, vertically-integrated monopolist controlled all the inputs.[40]

Another problem specific to easy patentability may occur in sectors with a relatively small group of major players (such as agribusiness). There, it can lead to inefficient and potentially anticompetitive patent hoarding strategies. In that situation, firms amass patents not because they intend to practice them, but because they want to use the patents to prevent entry, or as leverage against others who could file infringement lawsuits against them. This phenomenon is discussed in more detail below in Part VI.C.2.

The difficulty for policymakers is that it is virtually impossible to quantify the net value of the innovation that will be gained or lost if they opt for a tighter patent policy on the one hand, as opposed to doing nothing or easing it on the other.

4.2. Is There an Anticommons Problem in Biotechnology?

Several years ago, concern over low standards of patentability led to an argument that in some circumstances patents may actually discourage innovation rather than encourage it. The basic point was that if too many complementary inputs are covered by IPRs, they may all be underutilised, leading to a "tragedy of the anticommons."[41] In industries with the anticommons problem, companies have a difficult time innovating because anything they invent will probably depend on a tangled web of IPR held by a multitude of parties. That, in turn, makes it expensive and time-consuming to identify and obtain all of the necessary licenses, and increases the risk of litigation. If the problem is severe enough, most or all of the IPR will lay dormant and the pace of innovation will suffer.

Biotechnology appears to be an industry that is susceptible to an anticommons problem. First, there has been a proliferation of patents, particularly with respect to upstream research tools that facilitate the discovery and effectiveness of downstream products. Second, the patents are held by a large number of participants in the market. Third, universities are also fuelling the proliferation because they, too, are patenting more and more of the research tools they invent. Fourth, companies may be accumulating biotechnology IP for defensive purposes, *i.e.*, not so much because they want to use the IP themselves, but because they want to use it as leverage in negotiations with other companies who hold desirable IP. But has all that been enough to trigger the anticommons problem in biotechnology?

A reading of the transcripts from the 2002 U.S. Federal Trade Commission and U.S. Department of Justice joint hearings on "Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy" suggests that this is merely a theoretical concern, at least so far.[42] One reason may be that inventors have been able to reach fair licensing agreements that enable them to continue with their work while leaving enough incentive intact for them to follow through with it. Another reason could be that because biotechnology is still a relatively new field, there may be large spaces to work in that are still untouched by research. That possibility is supported by a pair of recent studies, one German and one American, which found that biotechnology companies tend to avoid areas of research that will inevitably lead to dependent patents.[43] One could argue that this is a negative result because it shows that patent proliferation is discouraging follow-on innovation. One might also conclude, however, that this result shows the patent system is doing exactly what it should do by encouraging companies to apply their resources toward novel work.

The German study concluded that patents on research tools have not had a noticeable effect on either the pace or the cost of biotechnology research in Germany.[44] Those results largely conformed with the findings of the American study, which found that "the vast majority of respondents say that there are no cases in which valuable research projects were stopped because of IP problems relating to research inputs," and that "drug discovery has not been substantially impeded" by the increase in patents on research tools. The authors attribute the generally mild effects on innovation to the ability of firms and research organisations to find what they call "working solutions" to problems caused by IP. Licensing, inventing

around the patents, informally relying on a research exemption while technically infringing, and court challenges all constitute working solutions.[45]

The American study did find some evidence that the process of negotiating access to the growing body of patented research tools is delaying further innovation, and that patents on genetic diagnostics are interfering with university research.[46] Nevertheless, as Richard Epstein has pointed out, the "vast and sustainable increase in the rate of genomic patent filings is not consistent with the view that new patents strangle innovation, but points to the opposite conclusion."[47] In sum, although most of the available evidence does not indicate that there is an anticommons yet, the potential for one to arise in the future does exist.

4.3 How the Experimental Use Exemption Affects Innovation and Competition

One way to offset some of the effects of an anticommons is to exempt purely experimental, as opposed to commercial, uses of patented technology from infringement liability. In fact, even if there is no anticommons yet, the question whether there should be an experimental use exemption is especially important in industries such as biotechnology, where research tools receive a very substantial share of the patents awarded. Sometimes research foundations, universities, or companies may wish to use a patented invention simply to see whether it actually works as described in the patent. Alternatively, they may want to use it to see if they can come up with any additional applications for it, or to see if it gives them ideas for other research projects. Sometimes, in other words, a patent might technically be infringed, but the "offender" is not infringing for the purpose of making and selling copies of the patent holder's work. Furthermore, sometimes that technical infringement leads to follow-on innovation that increases consumer welfare.

This creates a policy challenge. How can governments protect patent holders sufficiently from incentive-killing free-riding by others, while still allowing harmless – and indeed often helpful – research?

Most countries' patent systems recognise an exception to liability for patent infringement for uses of patented inventions that are for "experimental" or "research" purposes. Article 11.2 of Germany's Patent Act of 1981, for example, provides that patent rights shall not extend to acts done for experimental purposes relating to the subject matter of the patented invention. Many other European nations have similar laws. Section 69.1 of the Japanese Patent Law contains a statutory exemption that does not permit patent rights to extend into experimental research. It does not, however, define what an "experiment" is.[48] In some other countries, there is no statutory exemption, but one is recognised in the common law applied by the courts.

The experimental use exemption has enabled university researchers, among others, to use patented innovations for some non-commercial purposes. This seems to be a sensible policy because it fosters the continued expansion of knowledge without depriving private inventors of any incentive to innovate.

The problem is that not all universities limit their activities to pure research. Many obtain, sell and license IP, and if they were permitted to use third party IP freely, they might do so under the guise of scientific inquiry to develop their own for-profit inventions. Thus it may not be altogether surprising that some courts have adopted a narrow interpretation of the exemption, insisting that it covers only "actions performed for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."[49] In one case, *Madey v. Duke University*, the court ruled that the experimental use defence:

> does not immunize any conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications. For example, major research universities . . . often sanction and fund research projects with arguably no commercial application whatsoever. However, these

> projects unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects.[50]

In jurisdictions where the experimental use exemption is more accessible, businesses may try to make use of the exemption, as well. Competitors in the pharmaceuticals industry, for example, may want to conduct tests on a drug that has been patented for a particular application so that they can determine whether it might have other useful applications. Other competitors might use the exemption to conduct tests on their version of a patented drug so that they may receive regulatory approval for launching it in the market the instant that the patent expires.[51]

There are some good reasons for allowing the exemption in such cases. In the former case, the inventor has already been rewarded with a patent for one application, and it has an incentive to find all other possible applications that could generate profits, as well. However, the inventor may not, for any one of a number of reasons, actually find the other applications. If there are any, it does not seem wise or necessary to prevent others from finding them and bringing them to the market during the life of the initial patent. In the latter case, competition is introduced as quickly as possible, but the original inventor still receives the full period of statutory protection to which it is entitled in the marketplace.

In fact, the experimental use exemption has been upheld by German courts for both of these purposes.[52] Germany, however, may be considered quite liberal in this regard compared with some of its neighbours. The United Kingdom and Sweden, for example, consider clinical trials of patented material to be infringement.

5. Possible roles for competition agencies in the application and structure of intellectual property policy

The discussion so far has been leading toward a central question: What is the proper role for competition agencies with respect to IP? The possibilities include participation in the formulation of IP policy, in its execution, and in the application of competition law to IP-related business activities. At a minimum, agencies will need to apply competition law to matters involving IP at some point. For example, it would be difficult to defend a decision not to challenge a merger of duopolists just because each of them had a patent portfolio. The patents could be at the root of the competition that would be eliminated by the deal. Several other types of potentially anticompetitive conduct involving IP are discussed in Part VI below.

The only choice to be made, therefore, is whether to leave the formulation and application of IP policy to lawmakers and IP agencies, or to be involved in it. Can competition agencies make contributions that will improve the IP system? Should they? Before addressing those issues directly, it makes sense to consider some of the problem-solving mechanisms that are already built into IPR markets.

5.1 Ways in Which Private Parties Can Address IP Problems

Private parties can accept, challenge or circumvent the fact and scope of IPRs with a wide variety of tactics.

- **License**. Most obviously, private parties may negotiate a license to use the IP. This may solve blockage problems, but it leaves licensees susceptible to supra-competitive pricing and possibly restrictive licensing terms. If the IP's validity or scope is suspect, that could be problematic from a competition policy perspective.

- **Request a re-examination**. If licensing is not a viable solution, private parties may ask for a re-examination of granted patents in the patent offices of most countries. The result of a successful

challenge may be a reduction in the patent's scope, or even revocation of the patent. Procedural rules for these processes sometimes require evidence that there was a concrete problem with the examination process, though. For example, challengers may have to demonstrate that certain relevant prior art was not previously considered, rather than simply alleging that a patent is invalid or too broad.

- **Litigate**. Furthermore, private parties may resort to the courts in some instances.[53] Legal challenges, however, tend to be very expensive, time consuming, and unpredictable. It has been estimated that litigating a patent challenge in the biotechnology field may take two or three years and cost five to seven million U.S. dollars.[54] Moreover, there is a collective action problem with some patent invalidation litigation because while one firm bears the litigation cost of the challenge, other firms may benefit from the invalidation. These factors combine to make privately funded challenges unattractive, especially to the smaller firms that are common in the biotechnology industry.

- **Form a patent pool**. Patent pools are another possibility, and they have the potential to clear away much or even all of a patent thicket.[55] So far, there is little evidence that patent pools are forming in the biotechnology industry.

- **Invent around the patent**. In addition, parties might invent around the patents. In traditional diagnostics, for example, a company may patent a kit for disease testing. Later, another company may evade the patent by making a completely different and better kit for detecting that disease. It is impossible to invent around something that is unique and essential, however, and genetic codes can fit that description. Therefore, if a company has a patent on a gene and any means of testing for its presence or mutation, then there is no room for a competitor to develop a non-infringing, alternate test for that gene.[56]

- **Go offshore**. For some companies, avoiding IP by going offshore is sometimes the most attractive choice – but this is usually an option only for well-funded pharmaceutical companies, not smaller firms.

- **Use the patent only for experimental purposes**. Relying on the experimental use defence/exemption is another possibility. That manoeuvre may not help those with commercial aims, however, and in any case its applicability appears to be shrinking, at least in the United States.

- **Infringe.** If all else fails, private parties may simply decide to risk a lawsuit and infringe the patent. Infringement can be hard to detect, especially research tool infringement because it takes place behind closed laboratory doors.[57] This, however, is certainly not a solution that competition agencies would encourage.

- **Form a non-profit knowledge association**. Finally, firms might band together to form associations that voluntarily put their inventions in the public domain, thereby avoiding the IP system altogether. See Box 3 for an example. Consortiums such as SNPC are not common, however. That is probably the case because corporate interests rarely align well enough to make them happen. Thus it can be seen that there are substantial drawbacks to each of the strategies listed above. If we then assume that the private sector cannot solve all competitive problems related to the ease of patentability or the over breadth of patent claims, we may return to the issues of whether, when and how competition agencies should get involved.

Box 3. The SNPC Consortium.

The SNP Consortium is a non-profit foundation organised for the purpose of providing a high-quality SNP map of the human genome to the public without IP restrictions. SNPs are single nucleotide polymorphisms, which are common DNA sequence variations among individuals. It was anticipated that the map would help to a) identify specific genes involved in diseases, thereby facilitating the discovery of new ways to intervene in the disease process; b) develop new diagnostic tests; and c) create new "personalised" medicines based on an understanding of minute genetic variations that predict response to therapy. SNPC was formed by a medical research charity, 11 major pharmaceutical and technological companies, and several academic research centres. Initiated with a $45 million budget, its mission was to develop up to 300,000 SNPs distributed evenly throughout the human genome. Ultimately, SNPC discovered 1.5 million SNPs.[58]

Why did SNPC arise? According to the members, they expected the collaboration to produce a high-quality map sooner, with shared financial risk and less duplication of effort, than if each company had pursued development of a SNP map on its own.[59] Behind that short answer may be a potent lesson about the patent system. First, because all of SNPC's work took place even without any IP incentive, it appears that the patent system is over-rewarding some types of research. Second, SNPC's mission suggests that the patent system may actually be getting in the way of biotechnological progress, at least in some circumstances (here, far upstream in the research process). One could infer that SNPC was formed to speed up the SNP search process so that SNPs could be publicised (and thus rendered obvious), thereby preventing anyone from patenting them and making the consortium members pay licensing fees for them. Beyond that, the fact that SNPC produced five times more information than originally planned shows that such collaborations can be very successful and contribute a great deal to society with no help at all from the patent system.

5.2 Some Ways in Which Competition Agencies Might Get Involved and the Pros and Cons of Each

5.2.1 Taking an Advisory Role

Competition agencies enjoy a comparative advantage in identifying and analysing the anticompetitive effects of overly broad or invalid patents. There is little doubt that competition agencies could improve the IPR/competition balance by advising patent offices about the possible anticompetitive effects of decisions affecting patent breadth and ambiguity. By the same token, patent offices could provide extremely valuable legal and technical advice on IP to competition agencies who are investigating IP-related conduct.

This exchange of information could take the form of generally applicable findings and advice, such as that which the U.S. Federal Trade Commission issued after it held joint hearings on competition and patent policy with the Department of Justice. The FTC report contains concrete suggestions for improving patent quality and minimizing the anticompetitive impact of the patent system. The recommendations are directed toward Congress, the courts, and the Patent and Trademark Office.[60]

Alternatively, the exchange of information could be case-specific, with the competition agency acting as a consultant for the patent agency. This might occur at the patent agency's invitation, or the competition agency might request that the patent agency re-examine a questionable patent. Furthermore, competition agencies could take a more active role in patent lawsuits that have important competitive ramifications by filing amicus, or "friend of the court," briefs spelling out the consumer welfare effects of the issues being considered by the court.

Finally, competition agencies could make efforts to promote greater understanding and implementation of economics by IP agencies. Having benefited from a similar course of action themselves many years ago, competition agencies would be in a good position to make this case.

5.2.2 Addressing patent validity and breadth problems at the patent examination stage.

The earliest stage at which competition agencies might be involved in the patent process is after the patent application is filed and a decision must be made whether to approve it. If competition agencies were involved at this point, they could help to weed out invalid patents or to limit overly broad claims that would likely cause competitive problems.

There seems to be very little reason to favour this approach, though. A troubling threshold question is why competition authorities would presume to get involved in assessing patent validity and scope when patent office personnel clearly have more experience in dealing with the issue. In fact, patent examiners are likely to have more skills relating both to patent law and the particular technology at issue. Similarly, neither competition agencies nor patent offices can determine optimal patent breadth, and of the two, patent offices may be better poised to balance incentives for primary versus follow-on innovation.

Furthermore, requiring competition agency approval would impose delays on the patent process. That, in turn, may dilute the incentive to innovate and retard the benefits that would flow from the patent, such as disseminating technological information and facilitating pro-competitive licensing agreements.

In addition, it would be overkill for competition agencies to be involved in every patent application decision. The vast majority of them do not raise any competition issues.[61] Even if they did, few if any competition agencies would have the resources to assume that level of responsibility given that patent agencies themselves are hard-pressed to get the job done.[62] Finally, even if competition agencies did have the necessary resources, it is far from clear that competitive problems would be apparent at the time of filing, especially in rapidly changing and complex industries like biotechnology.

5.2.3 *Challenging questionable patents via litigation.*

Rather than trying to address invalid and overly broad patents that might pose competitive problems at the examination stage, competition agencies might deal with them at some point after the patent has been granted by challenging them in court.

One benefit of this "wait and see" approach is that it would free the competition agencies from the crushing burden of having to review so many patents at the examination stage. In addition, more time will have passed, during which the actual effects of the patents can be observed. That will improve the quality of the decision about whether a patent is actually harming, or is likely to harm, competition.

Another benefit to litigation is that legal decisions create precedent. That means competition agencies will have a direct role in shaping overall patent law and policy, as opposed to merely one-off outcomes. Furthermore, when a government agency shoulders the litigation burden of challenging a patent's validity, it solves the private sector's collection action problem.

On the negative side, one could argue that patent offices should retain exclusive jurisdiction over patent validity and breadth because they are involved earliest in the process. If a different government agency takes steps to invalidate patents or curtail their breadth at some point after the patent office approves them, this would create greater uncertainty about the rewards for inventors. That greater uncertainty may have the unintended effect of reducing innovation.

A problem with that argument, at least with respect to over breadth, is that patent offices may not immediately realise how wide a patent's claims are. This is especially likely to happen with inventions in technologically complex or young industries such as biotechnology.[63] It may take a number of years before anyone realises that a biotechnology patent was worded too broadly. For example, a company might have obtained a use patent on a particular gene before anyone knew how important that gene would prove to be. If the gene turns out to play a crucial role in a severe disease and the company's patent broadly covers "all diagnostic uses" of the gene, then the company will have gained control over very

valuable IP even though it never identified, let alone conceived of, its most important applications. The resulting rewards may be difficult to justify.

Consequently, it may be desirable to have a safety net available, and competition law is a candidate. If, with the benefit of hindsight, it is clear that a patent is invalid or excessively broad, and that patent has contributed to unlawful anticompetitive behaviour, competition authorities could challenge the patent in court.

6. Competition law enforcement issues

In the increasingly "knowledge-based economy," it is virtually certain that competition agencies will confront matters involving IPRs, and that they will eventually have to take some action to limit the use of those rights. This is as it should be. IPRs do not convey total immunity to competition law. After all, the main objective of patent laws is to encourage the advancement and propagation of scientific knowledge, not to enrich patent owners.[64]

This section of the paper explores some of the IP-related conduct that competition agencies may encounter. While there are other types of behaviour that are not discussed here, the issues below are highlighted because they are among the less clear-cut in terms of their implications for IP and competition policy.

6.1 Premises

Licensing is usually pro-competitive. Patent licensing is a means of diffusing proprietary technologies among a larger number of innovating entities. Licenses also allow firms to concentrate on their strongest areas of competence while relying on others for complementary technologies. In addition, licenses are a means for firms to benefit from technologies that they cannot use themselves, while encouraging additional investments in innovation at the same time. Licensing may also be a good way to exhaust the revenue opportunities that an invention has. If the patent has more applications than the inventor can diversify into, then he or she can still share in at least part of the potential profits by licensing the invention to others.

Moreover, licensing can also be a good way for inventors to share risk. When the commercial success of an invention is uncertain, inventors can unload some of the risk of marketing it by licensing others to either do it for them or to share in the work.[65]

Distinguishing horizontal versus vertical relationships is important. IPR licensing usually brings complementary inputs together. Transactions involving complements are essentially vertical because they facilitate progress down the chain of production. Complementary transactions can be vertical even when the licensor and licensee otherwise compete in manufacturing products that use the licensed IP.[66] Nevertheless, IPR licensing occasionally has distinctly horizontal characteristics, such as when a company grants a license but, in order to fend off any competitive repercussions from improvements that the licensee might make, requires that all follow-on IPR created by the licensee be licensed back to the grantor.

Some agencies explicitly distinguish between horizontal and vertical licensing arrangements, and it is a distinction that is worth making because the horizontal arrangements are inherently more problematic from a competition standpoint. The European Union's Technology Transfer Block Exemption, or "TTBE," unlike its 1994 predecessor, distinguishes horizontal and vertical licensing relationships for the evaluation of restrictions imposed in license agreements.[67] The United States' policy makes the same distinction in general.[68]

6.2 Potentially Anticompetitive Bilateral Licensing Conduct

Patent Pools. When patents held by two or more parties are licensed as a package, the parties have formed a patent pool. Frequently, pool members assign or exclusively license their IP to a separately administered entity, which then controls the licensing of the patent portfolio back to the members and, if the pool is "open," to third parties, as well.[69] The terms of these arrangements vary. Members might be entitled to use the bundle of IP on a royalty-free basis, or they might have to pay. Moreover, licensing revenue generated by the pool can be divided up in many different ways, and management of the pool may involve diverse voting structures or veto rights.

The potential role of patent pools in the biotechnology industry has received considerable attention in the literature. Some have argued that in view of possible royalty stacking, anticommons, and other situations where existing patent rights could become impediments to further R&D, patent pools have significant benefits and therefore should be encouraged. For example, a U.S. Patent and Trademark Office document suggested that patent pools could help the biotechnology industry by reducing risks associated with blocking patents and an anticommons; reducing licensing transaction costs; enabling firms to share R&D risks; and institutionalising the exchange of technical information not covered by patents.[70]

Others have questioned whether patent pools would solve problems in markets for genetic inventions. In a recent OECD study, for example, respondents to a German survey, representing various biotechnology and pharmaceutical companies, genetic testing centres, and public research organisations, did not consider patent pools or cross-licensing agreements to be helpful in increasing access to genetic inventions. Their reason was that it is too difficult to measure the value of the contributions that each party would bring to the arrangement.[71] Commentators have identified a number of characteristics of the biotechnology industry that could limit the usefulness of patent pools and may explain why they apparently have not been widely used (yet).[72]

6.2.1 Competition concerns associated with patent pools.

Even though the utility of patent pools for the biotechnology industry is debatable, competition authorities may confront biotechnology pooling arrangements in the future. It is generally accepted that patent pools may benefit both IP owners and consumers, provided the pool is limited to complementary and/or blocking patents. Under these conditions, patent pools may facilitate the integration of complementary technologies, reduce transaction costs, facilitate the clearing of blocking patent positions, and avoid infringement litigation.[73] On the other hand, there is also agreement that patent pools can create risks for competition in a number of ways:

- *Reducing competition in horizontal technology markets*: Most importantly, if the pooled technologies are not complements, but substitutes (and not blocking), patent pools may become a horizontal arrangement eliminating competition among technologies that would exist without the pooling arrangement. For instance, such pools could become a simple price fixing scheme under the guise of a patent license arrangement.[74] Pools can also harm competition by including invalid patents and making validity challenges less likely, thus prolonging exclusive rights and market power that are not justified on IP policy grounds.

- *Facilitating collusion in downstream product markets*: Second, patent pools could reduce horizontal competition in downstream markets. If patent pools standardise an input for the downstream market and the license fee charged by the pool is high relative to the total cost of manufacturing the downstream product, collusion among the downstream firms becomes easier. This possibility is particularly worrisome when the pool members are also participants in the

downstream market because that creates an incentive to form the pool for the purpose of fixing downstream prices.

- *Foreclosing competing technologies*: Patent pools might foreclose technologies that are not included in the pool, but that compete with the pooled technologies. That may happen, for example, if licensees find it more convenient to sign up once with the pooled technologies rather than searching and contracting for alternative technologies.

- *Reducing incentives to innovate:* Pooling arrangements may harm innovation by reducing incentives to invent around other technologies in a pool, or by reducing incentives for creating follow-on inventions (which might happen if pool members are required to license their follow-on inventions to the pool, for example).

The following section discusses the legal frameworks developed by two competition authorities to address these concerns. The discussion shows that the frameworks are similar, but they do not appear to be identical.

6.2.2 Policies to address competition concerns about patent pools.

EC Guidelines

The new Commission Guidelines extensively discuss the criteria used to assess the competitive effects of patent pools.[75] The Commission's emphasis is on ensuring that pooled patents are complements and not substitutes. The Guidelines state that the inclusion of substitute technologies in a pool likely will infringe Article 81(1), while the conditions for an 81(3) exemption will not likely be fulfilled.[76]

Although its requirement that pooled patents be complementary to each other is strict, the Commission appears to be slightly more flexible with respect to whether any pooled patents may have substitutes outside the pool. (In Guidelines terms, technologies having no substitutes outside the pool are "essential"). While recognising the risk that non-essential pooled patents may foreclose third-party technologies outside the pool, the Commission indicates that it would be willing to examine on a case-by-case basis whether foreclosure effects would likely result from the inclusion of non-essential technologies.[77]

The principal factor for assessing foreclosure effects would be the "position" of the pool in any relevant market, which one might assume refers to considerations such as how much downstream demand is met by the pooled technologies. Other factors the Commission will take into account include any pro-competitive reasons for including non-essential patents; whether licensors remain free to license their technology individually; and whether separate license packages are available instead of a single package.

The Commission Guidelines also emphasize the requirement that licensors be free to grant individual licenses outside the pool. In addition, grant-backs should be non-exclusive so as not to reduce the incentive to innovate. Moreover, pools should be designed so that they cannot be used to exchange competitively sensitive information. The Commission Guidelines also appear to prohibit no-challenge clauses and require that where the validity of a licensed patent is challenged, a right to terminate a license be limited to the technology of the licensor who is the owner of the challenged patent. Presumably, this requirement should limit the risk of a challenge.

U.S. Guidelines and DOJ business letters

The U.S. Guidelines have no detailed discussion of the analysis the agencies would follow with respect to patent pools. They list in rather general terms the potential competitive advantages of pooling arrangements,[78] along with possible anticompetitive effects of pools. The latter include collective price setting and output restraints without offsetting efficiencies, the disincentives of grant-back provisions for innovation as well as – especially in the presence of market power – foreclosure of third parties that do not have access to the pool.[79]

Several DOJ business review letters[80] related to patent pools in the context of standard setting have discussed in much greater detail the limitations that may be required to minimize antitrust risks associated with patent pools.[81] Although highly fact-specific, they are viewed by many as providing useful guidance on how to set up a patent pool that will not violate competition laws. Commentators have identified the following criteria and limitations that should be taken into account when setting up pools:

- pooled patents must be valid and unexpired;
- pooled patents must be *essential*;
- royalties should be small relative to the total manufacturing costs of downstream products incorporating the pooled technology;
- licensing should be non-discriminatory to all interested persons;[82]
- each patent holder must be allowed to license its technology outside the pool;
- access to competitively sensitive information must be limited; and
- grant-back provisions should not limit incentives to innovate.[83]

The first two criteria address concerns about competition in technology markets. In addition to the basic requirement that pooled patents must be valid, a key element in the DOJ's assessment of patent pools is the requirement that pooled patents be essential. "Essential patents, by definition, have no substitutes; one needs licenses to each of them in order to comply with the standard."[84] Thus, essentiality requires both that the patents are complements (internal requirement), and that none of the pooled patents has a substitute outside the pool (external requirement). The justification for the essentiality requirement has been expressed as follows:

> The limitation of the Portfolio to technically essential patents, as opposed to merely advantageous ones, helps ensure that the Portfolio patents are not competitive with each other and that the Portfolio license does not, by bundling in non-essential patents, foreclose . . . competitive implementation options[.][85]

Determining when a patent meets the essentiality requirements may be a complex task. In the technology pools addressed in the DOJ Business Review Letters, outside experts had been retained to identify which patents could be deemed essential and therefore were included in the pool, and which should remain outside. Experts also played a role during the operation of the pool.[86]

Not surprisingly, the brief overview of EC and U.S. policies towards patent pools demonstrates that the agencies in both jurisdictions are equally strict in prohibiting patent pools involving substitute technologies. It is conceivable that strict complementarity requirements could create higher antitrust risks

when pools are formed in an industry like biotechnology, where the exact scope of patents and/or downstream uses of licensed technology may not yet be known to right holders at the time they consider forming a pool.[87] Finally, the Commission Guidelines appear to focus primarily on possible horizontal effects of patent pools among the members of the pool, and they seem more flexible than the U.S. with respect to (vertical) foreclosure effects involving third party technology.[88]

Lerner and Tirole have examined the competitive effects of patent pools and pointed out that while the distinction between complements and substitutes is a useful first step in antitrust analysis, patented inventions are rarely perfect complements or perfect substitutes for each other. Moreover, the relationship between patents can change over time, as patents can enable new products that compete downstream.[89] This suggests that in certain pooling arrangements it may be difficult to maintain the strict distinction between complementary and substitutable patents.

Reach-Through Licensing Agreements. Reach-through licensing agreements assess royalties based on the revenue generated by a downstream product, regardless of whether it is made using the licensed technology. For example, the licensed technology may help to identify and develop the product, but have nothing to do with producing or selling it. This is a typical scenario in the research tool segment of the biotechnology industry, where reach-through licenses provide downstream companies with access to patented research platforms in exchange for royalties on future products that would not have infringed the upstream patent. Should it be a violation of competition law for a company to use its patent rights to extract profits from something other than what it patented? And why would any downstream firm agree to such an arrangement?

First, it has to be taken into account that there can be some substantially pro-competition features of reach-through licensing agreements. Sometimes, for example, it is extremely difficult to know what a fair licensing fee is. This valuation problem is more likely to occur when technology is licensed for the purpose of helping to discover downstream products rather than making them. The problem can arise because, at the licensing stage, it is unclear:

a. whether the patented technology will ever lead to the invention of a financially successful downstream product;

b. how successful any such product will be; and

c. how much of the success, if any, should be attributed to the upstream technology.

This uncertainty can lead to a great deal of argument about how much an invention is worth. In fact, even after a successful product is eventually developed, there may still be arguments about whether and how much the upstream technology was involved.

Reach-through royalties offer a solution to the upstream patent valuation problem by simply pegging the licensing fees to sales of the licensee's downstream product(s) with no regard to whether the two wind up having anything to do with each other. Thus the reach-through mechanism facilitates licensing that might not otherwise occur.

Furthermore, signing a reach-through agreement frees the licensee from paying up-front fees. Seen in this light, they are a financing instrument that could actually be preferred by small, cash-poor biotech start-ups, giving them access to technology that they might not otherwise be able to afford.

On the other hand, reach-through royalty arrangements may not always be harmless. If it is clear from the beginning of a reach-through agreement that royalties will be taken from revenue generated by a totally unrelated product, for example, the agreement appears to be more questionable because it is using

the power of the patent to collect profit in a market that is unconnected to the patent. Indeed, such arrangements may be forms of patent misuse.[90]

The TTBE would apply to a reach-through royalty arrangement only if the license agreement refers to a product that will be produced under the license.[91] It is not entirely clear how specific the reference to a product has to be to ensure the applicability of the TTBE. It is quite possible, however, that at the time biotechnology research tools licenses are signed, parties will frequently be unable to identify the product that the licensee will develop, which would preclude the application of the TTBE.[92]

In the United States, conditioning the grant of a license on the payment of royalties on unpatented inventions is technically a form of patent misuse.[93] Courts, however, have also permitted such licenses when parties agree to them voluntarily for their mutual convenience,[94] which may be an exception that swallows the rule.

The U.S. Guidelines do not directly address reach-through royalties, though they contain language that could be used to challenge them as unlawful exclusive dealing arrangements. The U.S. Guidelines state:

> Exclusivity may be achieved by an explicit exclusive dealing term in the license or by other provisions such as compensation terms or other economic incentives. Such restraints may anti-competitively foreclose access to, or increase competitors' costs of obtaining, important inputs, or facilitate co-ordination to raise price or reduce output, but they also may have pro-competitive effects.[95]

With respect to agreements between non-competitors with reach-through royalties that do not fall under the TTBE, the European Guidelines explain that the Commission would examine whether royalty rates that are based on products not incorporating the licensed technology could have foreclosure effects, thus suggesting that the Commission's approach would be similar to the approach under the U.S. Guidelines.[96] For agreements among competitors, the Guidelines suggest that the Commission might take a more restrictive approach, and generally would consider royalty arrangements based on products not covered by the licensed technology to be a hardcore restriction. The Guidelines explain, however, that such arrangements may benefit from an individual exemption where the restriction is considered indispensable for pro-competitive licensing to occur.[97] It appears that this reasoning could cover reach-through royalties in the biotechnology industry, such as when it can be shown that the arrangement is the most effective way to address valuation problems and is not intended to restrict the licensee's freedom to use its own or third party technology.

The Japanese Guidelines take a similar approach that focuses on potential foreclosure effects.[98]

One could certainly argue that forbidding reach-through licenses altogether would discourage innovation because without them, upstream innovators would not be able to earn enough from their inventions to make the necessary investments worthwhile. One might also argue, however, that forbidding reach-through licenses would simply force the parties to come up with a different way to put a value on the upstream technology. In other words, where there is a will, there is a way.

At least, where there is an adequately powerful will, there is a way. Large pharmaceutical companies have adopted that principle in their dealings with upstream tool makers who, being well aware of the financial potential of downstream blockbuster drugs, increasingly prefer reach-through licenses for their tools. The pharmaceutical firms, however, tend to put up a strong fight, preferring to pay fixed, up-front fees rather than concede shares of downstream revenue that could be measured in billions. When tool makers balk at taking up-front fees, it is not unprecedented for pharmaceutical firms to respond by going to considerable lengths to avoid having to pay any licensing fees at all for the tool. With their typically deep

pockets, they can move their operations offshore to test their drug candidates against patented gene targets. Alternatively, they can create a DNA sequence that is different enough from the tool maker's patented sequence to avoid infringement, but similar enough to it to be useful as a drug target.[99]

That consideration brings us back, full circle, to wonder why agencies should bother thinking about restricting or banning reach-through licenses (at least for tool makers in the biotechnology industry) in the first place. If the supposed "victims" of these licenses are able to avoid them, are they really having an impact on innovation?

It is true that big pharmaceutical companies are not the only ones who use biotechnological research tools. Other biotechnology firms use them, too, but, the facts do not seem to weigh in favour of intervention in their situation, either. Biotechnology firms tend to have much less cash on hand than big pharmaceutical companies. They are therefore more likely to agree to reach-through licensing terms.[100] This is true not only because biotechnology companies often lack the financial strength to make the kind of up-front cash payments that can counter upstream innovators' desire for reach-through licenses, but because the biotechnology firms often lack the funds to make any substantial up-front payment at all. For them, therefore, reach-through licenses are a type of financing arrangement that allows them to use patented technology without paying for it unless and until they develop a product themselves that earns revenue. In this context, then, reach-through licenses seem to be conducive to innovation because licensees willingly agree to them and actually prefer them to paying cash at the outset of the licensing period.

Grant-backs. These occur when, as a condition of licensing a technology, a patent holder requires licensees to grant a license back to it for any follow-on technology that the licensees patent. Sometimes the patent holder will even require its licensees to grant it an exclusive license or an outright assignment of rights.

Grant-backs, like many licensing arrangements, set a variety of effects in motion that do not necessarily head in the same direction. Grant-backs may enable licensing transactions that contribute to efficient transfers of technology that might not otherwise take place. For example, a grant-back could take the place of royalties, giving cash-poor licensees a mean of affording the technology. Alternatively, grant-backs can be used to protect licensors from the danger that a rival licensee will improve on the licensor's technology and drive it out of the market. In addition, grant-backs may strengthen upstream innovators' incentives to create IP that others find useful. Furthermore, grant-backs allow the licensor and licensee to share the risks and rewards of follow-on innovation.

In the biotechnology sector, grant-backs are also frequently used when the licensee is a non-profit entity that does not create marketable products but might create IP.[101] This may be the case, for example, with a research foundation or a university. For those types of licensees, a reach-through licensing arrangement probably would not help the licensor, but a grant-back provides a way to get some value out of the transaction. In the United States, where the experimental use defence is becoming narrower,[102] non-profit researchers may increasingly rely on grant-backs to get licenses they previously did not need.

At the same time, some grant-backs have potentially anticompetitive effects. For instance, they might extend the original inventor's control over one product to encompass control over others in the future, including some that would otherwise have been competitive substitutes. That problem is, of course, most acute when the grant-back requires an assignment of follow-on IP rights. In addition, grant-backs reduce licensees' incentives to conduct follow-on research because anything they invent that is worth patenting will have to be shared with – or completely surrendered to – the licensor. On the other hand, when the licensee is a non-profit organisation, its research agenda is less likely to be weakened by a grant-back.

A uniformly tough competition policy toward grant-backs would be counterproductive. First, a distinction should be made between non-exclusive licenses, exclusive licenses (where the follow-on inventor retains rights to its invention), and assignments (where no rights are retained). There is a much lower risk of competitive harm when the licenses are non-exclusive. In fact, such licenses may be pro-competitive because they allow more than one firm to use the follow-on technology. Second, if competition agencies sought to enjoin all grant-backs, they would probably encourage inefficient refusals to license.[103]

A better overall result may be reached by exempting grant-backs to non-profit entities and permitting other grant-backs as long as they do not give the original licensor either an assignment of follow-on rights or an exclusive license to them. This policy would ease licensors' fears about losing market share to licensees while leaving licensees with at least some incentive to innovate.

The TTBE suggests that the Commission has adopted a more permissive approach towards exclusive grant-backs than was the case under the preceding TTBE. The TTBE takes a neutral stance towards exclusive grant-backs and assignment-back clauses concerning improvements that are considered severable, *i.e.*, improvements that can be used without infringing the initially licensed technology. Such grant-backs/assignment-backs are "excluded," which means that they are neither block-exempted nor prohibited under the TTBE.[104] The Commission Guidelines explain that an assessment of whether grant-backs/assignment-backs restrict competition will depend on a variety of factors, including the significance of the licensed technology, the existence of parallel networks of license agreements with similar obligations, or cross license arrangements with grant-backs.[105]

The JFTC Guidelines appear to take a slightly stricter approach, suggesting that because ". . . there is not usually a reasonable justification for the licensor to impose such a requirement, it is highly unlikely to fall within the category of unfair trade practices and be in violation of the Antimonopoly Act."[106]

According to § 5.6 of the United States Guidelines, anticompetitive effects from grant-backs are considered likely only if (1) the licensor and licensee would otherwise have been rivals in research and development, and (2) the licensor has market power.[107]

Ultimately, the choice of how strictly governments should treat grant-backs (and reach-through licenses, for that matter) depends on whether they are more concerned about motivating upstream or downstream innovation. A stronger focus on upstream innovation logically leads to a more permissive policy toward grant-backs and reach-through licenses. Concentrating more on downstream innovation, on the other hand, leads to a more restrictive policy.

One reason to favour downstream innovators is that upstream research tends to cost less and receive more public subsidization than downstream work. Many of the seminal upstream biomedical research discoveries were government funded. That raises doubts about whether the incentives for upstream innovation need greater support. In fact, Eisenberg points to indications that those incentives may already be too strong.[108] In the same article, however, she reminds readers that reach-throughs and grant-backs provide a solution to valuation problems, serve as a form of much-needed financing for many cash-strapped biotechnology firms and universities, and give upstream innovators the financial motivation they need to transfer their technology to others. Eisenberg therefore concludes that "[i]n this evolving market, it seems unwise to stretch the limits of antitrust law in order to foreclose the use of such terms in license agreements."[109]

Price Restraints. Controlling the price that the licensee can charge for products using the licensed technology is conduct that runs afoul of the language in the guidelines of the European Union, Japan, and the United States. Resale price maintenance ("RPM") precludes the application of the TTBE.[110] The

characterisation of RPM as a "hardcore" restriction makes it highly unlikely that it would qualify for an individual exemption.[111] The Technology Transfer Regulation states that "Article 1 and Article 2(2) shall not apply where . . . one party is restricted in the determination of prices, components of prices or discounts for the licensed products."[112] The Japanese Guidelines state that "[r]estricting resale prices of patented goods in Japan" is conduct that is "highly likely to fall under unfair trade practices."[113] The U.S. Guidelines state that "the Agencies will enforce the per se rule against resale price maintenance in the intellectual property context,"[114] but they also limit per se treatment to cases in which the restraint cannot "be expected to contribute to an efficiency-enhancing integration of economic activity."[115]

The U.S. caveat is significant because licensor-imposed restrictions on the pricing decisions of licensees with respect to the licensed technology do not usually lead to greater anticompetitive effects than would occur if there were no licensing at all. Inherent in a patent is the right to set the price of patented goods. It is difficult to see how consumers would gain from prohibiting restrictions on licensee pricing if this simply causes patent holders to refuse to license. Such a refusal could easily mean foregoing efficiencies of combining IPR with complementary resources owned by potential licensees. Thus the most sensible policy may be to allow license restrictions that lead to more competition than there would be absent any license.[116]

Other Types of Restrictive Licenses. There are innumerable ways to restrict competition with IP license terms. Some are easier to recognise than others. At the easier end of the spectrum are licenses that dictate the price a licensee can charge for a product that does not use the licensed technology, or that prohibit the use of the licensed technology after the patent expires.

Towards the middle of the spectrum are licenses that probably restrict competition, but for one reason or another may not be compelling candidates for challenges based on competition law. Suppose, for example, that a firm has been caught infringing a competitor's patent. The competitor agrees to a settlement, but only on terms that substantially weaken the infringer's ability to compete. Specifically, let us say that the dominant patent holder requires its rival to agree not to merge with a certain other company for two years. If that merger would have created a strong challenger to the dominant patent holder, can competition authorities intervene and nullify the agreement?

Taking into account the practical consideration that by the time the agency becomes aware of the agreement, conducts its investigation, obtains a trial date, litigates the case and receives a judgment, at least two years are likely to have passed, there may be little that a competition agency can do. Even apart from those considerations, what if the defendant quite plausibly argues that if there had been no settlement, the resulting judgment and monetary damages would have weakened the infringer even more than the settlement terms did? The realistic choice here would seem to be to let this conduct go unchallenged.

Further along the spectrum are licensing agreements that could be either legitimate or unlawful, depending on the particular situation. For example, a license might include terms that require licensees to continue making royalty payments after the patent has expired. This might be a clearly unlawful means of extending patent privileges if the royalties are calculated based on use of the invention that occurs after the patent expires.[117] However, if the royalty fees are based on sales that occurred during the patent's life but some or all of the actual payments are made after expiration, it looks more like an innocuous way to finance legitimate fees that the licensee might not have been able to pay earlier. Alternatively, if the royalty fees are based on sales that occur after the patent's expiration but are meant to compensate for the use of the subject invention prior to the expiration of the patent, then they might also be permissible.[118]

6.3 Potentially Anticompetitive Unilateral Licensing Conduct

Unilateral Refusals to License. This conduct may be especially potent in the biotechnology industry because so much of the work is dependent on patented upstream technologies. Withholding access to those technologies can have powerful effects on follow-on innovation and, in some instances, on competition. That does not necessarily mean that unilateral refusals to license should always be treated as violations of competition law, though.

Nearly 100 years ago, the U.S. Supreme Court held that a patent holder's refusal to license a patent cannot form the basis of an antitrust claim.[119] Over the years, a number of matters have arisen in which additional conduct was enough to justify paring down or removing the right to exclude that was originally granted with the IPR.[120] The principle that a bare unilateral refusal to license IP is beyond the reach of antitrust law has, however, endured in the U.S.[121]

The European Court of Justice, in contrast, has found that a copyrighted television guide was an essential facility and ordered compulsory licensing.[122] Quite recently, it confirmed in another copyright case that a dominant firm's refusal to grant a license may be unlawful in certain circumstances. In *IMS*, the Court held:

> It is clear from the case-law that, in order for the refusal by an undertaking which owns a copyright to give access to a product or service indispensable for carrying on a particular business to be treated as abusive, it is sufficient that three cumulative conditions be satisfied, namely, that that refusal is preventing the emergence of a new product for which there is a potential consumer demand, that it is unjustified and such as to exclude any competition in a secondary market.[123]

The Court made it clear that the "secondary market" requirement did not refer to a separate antitrust market. Rather, it was sufficient that two different, interconnected stages of production could be identified where the upstream product was a necessary input for a downstream product that the competitor sought to produce and supply. It would appear that whenever a competitor needs access to intellectual property to produce a good, this secondary market requirement would be met. The requirements that the refusal to license must exclude *any* competition and that the third party must seek to produce a new product appear to somewhat limit the potential reach of the judgment. Unfortunately, the Court refrained from explaining when a refusal to license could be justified, leaving a significant question unanswered.

It is unclear what effects this judgment could have on biotechnology cases in the E.U. It may well be that in markets characterised by dynamic developments of new technologies and products, a refusal to license will rarely result in the exclusion of all competition, especially if competition must be excluded for a significant time period. Moreover, it may be that substantial investment in the development of patented technology will be found to constitute an objective justification for a refusal to license.

Compulsory licensing is in some respects a tempting tool for competition agencies, particularly when they are dealing with a dominant firm. Making the IP accessible can open up the market to competitors relatively quickly. Furthermore, it may permit follow-on innovation that had been blocked by the dominant firm's refusal to license.

At the same time, forcing an IP owner to grant licenses eliminates some of the control over the invention that served as an enticement to create it in the first place. Indeed, if competition law generally prevented IP owners from refusing to license, it would proscribe exactly the same behaviour that IP laws permit and therefore damage the incentive to innovate.

In addition, if a dominant firm is forced to license its technology to its competitors, then the competitors will no longer have the same incentive to invest in ways to invent around the original patent. Improvements that would otherwise have occurred may therefore be lost.

A major drawback to compulsory licensing is that it requires competition authorities or courts – or both – to have at least some involvement in setting the terms of the license, and perhaps in monitoring its execution in practice, as well. Without such involvement, the licensor may impose terms that amount to a virtual refusal to license. Agencies and courts may find it cumbersome to have initial and ongoing involvement in licensing practices.[124]

Still, it is useful to try to identify some types of unilateral refusals to license that might justify intervention. At the outset, it seems clear that no unilateral refusal to license IP should be deemed to have an unlawful competitive effect unless the IP owner has some degree of market power. Furthermore, because of the danger of harming incentives to innovate by restricting IP owners' right to keep their IP to themselves, defendants ought to have some opportunity to show that their refusal to license had pro-competitive effects.

One possibility is to target situations in which a company selectively refuses to license competitors, but not others. This conduct may not be enough to justify intervention by competition agencies, however, because the right to decide whom to exclude is inherent in the patent. Furthermore,

> [w]here intellectual property licenses are at issue, there are even stronger policy reasons than normal not to impose a non-discrimination obligation in the choice of licensees. . . . If an intellectual property owner who once licenses a right is thereafter compelled to make licenses available to all comers on substantially equal terms, the likely effect will be to discourage licensing altogether. Certainly the effect would be to prohibit exclusive licensing, which is often the most efficient means of extracting value from an intellectual property right.[125]

It also seems useful to distinguish situations in which a patent covers a tool that has been licensed to and relied upon by a range of competitive research instrument makers and/or products, and the patent holder suddenly decides not to renew the license. This might be the most compelling scenario for attacking a unilateral refusal to license based on competition law. The conduct is especially harmful because it encourages competitor-licensees to absorb sunk costs in reliance on a license, but then suddenly renders their investments worthless.

Outside of cases where IP is found to constitute an essential facility or where a firm uses its IP in one market to monopolise another market, it is not easy to find an example of a unilateral refusal to license IP that would generally be considered deserving of condemnation by most commentators or under the competition laws of most countries. An American appellate court noted not long ago that, at least with respect to its jurisdiction, there was "no reported case in which a court has imposed antitrust liability for a unilateral refusal to sell or license a patent."[126]

Patent Hoarding. There are at least two types of patent hoarding. One occurs when a firm obtains patents not just on processes and products it intends to use and sell, but on a wide variety of competing processes and products that it intends to leave idle so that other companies cannot legally use them. The objective is to acquire or maintain market power. Let us call this the "blanket strategy." Another type of patent hoarding occurs when a firm amasses patents that it does not intend to use commercially, but that its competitors are likely to infringe. The objective of this strategy is to gain leverage against rivals whose patents one might already be infringing, and possibly to deter entry by firms who do not have an equally formidable patent stockpile. This may be called the "détente strategy."

Both strategies are somewhat troubling from a competition standpoint. They create inefficiencies because firms are spending resources to create inventions that they do not use. In addition, the blanket strategy may protect and extend market power, and the détente strategy may entrench the position of incumbents in a tight oligopoly. It is noteworthy that both of these strategies are easier to carry out and more likely to be deemed necessary when patentability standards are at the easy end of the spectrum.

6.3.1 The blanket strategy.

The blanket strategy is a straightforward means of gaining or holding on to market power, and possibly a dominant position. What is not quite so straightforward is whether it should be unlawful.[127]

Most European and several other countries have statutory provisions for compulsory licensing that could be applied against a firm that is using the blanket strategy. In those jurisdictions, if a company is not using its patent, a court may issue an order requiring that the patent be licensed to someone who will use it.[128]

An argument in favour of that approach is that it does not appear to create a risk of depriving society of the benefits of the idle technology, given that it was not being used anyway. In fact, it would be likely to have the opposite effect. Incumbents would stop shielding themselves with protective but unused patents, leaving others to develop and use those technologies. That, in turn, would open the market to more competition.

On the other hand, if we look back a step further in time from the perspective of the incumbent, we see that if competition agencies show an inclination to attack the blanket strategy, they may discourage the innovation that led to the product that the incumbent *does* use. That might happen because the company would recognise that it cannot build an idle IP wall around its invention to ensure that it acquires and maintains a monopoly. Thus the initial invention has a lower expected value.

Those arguments are rooted in fundamentally different assessments of the incentives necessary for entering a market. The first argument assumes that competitors would find it worthwhile to enter the market by licensing or developing competitive IP, even though they would have to compete with an incumbent. The second argument assumes that even the incumbent would not have entered the market if it could not be monopolised.

Competition agencies can make assessments about whether entry is likely. They might reasonably decide not to take action against a company that is using the blanket strategy if they determine that no one would have entered the market anyway. That would suggest that the incumbent is behaving irrationally, though, because if no one is going to enter unless they can have a monopoly, why bother accumulating all those patents?

Another consideration is that the incumbent already has a patent on the invention that it uses, and that alone is the incentive that has been deemed sufficient by governments to encourage innovation. It is the cost that society is willing to pay in exchange for the benefits of the invention. But patent systems are not designed to guarantee monopolies. If the patent itself is not enough to encourage a particular company to innovate, that does not necessarily mean society should tolerate a greater restriction of competition so as to ensure that the incumbent gains and maintains a monopoly.

It is not easy to discern a correct outcome to this debate, though. For example, there is still something to be said for the point that everyone else had the same opportunity as the incumbent to get those idle patents, and they failed to do so. Moreover, when the U.S. Supreme Court held that a patent holder's bare refusal to license a patent cannot form the basis of an antitrust claim, it reached the same conclusions with

respect to refusals to use patents.[129] Consequently, at least some agencies will have to identify additional anticompetitive conduct before taking action against firms who obtain patents only to mothball them.

6.3.2 The détente strategy.

When most of an industry's patents are in the hands of firms in an oligopolistic market structure, the players may all be technically infringing each other's patents. Consequently, a situation may arise in which cross-licenses are implicitly granted. Each player is deterred from suing the others for infringement because of the fear that the others could retaliate by filing equally legitimate infringement countersuits. Rather than upsetting the status quo, then, the parties may tacitly agree to infringe each other's patents as long as no one complains. Alternatively, the incumbents may reach an explicit cross-licensing agreement, but when going into the negotiations, they will still want to be armed with at least as much IP firepower as the other parties.

As a result, there is an incentive to obtain patents just because competitors are likely to infringe them.[130] Cohen, Nelson and Walsh observed this phenomenon in their 2000 survey of nearly 1500 American R&D laboratory managers, noting that a common use of patents in complex product industries was

> . . . to become or remain a major competitor (i.e., "player") in an industry, often via the amassing of large portfolios. . . . [F]irms patent not only to protect their own technology, but to hold their rivals hostage by controlling technology that they need. . . . The ransom demanded by the firm is either formal access to rival technology realised through liberal cross-licensing, or at least the ability to do work similar to that of its rivals without being sued. . . . By conferring nonexclusive access to a market in such settings, patents are less an instrument for appropriating rents directly from the firm's own patented inventions (via their commercialisation or licensing), and more an instrument for appropriating a share of the oligopolistic rents accruing to the new technologies of all incumbents.[131]

The strategy of accumulating patents that rivals need solidifies the status quo in an oligopoly by ensuring that one has enough threatening IP to deter the other players from suing. If easy patentability also facilitates sharing oligopolistic rents, competition policy would ordinarily cast at least a suspicious glance at it. On the other hand, if the alternative to oligopoly is a market dominated by only one or two firms who were able to meet stringent patentability standards, one might prefer the easy-patentability/oligopoly scenario. Unfortunately, even in an easy patentability environment, time and resources are wasted in the acquisition of "bargaining chip" patents because they do not promote the introduction of any new product that would not have been made without the patent.

In addition, in an easy patentability environment, potential entrants may be virtually locked out of the market. While it is likely that entrants will infringe one or more of the incumbents' patents, it is less likely that they will come equipped with enough countervailing IP to achieve détente against the formidable portfolios of the incumbents. Entrants may therefore perceive a strong likelihood of being sued, so entry would be more difficult for them than it was for companies who entered earlier and grew to become incumbents.

An alternative would be to seek the necessary licenses from the incumbents, but when added to the projected cost and uncertain outcome of their own R&D investments, entrants may find this alternative infeasible. Finally, even if entrants were to risk the extra cost of obtaining licenses, they would still have to share any supra-competitive profits earned from their innovations with the incumbents, which will further discourage them from entering.[132]

It may be tempting to ignore the problems presented by the détente strategy, at least in the human health segment of the biotechnology industry, because it has not tended toward an oligopolistic market structure. The proliferation of patents, however, has caused some concern that the strategy will nevertheless begin to appear.[133]

Is there anything that competition agencies could or should do in these circumstances? One possibility is to use competition law to allow entrants a defence against infringement actions when the necessary technology is already being licensed (expressly or implicitly) among the major competitors of a concentrated industry, but is not offered on reasonable terms to others. That, however, opens a debate similar to the one above regarding the blanket strategy.

7. Conclusion

Ideally, competition policy toward IP in the biotechnology industry would be backed by a firm sense of how to allocate patent rights on the path from initial research to ultimate product so as to encourage the highest yield of useful, marketed innovations. This challenge is daunting, not only because of the industry's complexity, but because of the sensitive structure of innovation incentives, which often shifts in more than one direction in response to each patent and competition policy change. Increasing patent protection and behavioural freedom for upstream innovators, for example, would raise their incentive to innovate but would also tend to discourage downstream R&D.

When contemplating IP-related policy moves, therefore, competition agencies' wisest course of action may be to focus on areas that are a) not subject to the shifting incentives effect described above; or b) so clearly out of balance that it is evident which incentives need to be strengthened even at the cost of weakening others. Category a) would include many of the things that competition agencies could do in an advisory role, such as advocating a better understanding and implementation of economics, or holding regular meetings with patent office officials to discuss IP/competition policy issues.

A simple category b) example is suing the parties to an infringement settlement agreement because it transforms them from two research tool competitors into participants in a price-fixing scheme. That would arguably reduce the upstream tool makers' incentives to innovate, but when weighed against the cost of tolerating price fixing and the dampening effect that would have on downstream tool users, the correct policy choice is easy to identify. Another category b) example is suing a dominant licensor who insists on receiving reach-through royalties on every downstream unit produced by licensees even though it is fairly easy to ascertain which downstream items incorporated the licensor's technology and which did not.

Inevitably, agencies will encounter middle-ground cases in which the correct course of action is not so apparent. In such cases, it is probably best to err on the side of caution and refrain from intervening because the long term harm from inadvertently reducing incentives to innovate is so great.

NOTES

1. A gene contains hereditary information encoded in the form of deoxyribonucleic acid ("DNA") and is located at a specific position on a chromosome in a cell's nucleus.

2. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

3. OECD Ministerial Report, *Patents and Innovation: Trends and Policy Challenges* (2004), at pp. 11-13, 22.

4. A genome is the full set of DNA in a cell or organism.

5. *See, e.g.*, the web site of Geron Corporation at www.geron.com/.

6. OECD Ministerial Report, *Patents and Innovation: Trends and Policy Challenges* (2004), at p. 22; Ronald Hirshhorn and Jock Langford, *Intellectual Property Rights in Biotechnology: The Economic Argument*, paper prepared for the Canadian Biotechnology Advisory Committee on Intellectual Property and the Patenting of Higher Life Forms, (2001), available at http://cbac-cccb.ic.gc.ca/epic/internet/incbac-cccb.nsf/vwapj/EcoArgument_Hirshhorn_Langford_f.pdf/$FILE/EcoArgument_Hirshhorn_Langford_f.pdf , at pp. 18-19.

7. Japanese Fair Trade Commission, *Guidelines for Patent and Know-how Licensing Agreements under the Antimonopoly Act* (30 July 1999), available at www2.jftc.go.jp/e-page/guideli/patent99.htm (hereinafter, "Japanese Guidelines"); United States Department of Justice and Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* § 2.0 (April 6, 1995), available at www.usdoj.gov/atr/public/guidelines/ipguide.htm (hereinafter, "U.S. Guidelines"); Commission Notice, Guidelines on the Application of Article 81 of the EC Treaty to Technology Transfer Agreements, O.J. C101/2 (2004) (hereinafter, the "Commission Guidelines").

8. Frank H. Easterbrook, "Ignorance and Antitrust," in Antitrust, Innovation, & Competitiveness 82, 122-23 (Thomas M. Jorde & David J. Teece, eds. 1992); *accord* F.M. Scherer & David Ross, Industrial Market Structure and Economic Performance 613 (3d ed. 1990).

9. Edmund Kitch, *Elementary and Persistent Errors in the Economic Analysis of Intellectual Property*, 53 Vanderbilt Law Review 1727, 1729-38 (2000).

10. U.S. Guidelines § 2.0 (1995).

11. Rebecca S. Eisenberg, *Reaching Through the Genome*, 50 Advances in Genetics 210, 211 (2003).

12. *Id*. at 212.

13. *Id*. at 218.

14. OECD, *Genetic Inventions, Intellectual Property Rights and Licensing Practices* (2002), at 38, 65.

15. *See* FTC Report (2003), Ch. 1, p. 34 (one panellist noted that the time available to patent examiners in the United States was "clearly inadequate given the complexity and difficulty of biotechnology patents").

16. OECD, *An Overview of Biotechnology Statistics in Selected Countries* (STI Working Paper 2003/13)," DSTI/DOC (2003)13, at 21.

17. OECD, *Genetic Inventions, Intellectual Property Rights and Licensing Practices* (2002), at 33-38.

18. OECD, *An Overview of Biotechnology Statistics in Selected Countries* (STI Working Paper 2003/13), DSTI/DOC (2003)13, at 19.

19. *Id*. at 39.

20. *Id*. at 69.

21. Joshua Gans, David Hsu & Scott Stern, *When Does Start-Up Innovation Spur the Gale of Creative Destruction?*, 33 Rand Journal of Economics (2002) (patents are relatively more effective in protecting IPR in the biotechnology industry than in other industries); F.M. Scherer, *The Economics of Human Gene Patents*, 77 Academic Medicine 1348, 1353-54 (2002) (noting that the evidence is not entirely one-sided but concluding that "[f]or investments to develop new pharmaceutical and biological therapies, it seems clear that having patent protection is in most cases quite important."). Patents also have an unusually prominent role in pharmaceuticals innovation. *See* Wesley M. Cohen, Richard R. Nelson & John P. Walsh, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not), National Bureau of Economic Research*, Working Paper No. 7552 (2000) (concluding that patents are particularly important to innovation in the pharmaceutical industry); Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 Management Science 173 (1986) (finding that an absence of patent protection would have had little or no effect on innovation for most firms in most industries except pharmaceuticals).

22. In many industries, companies place patents low on the list of factors they take into account when making R&D investment decisions. Companies tend to believe that other measures, such as keeping their work secret and striving for a strong first mover advantage, are more effective than patents in protecting earnings from inventions. Cohen, Nelson & Walsh (2000) at 1-2 & n.2.

23. OECD, *An Overview of Biotechnology Statistics in Selected Countries* (STI Working Paper 2003/13), DSTI/DOC (2003)13, at 28.

24. United States Department of Commerce, *A Survey of the Use of Biotechnology in U.S. Industry* (October 2003), available at http://www.technology.gov/reports

25. FTC Report (2003), Ch. 3, p. 16.

26. Joshua Gans, David Hsu & Scott Stern, *When Does Start-Up Innovation Spur the Gale of Creative Destruction?*, 33 Rand Journal of Economics (2002); OECD, *Genetic Inventions, Intellectual Property Rights and Licensing Practices*, (2002) at 47; F.M. Scherer, *The Economics of Human Gene Patents*, 77 Academic Medicine 1348, 1353-54 (2002).

27. OECD, *Biological Resource Centers: Underpinning the Future of Life Sciences and Biotechnology* (2001).

28. Francis Collins, *et al.*, *A Vision for the Future of Genomics Research: A Blueprint for the Genomic Era*, 422 Nature 835 (24 April 2003).

29. OECD Ministerial Report, *Patents and Innovation: Trends and Policy Challenges* (2004), at p. 8, 23; FTC Report (2003), Chs. 2, 3.

30. FTC Report, Ch. 4, pp. 6-8.

31. Of course, if loose patentability standards make it easy not only to get an original patent in a given area, but also make it easy to get follow-on patents that arguably impinge on the original patent's territory, then these effects may be offset and follow-on inventors may be emboldened. Which effects are set in motion depends on which of the patentability standards (novelty, non-obviousness, and utility) are relatively easy.

32. *See* Part IV.B. regarding the "Anticommons".

33. Josh Lerner, *Patenting in the Shadow of Competitors*, 38 Journal of Law and Economics 463, 465, 489-490 (1995) (the cost of litigation discourages biotechnology companies from seeking patents in areas where rivals already have patents).

34. Gene splicing is a technique that attaches a gene to another piece of DNA to create a new molecule. Gene splicing is often used to introduce DNA from one organism into another, which results in a genetically modified micro organism, cell, or "transgenic" animal.

35. Eisenberg (2003), at 219.

36. OECD, *Genetic Inventions, Intellectual Property Rights and Licensing Practices* (2002), at 13.

37. *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 916-919, 927 (Fed. Cir. 2004).

38. European Patent Office, Japan Patent Office, and United States Patent and Trademark Office, Trilateral Project B3b, Mutual understanding in search and examination, Report on Comparative study on biotechnology patent practices (2001), available at www.jpo.go.jp/saikine/tws/report/B3b_report_pdf/B3b_reachthrough_text.pdf; all of the studies are available at www.jpo.go.jp/saikine/tws/sr-3.htm.

39. *See* U.S. Patent and Trademark Office, *Utility Examination Guidelines* (2001), available at www.uspto.gov/web/offices/com/sol/notices/utilexmguide.pdf

40. Joseph J. Spengler, *Vertical Integration and Antitrust Policy*, 58 Journal of Political Economy 357 (1950); Carl Shapiro, *Navigating the Patent Thicket*, in 1 Innovation Policy and the Economy 119, 123, 149 (Adam Jaffe, Josh Lerner, Scott Stern, eds., 2001).

41. Michael A. Heller and Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 Science 698 (1998).

42. The transcripts are available at www.ftc.gov/opp/intellect/. The hearings took place over 24 days in 2002. More than 300 panellists, including business representatives, independent inventors, leading competition and patent practitioners, and prominent scholars participated.

43. OECD, *Genetic Inventions, Intellectual Property Rights and Licensing Practices* (2002), at 47, 51.

44. *Id.* at 47.

45. John P. Walsh, Ashish Arora, & Wesley M. Cohen, *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, in Patents in the knowledge-based Economy (Wesley M. Cohen and Stephen A. Merrill, eds., 2003), at pp. 285-286.

46. *Id*., at 286.

47. Richard Epstein, *Steady the Course: Property Rights in Genetic Material*, John M. Olin Law & Economics Working Paper, No. 152, The Law School of the University of Chicago (2003), at p. 19, available at www.law.uchicago.edu/Lawecon/index.html.

48. The exemption was enacted in 1909. Katsuya Tamai has argued that, at least at that time, the experimental research exemption made perfect sense. In the early 1900s, Japan was still a developing country. It needed to be able to reverse engineer patented inventions without fear of litigation so that it could use them to develop new technologies. Katsuya Tamai, *The Experimental Use Exception: A Japanese Perspective*, Symposium, Reconciling Competing Interests in Intellectual Property, University of Washington Center for Advanced Study and Research on Intellectual Property (July 2002), available at www.law.washington.edu/casrip/. This reasoning suggests that the exemption may no longer be needed in Japan today.

49. *Madey v. Duke University*, 307 F.3d 1351, 1362 (Fed. Cir. 2002).

50. *Id.*

51. Heinz Goddar, *The Experimental Use Exception: A European Perspective*, Symposium, Reconciling Competing Interests in Intellectual Property, University of Washington Center for Advanced Study and Research on Intellectual Property (July 2002), available at http://www.law.washington.edu/casrip/

52. *See Clinical Trials I*, 130 BGHZ 259, 1996 GRUR 109, 1997 IIC 103, 1997 RPC 623 (1995) (using a patented drug in experiments, including clinical trials, for the purpose of finding indications other than the patented one, does not infringe the patent); *Clinical Trials II*, 135 BGHZ 217, 1997 NJW 3092, 1998 RPC 423, *affirmed*, GRUR 2001 at 43 *et seq*. (2001) (clinical trials are permitted when their purpose is to obtain data necessary for clinical approval of a product, even if it is for the same indication as that of the patented product).

53. In the U.S., for example, competitors are not permitted to seek patent invalidation by a court unless the patent holder has threatened them with litigation. This rule raises the risk of entry in markets affected by patents because the IP owner may wait until the entrant has invested in the sunk costs necessary to enter the market, and only at that point will it file an infringement lawsuit. On the other hand, the rule has the virtue of minimizing opportunities for competitors to harass IP owners with nuisance lawsuits.

54. FTC Report (2003), Ch. 3, III.

55. In a patent pool, multiple parties agree to put their patents into a common pool, thereby making it easier to license all of the necessary technologies for new product development, either to each other or to third parties. See Part VI.B.1. for more on patent pools.

56. This occurred in the case of two genes patented by Myriad Genetics called BRCA1 and BRCA2. Women with BRCA1 and BRCA2 mutations are seven times more likely to develop breast cancer than women with normal BRCA1 and BRCA2 genes. Myriad has exclusive rights to diagnostic tests for BRCA1 and BRCA2 mutations. Competitors cannot legally invent around Myriad's patent because any test they create will necessarily involve the patented gene.

57. OECD, *Genetic Inventions, Intellectual Property Rights and Licensing Practices* (2002), at 47.

58. *See* SNPC's web site, at http://snp.cshl.org/about/; *see also* Wellcome Trust's 15 April, 1999 press release about SNPC, at http://www.wellcome.ac.uk/en/1/awtprerel0499n123.html

59. Wellcome Trust press release (15 April 1999), at http://www.wellcome.ac.uk/en/1/awtprerel0499n123.html

60. United States Federal Trade Commission, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy (2003), hereinafter, "FTC Report." The FTC Report is based on joint hearings held by the FTC and DOJ over 24 days in 2002.

61. FTC Report, Chapter 5, p. 1 & n.2 (noting that most patent applications involve claims of little economic significance, and that only a small percentage of patents actually reaches the market).

62. *Cf.* Mark Lemley, *Rational Ignorance in the Patent Office*, 95 Northwestern University Law Review 1495 (2001). Lemley argues that it is not advisable for the patent office to conduct detailed examinations of every patent application because the vast majority of them are never asserted against competitors. For society, it is much more efficient for courts to make careful validity determinations in the minority of instances where patent rights are asserted against competitors. If his reasoning is correct that patent offices should not do a very thorough job of examining patents, then it certainly does not make sense for competition agencies to do so.

63. Eisenberg (2003), at 218-219 & n.37 (noting that it is common for groundbreaking inventions in new markets to receive broad patents because the main constraint on the scope of patent claims is the prior art in the relevant field).

64. *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 511 (1917). *See also Sony Corp. of America v. Universal City Studios, Inc.*, 464 U.S. 417, 429 (1984) ("The monopoly privileges that Congress may authorize are neither unlimited nor primarily designed to provide a special private benefit. Rather, the limited grant is a means by which an important public purpose may be achieved. It is intended to motivate the creative activity of authors and inventors by the provision of a special reward, and to allow the public access to the products of their genius after the limited period of exclusive control has expired.").

65. *See* Japan Fair Trade Commission, Guidelines for Patent and Know-how Licensing Agreements under the Antimonopoly Act (1999), at ¶1; Commission Regulation (EC) No. 772/2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements (also known as the Technology Transfer Block Exemption, hereinafter "TTBE"), O.J. L 123/11 (2004), recital 5.

66. It is worth noting, however, that under the U.S. Guidelines and the TTBE, the parties in this situation would still be considered competitors for purposes of analysing the agreement. U.S. Guidelines § 3.3, ¶2; TTBE Article 1(1)(j) in conjunction with Articles 3(1) and 4(1).

67. TTBE rec. 4. *See* Article 3 TTBE (providing for higher exemption thresholds in the case of vertical license agreements). *Compare also* Article 4(1) TTBE (blacklisted restrictions in license agreements between competitors) and Article 4(2) TTBE (blacklisted provisions in vertical license agreements). The Commission Guidelines provide a fuller discussion of the distinction between competitors and non-competitors at ¶¶26-33.

68. U.S. Guidelines § 3.3 (1995).

69. Cross-licensing is a generalization of a closed patent pool, where two firms permit each other to use certain technologies in what is basically a *quid pro quo* agreement. The competitive issues raised by cross licensing arrangements are similar to those discussed in the text in connection with patent pools. To limit the scope of his paper, the focus will be on patent pools.

70. USPTO, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* (2000). *See also* Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, in 1 Innovation Policy and the Economy (A. Jaffe, *et al*. eds., 2001); FTC Report (2003), Ch. 3, pp. 27-28.

71. OECD, *Genetic Inventions, Intellectual Property Rights and Licensing Practices* (2002), at 48. Interestingly, a biotechnology trade association was strongly supportive of patent pools in a submission to the FTC and DOJ hearings. FTC Report, Chapter 3, at 27.

72. For example, the lack of longer inter-firm relationships and homogeneity of interests of right holders was found to reduce the likelihood of patent pools. Uncertainties concerning the validity and scope of patents, as well as valuation problems, were also factors that inhibit patent pools. *See, e.g.*, Arti K. Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 Northwestern University Law Review 77 (1999); COMMENT: *Evaluating the Use of Patent Pools For Biotechnology: A*

Refutation to the USPTO White Paper Concerning Biotechnology Patent Pools, 19 Santa Clara Computer & High Tech. Law Journal 229 (2002).

73. U.S. Guidelines, §5.5.

74. *See, e.g.*, U.S. Federal Trade Commission, *Summit Technology, Inc. and VISX, Inc.*, Press Release, March 24, 1998 available at http://www.ftc.gov/opa/1998/9803/eye.htm (announcing enforcement action against a cross license arrangement on the grounds that the arrangement involved substitute technologies and was designed to eliminate competition between the right holders).

75. The TTBE does not cover patent pools. *See* Commission Guidelines ¶41.

76. Commission Guidelines ¶219.

77. Commission Guidelines ¶222.

78. Integration of complementary technologies, reduction of transaction costs, clearance of blocking positions, and avoidance of costly infringement litigation.

79. Anticompetitive effects of pools are considered unlikely unless access to the pooled technology is necessary to compete in the downstream market, and the pool participants collectively have market power in the downstream market. In those circumstances, it would have to be examined whether the limitations on participation are reasonably related to the efficient development and exploitation of the pooled technology. Similarly, when considering the effects of grant-back provisions, the Guidelines explain that requirements to license developments back at minimal costs may have detrimental effects on the incentive to innovate, but may have pro-competitive effects; anticompetitive effects were likely only if the grant-back provisions affected a large segment of the potential R&D in an innovation market. U.S. Guidelines, §5.5.

80. Business Review letters state the DOJ's current intention not to initiate enforcement action with respect to proposed business conduct described in the request for a review letter, based upon the requestor's representations and assurances.

81. MPEG LA Business Review Letter (June 26, 1997); DVD 3C Business Review Letter (December 16, 1998); DVD 6C Business Review Letter (June 10, 1999).

82. Note, however, that the business review letters concerned patent pools for the creation of industry standards which may have been the reason for the non-discriminatory access requirement. The U.S. Guidelines suggest that universal access to the pooled technology is not necessary *per se* for every pooling arrangement.

83. The list follows Howard Morse, *Cross Licensing and Patent Pools, Legal Framework and Practical Issues*, 3 Antitrust and Intellectual Property 42 (2002).

84. DVD 6C Business Review Letter.

85. MPGE LA Business Review Letter.

86. The continuing role of an independent expert to assess essentiality is an especially effective guarantor that the Portfolio patents are complements, not substitutes. The relevant provisions of the Agreement Among Licensors appear well designed to ensure that the expert will be called in whenever a legitimate question is raised about whether or not a particular patent belongs in the Portfolio; in particular, they seem designed to reduce the likelihood that the Licensors might act concertedly to keep invalid or non-essential patents in the Portfolio or to exclude other essential patents from admission to the Portfolio. MPEG LA Business Review Letter.

87. Another important compliance issue for biotechnology patent pools could be the fundamental premise that patents to be licensed in a pool must be valid. As discussed above, there might sometimes be considerable uncertainty over the validity of biotechnology patents. One commentator has raised the question whether entering in a patent pool on a reasonable, good-faith assumption that the pooled patents are valid should be sufficient to shield the pool from antitrust risks. Morse, *supra*, note 83. It also may be especially important for biotechnology patent pools to assure that a pool is not used to shield invalid patents from challenges. Royalty allocation formula can be used to reserve an incentive for other licensors to exclude invalid patents. It may also be important to preserve incentives for licensees to challenge invalid patents, for example by permitting for reduced royalties if a pooled patent turns out to be invalid. The Commission Guidelines' requirements concerning no-challenge provisions similarly attempt to preserve an incentive for licensees to challenge invalid patents in a pool.

88. It may well be, however, that the outcomes in actual cases would be the same under either the EC or the U.S. Guidelines. The DOJ Business Review letters concerned pools that aimed to set industry-wide standards. The Commission Guidelines indicate that where the pool has a significant position in a relevant market, the Commission would be concerned about foreclosure effects resulting from the inclusion of patents that had substitute patents outside the pool.

89. Josh Lerner & Jean Tirole, *Efficient Patent Pools*, American Economic Review, 94, 98 (June 2004); Morse, *supra*, note 83 at 399.

90. Alternatively, suppose a reach-through licensing agreement enables a licensee to use certain technology, and the licensee wants to use that technology in a portion of its downstream output. Suppose further that the technology has several non-infringing competitors and that the licensee wishes to use them in other portions of its output. In this case, the reach-through royalty may behave like an exclusive dealing arrangement if the licensee must pay the licensor a royalty on each unit produced, regardless of which technology it actually uses. The licensee's only rational decision is to use the licensor's technology in either all or none of the output. If the licensor is sufficiently dominant, using its technology for 100 percent of the output may be the only viable choice. To determine whether an exclusive dealing arrangement has a harmful effect on competition, the agency will have to analyze factors such as the market power of the party imposing it, the degree of foreclosure, and the duration of the arrangement.

91. TTBE, Article 2(1).

92. If the parties can sufficiently identify a contract product, the TTBE would be applicable to a license agreement that includes reach-through royalties between non-competitors where the parties' market shares do not exceed 30%. In agreements between competitors, royalties based on sales of products that do not incorporate the licensed technology are considered to be prohibited under the TTBE. Commission Guidelines, ¶157.

93. *E.g., Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 135 (1969).

94. *Engel Industries, Inc. v. Lockformer Company*, 96 F.3d 1398, 1408 (Fed. Cir. 1996); *Bayer AG v. Housey Pharmaceuticals, Inc.*, 228 F. Supp.2d 467 (D. Del. 2002).

95. U.S. Guidelines, § 4.1.2 (1995).

96. Commission Guidelines, ¶160.

97. Commission Guidelines, ¶81.

98. JFTC Guidelines, Part 4(3)(2)(a).

99. Eisenberg (2003), at 215.

100. *Id.*

101. *Id*. at 214.

102. *See* Part IV.C.

103. Herbert Hovenkamp, Mark D. Janis & Mark A. Lemley, IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law s. 25.2 at 25-2 (2004).

104. The Guidelines suggest that non-exclusive grant-backs and assignment backs would not be considered a restriction of competition and, in any event, they would benefit from the TTBE. Grant-back and assignment backs covering non-separable technology in principle are never considered restrictions of competition. *See* Guidelines, ¶ 109.

105. Commission Guidelines, ¶ 110.

106. JFTC Guidelines, Part 4(3)(5)(b).

107. Technically, the Guidelines state that anticompetitive effects are not likely unless the licensor has market power in a technology or innovation market. "Technology markets" consist of the intellectual property of interest (*e.g.*, the licensed technology) and its close substitutes—that is, the technologies or goods that are close enough substitutes significantly to constrain the exercise of market power with respect to the intellectual property of interest. § 3.2.2. "Innovation markets" consist of the research and development to produce new intellectual property. § 3.2.3.

108. Eisenberg notes the example of the United States' publicly funded Human Genome Project, which had already done much of the work necessary for completing the human genome sequence when a private company began racing the government to the finish line. The fact that a private firm devoted resources to a project that was already being sponsored by the government, instead of simply accepting the upstream gift and using its resources for downstream endeavours, suggests that upstream research was too richly rewarded. Eisenberg (2003), at 227-228.

109. *Id*. at 228-29.

110. Article 4(1)(a)&(2)(a).

111. Commission Guidelines, ¶75.

112. Article 3(1).

113. Part 1.3.(1).

114. § 5.2.

115. § 5.2.

116. On the other hand, it is easy to imagine that such a licensing arrangement could be a disguise for a price-fixing agreement. Suppose Company A, which owns certain patented technology for which there is currently no competitor, learns that Company B is planning to introduce a non-infringing competitive product. Rather than face competition from B's new product, A decides to try to maintain supra-competitive profits by sharing the market with B. It persuades B to abandon its product development and instead take a license for A's technology. The license controls the price B can charge for the product it will now introduce using A's technology. That price equals the price that A is currently charging for its

product, i.e., a monopolistic price. Thus the licensing agreement is a masquerade for a market sharing and price-fixing agreement.

117. *Brulotte v. Thys*, 379 U.S. 29 (1964).

118. *See Bayer AG v. Housey Pharmaceuticals*, 228 F. Supp.2d 467 (D. Del. 2002). In that case, the court held that it was not patent misuse for defendant to collect post-expiration royalties based on post-expiration sales of a drug as compensation for the pre-expiration use of a drug discovery research tool. In other words, the court upheld a type of reach-through royalty arrangement.

119. *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 US 405, 426-30 (1908).

120. *See, e.g.*, *American Cyanamid*, 72 F.T.C. 623, 684-85 (1967), *aff'd sub. nom. Charles Pfizer & Co.*, 401 F.2d 574 (6th Cir. 1968), *cert. denied*, 394 US 920 (1969) (patents acquired by inequitable conduct); *Dell Computer Corp.*, 5 Trade Reg. Rep. (CCH) ¶ 24,054 (May 20, 1996) (patentee acquired market power by failing to disclose patent, despite explicit request to do so, which controlled an industry-wide standard that would not have been adopted if disclosure had been made).

121. A recent Supreme Court decision strongly suggests that it will continue to endure. *Verizon Communications v. Law Offices of Curtis Trinko* involves a refusal to grant access outside the IP context, but its language is so strong that it necessarily has implications for unilateral refusals to license IP. 124 S. Ct. 872 (2004). *Trinko* involves an allegation that Verizon blocked a competitor's access to Verizon's local telephony loop and associated facilities. The Court ruled in favour of Verizon, noting that

> [f]irms may acquire monopoly power by establishing an infrastructure that renders them uniquely suited to serve their customers. Compelling such firms to share the source of their advantage is in some tension with the underlying purpose of antitrust law, since it may lessen the incentive for the monopolist, the rival, or both to invest in those economically beneficial facilities.

Id. at 879. Thus the Court found more reason to preserve the incentive to invest than to require access to facilitate competition. If anything, this reasoning would apply even more forcefully in an IP context, where the patent holder's right to exclude others is statutorily granted.

122. *Magill*, C-241/91 P (E.C.J. 1995).

123. Case C-418/01, *IMS Health Care GmbH & Co. KG v. NDC Health GmbH & Co. KG*, Judgment of April 29, 2004, at ¶38.

124. For a rather thorough discussion of the difficulties associated with implementing and managing compulsory licensing remedies, see Richard Epstein, *Steady the Course: Property Rights in Genetic Material*, John M. Olin Law & Economics Working Paper, No. 152, The Law School of the University of Chicago (2003), at pp. 29-34, available at www.law.uchicago.edu/Lawecon/index.html; *see also Verizon Communications v. Law Offices of Curtis Trinko*, 124 S. Ct. 872, 879 (2004) (noting that imposing obligations to grant access to or deal with other firms would require courts to "act as central planners, identifying the proper price, quantity, and other terms of dealing – a role for which they are ill-suited.").

125. *See* Hovenkamp, Janis & Lemley (2004), s. 13.2c at 13-7, 13-8.

126. *In re Independent Service Organizations Antitrust Litigation*, 203 F.3d 1322, 1326 (Fed. Cir. 2000).

127. That is to say, it is not straightforward when the firm uses its own research to execute a blanket strategy. If, on the other hand, it attempts to build a protective patent wall via acquisitions, it is much easier to conclude that the conduct should be unlawful.

128. *See, e.g.*, Competition Act, s. 32 (Canada); Patent Law 1999, s. 93 (Japan); Patents Act 1990 (Cth), ss. 133, 163-167 (Australia); Patents Act 1977, ss. 48A, 48B (U.K.).

129. *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 US 405, 426-30 (1908).

130. *See* Cohen, Nelson & Walsh (2000), at 19, 22, 25, 26.

131. *Id*. at 25, 26.

132. On the other hand, some scholars find the idea of limiting entry in industries where numerous firms hold patented pieces of a marketable technology to be appealing. They argue that as the number of firms in such industries grows, it becomes less and less likely that a product will ever be marketed because the incidence of prohibitively expensive, stacked licensing fees and sheer negotiation breakdowns grows. Heller and Eisenberg (1998); Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and Patent Law*, 5 Journal of Economic Perspectives 29 (1991); Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 Columbia Law Review 839, 860-861 (1990).

133. FTC Report (2003), Ch. 2, p. 30 n.208 (citing hearing testimony of Professor John Barton).

NOTE DE RÉFÉRENCE

1. Introduction

Depuis une trentaine d'années, la biotechnologie a repoussé les frontières de la connaissance humaine comme de la propriété intellectuelle. Les scientifiques ayant mis au point des techniques pour isoler et créer du matériel génétique[1] et ayant commencé à leur donner une application commerciale, un nouveau secteur s'est affirmé, tout comme sa volonté d'obtenir une protection de ces techniques par les brevets. L'arrêt de 1980 de la Cour suprême des États-Unis disposant que des organismes génétiquement modifiés pouvaient être brevetés a apporté une bonne part de la confiance et des incitations nécessaires aux innovateurs de la biotechnologie pour construire leur secteur.[2] Même si l'on continue de se demander s'il est sage d'accorder des brevets sur des éléments d'ADN, cela fait aussi un certain temps que la politique d'autres pays de l'OCDE consistant à autoriser de tels brevets a pu s'établir solidement. Pour l'innovation biotechnologique, la porte a donc été ouverte à un déferlement de la propriété intellectuelle et c'est ce qui s'est produit.

Depuis plusieurs années, le nombre de demandes de brevets du secteur des biotechnologies progresse plus vite que le nombre correspondant de demandes émanant d'autres secteurs. Des milliers de brevets biotechnologiques sont accordés chaque année, contribuant au développement de nouveaux produits, services ou instruments dans l'agriculture, la pharmacie ou les produits et procédés industriels.[3] Aujourd'hui, l'achèvement de la carte du génome humain[4] et l'utilisation complexe de cellules souches d'embryons humains, par exemple, ont porté les ambitions des entreprises biotechnologiques à des hauteurs inégalées. Elles mettent en effet en œuvre des techniques qui leur permettront par exemple de créer des cellules spéciales qui apprendront au système immunitaire humain la façon de détruire des cellules cancéreuses ou à régénérer des organes endommagés et malades.[5] Les inventeurs qui développent toutes ces innovations biotechnologiques s'appuient sur les droits de propriété intellectuelle (DPI) pour protéger et valider leurs travaux. Ils ont en outre recours à des licences de droits de propriété intellectuelle pour avoir accès aux instruments et aux techniques dont ils ont besoin. Des études empiriques sur le rôle des brevets ont, dans l'ensemble, affirmé leur importance pour encourager l'innovation dans le secteur des biotechnologies.

Toutefois, au-delà de certaines innovations importantes, la déferlante des brevets biotechnologiques a fait craindre que les brevets ne soient accordés trop facilement et trop généreusement. Un trop grand nombre de brevets couvrant un domaine trop étendu risque non seulement de porter préjudice à la concurrence, mais encore d'étouffer l'innovation en rendant la poursuite des recherches plus risquée, plus difficile et plus onéreuse. Parallèlement, certaines techniques de concession de licences qui sont utilisées dans le secteur des biotechnologies comme les rétrocessions de licence et les revendications sur les inventions ultérieures, peuvent aggraver ces problèmes. Conscient de l'importance croissante de ce secteur et des questions nouvelles qu'il suscite sur l'interface entre propriété intellectuelle et concurrence, le Comité de la concurrence a décidé en octobre 2003 d'organiser une table ronde traitant des problèmes situés au carrefour de la propriété intellectuelle et de la politique de la concurrence dans le domaine de la biotechnologie. Cette table ronde vient actualiser, sous un angle plus spécifiquement sectoriel, celle que le Comité avait organisée en 1998 sur le thème de la politique de la concurrence et des droits de propriété intellectuelle.

Les principaux points abordés par ce document sont les suivants :

- Certains observateurs craignent que la mise en œuvre des normes de **délivrance des brevets** par les offices spécialisés ne soit trop laxiste en ce qui concerne le secteur des biotechnologies et que les revendications de brevets même techniquement valables ne soient formulées en termes trop généraux. Cela étant, changer la politique en matière de **délivrance des brevets** et de l'étendue admissible de la protection des brevets peut avoir des effets aussi bien positifs que négatifs sur l'innovation et la concurrence.

- Il est vrai que la jeunesse relative du secteur des biotechnologies, sa complexité et son expansion toujours rapide tendent à compliquer le travail des vérificateurs de brevets lorsqu'il s'agit de réduire les revendications générales et de rejeter toutes les demandes qui ne répondent pas aux critères officiels de **délivrance des brevets**. Approuver des demandes de brevet qui auraient dû être limitées ou rejetées pourrait, dans certains cas, réduire la concurrence et les incitations à l'innovation. Par ailleurs, la dépendance du secteur vis-à-vis d'instruments de recherche brevetés en amont risque d'aboutir à un engorgement de brevets de nature à entraver le progrès technologique. Ce secteur a aussi contribué à l'apparition de certaines pratiques en matière de concessions de licence (comme les revendications sur les inventions ultérieures et les rétrocessions de licence) susceptibles de porter préjudice à la concurrence.

- On désigne couramment ce phénomène d'engorgement de brevets par le terme « anticommons » (anti-communs ou blocage par les biens privatifs). Dans ce type de situation, un si grand nombre de brevets ont été accordés qu'il devient difficile d'être au fait des licences nécessaires, de les négocier et de les payer au point que cela décourage la poursuite de l'innovation, quand cela ne la bloque pas totalement. Les éléments dont on dispose à ce jour tendent à montrer que le secteur des biotechnologies, même s'il est susceptible d'en connaître un, n'a pas encore abouti à un blocage par les biens privatifs.

- Les pays de l'OCDE ont adopté différentes variantes d'un principe généralement admis selon lequel l'utilisation d'une invention brevetée à des fins purement expérimentales ne saurait être assimilée à une contrefaçon. Cette exemption de l'utilisation expérimentale est importante non seulement parce qu'elles peut atténuer les effets d'éventuels biens privatifs, mais parce qu'elle peut aussi aboutir à plus de concurrence selon qu'elle est appliquée de façon plus ou moins libérale. Cela étant, cette exemption doit être utilisée à bon escient car elle peut décourager l'innovation si elle est appliquée à la légère.

- Lorsqu'elles étudient les effets sur la concurrence des mesures de protection de la propriété intellectuelle comme les normes en matière de **délivrance des brevets** et d'étendue de la protection des brevets, les autorités de la concurrence sont en droit de se demander jusqu'où elles peuvent intervenir dans la sphère des mesures de protection de la propriété intellectuelle. Doivent-elles limiter leur action sur ce terrain à l'application du droit de la concurrence dans des affaires de propriété intellectuelle, ou doivent-elles intervenir directement dans la formulation et la mise en œuvre des mesures de protection de la propriété intellectuelle ; les autorités de la concurrence doivent s'efforcer de limiter les aspects anticoncurrentiels des DPI tout en respectant leur nécessité. Il semble que le plus sage pour les autorités de la concurrence qui souhaiteraient influencer la politique de la propriété intellectuelle consiste soit à contester la validité de brevets illégitimes ou trop larges devant les tribunaux ou en demandant leur réexamen, soit à entamer un dialogue avec l'office de la propriété intellectuelle et de jouer un rôle de conseil (ou les deux).

- S'agissant des comportements en matière de concessions de licence, les groupements de brevets sont apparus comme une autre solution envisageable à un éventuel phénomène de blocage par les

biens biotechnologiques privatifs. Les groupements de brevets sont constitués lorsque deux ou plusieurs parties se réunissent et s"organisent pour que leurs brevets donnent lieu à des licences globales. Cela étant, les groupements de brevet, jusqu'ici au moins, ne sont pas courants dans le secteur et même s'ils devaient s'affirmer, ils risquent de poser certains problèmes de concurrence. Ces préoccupations portent notamment sur la réduction de la concurrence sur le marché horizontal des participants au groupement (s'ils sont concurrents), sur le risque de facilitation des collusions sur les marchés en aval, l'exclusion des technologies concurrentes ou la réduction des incitations à l'innovation. Les autorités de la concurrence de l'Union européenne et des États-Unis ont défini des critères largement analogues pour l'analyse des groupements de brevets. Ces critères cherchent à déterminer si les technologies ainsi regroupées sont des substituts ou des compléments, mais ils tiennent aussi compte d'autres considérations destinées à filtrer les dispositifs susceptibles de réduire la concurrence.

- L'un des mécanismes de licence qui est de plus en plus prisé dans le secteur des biotechnologies réside dans les revendications sur les inventions ultérieures. Les mécanismes de revendication sur les inventions ultérieures consistent à évaluer les redevances sur la base des recettes générées par un produit en aval, qu'il soit ou non fabriqué à l'aide de la technologie faisant l'objet de la licence. Bien que cette pratique puisse faciliter un octroi de licences efficient en résolvant des problèmes d'évaluation et de financement courants dans le secteur, elle peut aussi provoquer des effets d'éviction.

- Un autre mécanisme utilisé dans le secteur des biotechnologies réside dans la rétrocession de licences. Ces mécanismes imposent au concessionnaire de céder au concédant les droits sur toute technologie ultérieure que le concessionnaire fait breveter. De même que les revendications sur les inventions ultérieures, les rétrocessions peuvent encourager un octroi de licence efficient en servant de forme de financement pour les concessionnaires dépourvus de trésorerie. Toutefois, elles peuvent aussi servir à étendre ou à prolonger la puissance sur le marché d'un concédant. La surveillance extérieure exercée par les autorités de la concurrence est justifiée lorsque le concédant occupe une position dominante et que la rétrocession est assortie d'une licence exclusive sur les droits ultérieurs ou leur attribution en totalité.

- Les autorités de la concurrence peuvent rencontrer des situations dans lesquelles un refus unilatéral d'octroi de licence pose des problèmes de concurrence sur les marchés des biotechnologies, notamment compte tenu de la dépendance du secteur vis-à-vis d'instruments de recherche en amont. Un très récent arrêt de la Cour de justice des Communautés européennes démontre sa volonté d'imposer une obligation de licence lorsque le refus de licence en matière de propriété intellectuelle empêche l'apparition d'un nouveau produit, est « injustifié » et exclut toute concurrence sur un marché « secondaire ». Quelles sont exactement les conditions qui satisferont à ces critères, on ne le sait cependant pas. La licence obligatoire peut être un moyen efficace d'injecter de la concurrence sur un marché, mais elle présente certains inconvénients et contraintes qui affectent l'innovation, les autorités de la concurrence et les tribunaux.

- Un autre type de comportement unilatéral lié à la propriété intellectuelle réside dans la thésaurisation de brevets. Des entreprises peuvent thésauriser leurs brevets parce qu'ils essaient de s'entourer d'une muraille de propriété intellectuelle pour acquérir ou protéger une position dominante. Elles peuvent aussi thésauriser des brevets parce qu'elles veulent les utiliser comme monnaie d'échange lors de négociations avec des sociétés dont elles risquent de contrefaire les brevets. La thésaurisation de brevets est inefficace dans la mesure elle mobilise des ressources pour la création ou l'acquisition d'inventions qui ne sont pas affectées à une utilisation productive. Dans certaines circonstances, elle peut aussi dissuader l'entrée, mais les différentes juridictions ont des points de vue divergents sur la question de savoir si l'on peut considérer que

la thésaurisation de brevet est illégale. Il est intéressant de noter que l'on a plus de chances d'observer une thésaurisation de brevets lorsque les normes de **délivrance des brevets** sont plus souples, de sorte que cette pratique apparaît comme un éventuel thème de discussion intéressant entre les autorités de la concurrence et les offices de la propriété intellectuelle.

La Partie II du présent document présente un bref récapitulatif des tensions et des objectifs communs se situant au carrefour de la propriété intellectuelle et de la politique de la concurrence. La Partie III est une introduction à la biotechnologie et à ses caractéristiques distinctives vis-à-vis d'autres secteurs du point de vue de la propriété intellectuelle et de la politique de la concurrence. La Partie IV étudie la façon dont la **délivrance des brevets** et l'étendue de la protection du brevet affectent la concurrence dans le secteur des biotechnologies. La Partie V décrit ensuite certaines mesures que les autorités de la concurrence pourraient prendre pour influencer la formulation et la mise en œuvre d'une politique des brevets. Enfin, la Partie VI aborde les comportements liés à la propriété intellectuelle et certains problèmes connexes qui se posent dans ce contexte pour la mise en œuvre de la politique de la concurrence.

2. Brève présentation de l'interface de la propriété intellectuelle et de la politique de la concurrence

L'exploitation des droits de propriété intellectuelle (DPI) remet en cause certaines hypothèses traditionnelles sur les avantages des marchés concurrentiels. La politique de la concurrence vise généralement à protéger les avantages qui découlent pour les consommateurs de la tarification au coût marginal en favorisant la concurrence. Les lois sur la propriété intellectuelle, en revanche, veillent à la concrétisation des avantages qui résultent des nouveaux produits et des créations nouvelles en protégeant les innovateurs de certaines formes de concurrence, ce qui met en place les conditions du conflit apparent entre les deux régimes.

La politique de la propriété intellectuelle comme celle de la concurrence visent à encourager l'innovation, mais elles peuvent aussi la décourager toutes les deux si elles sont menées trop vigoureusement ou de façon laxiste. Du côté de la propriété intellectuelle, s'il est trop facile d'obtenir des brevets, par exemple, les inventeurs potentiels risquent d'être découragés d'innover en fin de compte, parce qu'il y a trop d'intervenants détenant de trop nombreux brevets de sorte qu'il devient trop difficile et onéreux de déterminer quelles sont les licences nécessaires et de les payer. Du côté de la concurrence, si la loi est appliquée avec une telle vigueur que les rivaux sont autorisés à profiter sans entrave des innovations d'une société, il n'y aura plus guère d'incitations à innover.

Il convient donc de trouver un équilibre fondamental en récompensant les inventeurs par une certaine protection temporaire vis-à-vis des parasites, après quoi la concurrence est facilitée en permettant à quiconque de reproduire et de vendre l'invention. Cet équilibre fondamental ne garantit cependant pas que les deux politiques sont toujours aussi en phase qu'elles pourraient l'être.

Encadré 1. Notions fondamentales sur la propriété intellectuelle.

Un brevet donne à son titulaire le droit exclusif de réalisation, d'utilisation et de cession d'une invention pendant une période limitée (généralement de 20 ans) dans le pays où la demande a été déposée. En contrepartie, le demandeur doit divulguer l'invention dans le texte de sa demande. Les brevets sont censés n'être accordés que pour des inventions novatrices, non évidentes et utiles (ayant une application industrielle). En outre, la demande de brevet doit comprendre un mémoire descriptif de l'invention assorti d'instructions suffisantes pour permettre à une personne compétente de produire ou de mettre en œuvre l'invention. En d'autres termes, la spécification doit être « suffisante ». L'invention proprement dite est définie dans les « revendications » qui font partie du mémoire descriptif. L'étendue de la protection par le brevet peut être déterminée à la lecture des revendications.

Il existe d'autres types de droits exclusifs de propriété intellectuelle (à savoir les droits d'auteur et les marques commerciales, mais les brevets assurent une protection plus large qui va au-delà de l'expression spécifique d'une invention pour s'étendre au concept de l'invention elle-même. C'est l'une des raisons pour lesquelles les brevets représentent le mode privilégié d'affirmation de la propriété intellectuelle dans le domaine des biotechnologies.[6]

Il est aujourd'hui difficilement contestable que les autorités de la concurrence prennent occasionnellement des mesures qui affectent les DPI. Pour réduire les incertitudes concernant le système de la propriété intellectuelle et la mise en œuvre du droit de la concurrence, il convient de déterminer et de faire connaître auprès des milieux d'affaires les circonstances dans lesquelles les autorités de la concurrence vont intervenir. Certaines juridictions, comme l'Union européenne, le Japon et les États-Unis, ont publié des lignes directrices qui servent à cet effet en ce qui concerne les contrats de concession de licence.[7] Toutefois, les autorités de la concurrence peuvent être amenées à décider s'il convient d'aller au-delà du droit de la concurrence proprement dit et d'intervenir plus directement dans les processus et politiques en matière de propriété intellectuelle. Les autorités de la concurrence pourraient, par exemple, traiter de problèmes comme celui de savoir si des brevets ont été obtenus en dépit du non-respect d'un texte relatif à la propriété intellectuelle, et même de savoir tout simplement en quoi doit consister les lois relatives à la propriété intellectuelle.

Indépendamment de la façon dont elles s'aventurent dans la sphère de la propriété intellectuelle, le problème pour les autorités de la concurrence réside dans la façon de minimiser les effets anticoncurrentiels des DPI tout en respectant leur existence et les objectifs sociétaux qu'ils sont censés promouvoir. Pratiquement, toutes les lois sur la concurrence comportent des exemptions ou des exceptions pour des droits explicitement accordés par le droit des brevets ne se trouvent pas niés. Les autorités qui limitent les DPI pour promouvoir la concurrence risquent par inadvertance de réduire les incitations à innover, provoquant par là-même beaucoup plus de dommages que le comportement auquel elles s'efforcent de remédier.

> Une politique de la concurrence qui réduit les prix de 5 % aujourd'hui au prix d'une diminution de 1 point du taux annuel auquel l'innovation abaisse les coûts de production serait calamiteuse. À long terme, un rythme continu de changements, par leur accumulation, finit par noyer les pertes statiques.[8]

En conséquence, comme pour la politique des fusions, la propriété intellectuelle est un domaine dans lequel les autorités de la concurrence doivent procéder à des arbitrages délicats dont les effets futurs sont incertains.

L'une des prémices fondamentales doit être qu'un DPI ne crée pas ou n'accroît pas nécessairement la puissance sur le marché. De nombreux brevets ont été délivrés pour des inventions qui n'ont jamais trouvé de marché, sans parler de puissance sur le marché. En outre, même lorsqu'une demande est déposée pour une invention, le brevet ne peut pas la protéger contre la concurrence de produits ne constituant pas une contrefaçon de DPI, produits dont certains peuvent être supérieurs du point de vue du prix ou de la qualité.

Il n'est donc pas surprenant que la plupart des brevets ne confèrent pas de puissance sur le marché.[9] C'est ce qui a amené certaines autorités de la concurrence à affirmer expressément qu'elles ne considèrent pas que la propriété intellectuelle induit une puissance sur le marché.[10] Pour autant, le droit et la politique de la concurrence et des brevets ont beaucoup d'autres occasions d'entrer en conflit.

3. Caractéristiques intéressantes du secteur des biotechnologies

3.1 Définition

Une définition très simple des biotechnologies est la « biologie appliquée ». Plus précisément, on pourrait les définir comme l'utilisation d'organismes vivants pour fabriquer ou améliorer une substance thérapeutique, un nouvel organisme ou un moyen d'identifier et de développer d'autres produits. Cette définition permet d'englober les méthodes traditionnelles utilisées pour la sélection de végétaux ou d'animaux et la fermentation. Certaines personnes n'utilisent le terme que pour désigner les domaines récents de la génétique. Dans ce contexte, les biotechnologies peuvent être définies comme l'ensemble des techniques qui s'appuient sur les attributs des cellules, comme leurs capacités de fabrication, et utilisent des molécules biologiques, comme l'ADN ou les protéines, pour réaliser des choses utiles.

3.2 Innovations destinées à améliorer la santé humaine

Applications thérapeutiques. Au début du secteur des biotechnologies, dans les années 70 et 80, les brevets portant sur des séquences d'ADN tendaient à couvrir un objet physique qui était utilisé pour fabriquer des produits curatifs. Ces brevets étaient traités à peu près de la même manière que les brevets relatifs à des composés chimiques et ne rencontraient pas de résistance substantielle dès lors que l'objet était suffisamment distinct d'un objet se produisant naturellement.[11]

Certaines grandes firmes biotechnologiques poursuivent leurs recherches sur des séquences d'ADN qui encodent des protéines thérapeutiques dans l'espoir d'en faire des produits pharmaceutiques. Mais les informations génomiques apportent bien d'autres choses précieuses que ce type de protéines.[12] Par exemple, les gènes peuvent servir d'instruments de diagnostic pour signaler la présence d'une maladie.

Applications pour la recherche. Actuellement, l'étude des gènes et de leurs fonctions (la « génomique ») ainsi que l'application de bases de données informatiques et d'algorithmes pour gérer les informations biologiques (la « bioinformatique ») sont devenus des facilitateurs d'une importance considérable pour la R-D biomédicale (par opposition aux produits finaux eux-mêmes destinés aux utilisateurs finaux). Ces applications sont utilisées de diverses façons pour accélérer l'identification, le développement et l'amélioration des produits thérapeutiques. Par exemple, l'information génomique et la bioinformatique peuvent servir à identifier les vecteurs de maladie ou les gènes qui offrent des perspectives prometteuses en tant que cibles de médicaments.

3.3 Innovations agricoles

La nature des brevets en matière de biotechnologie agricole varie en fonction des systèmes nationaux et des restrictions qu'ils prévoient sur les brevets biologiques. Dans certains pays, il est possible d'obtenir un brevet sur un gène et son application à un végétal. Il est aussi possible d'obtenir un brevet sur le végétal lui-même, ou sur des processus et inventions en rapport avec des végétaux ou des gènes de végétaux. Un exemple d'innovation biotechnologique en agriculture réside dans les végétaux génétiquement modifiés qui sont résistants à certaines maladies.

3.4 Caractéristiques distinctives des biotechnologies pour les politiques de la propriété intellectuelle et de la concurrence

Aucun des traits évoqués ci-après n'est propre au secteur des biotechnologies, mais leur présence combinée pose des problèmes spécifiques pour la politique de la propriété intellectuelle et celle de la concurrence.

Jeunesse. Le secteur des biotechnologies est relativement jeune, ce qui a des conséquences importantes pour la portée des revendications des brevets dans ce domaine. Les inventions pionnières qui créent de nouveaux marchés bénéficient couramment de brevets rédigés en termes généraux pour un certain nombre de raisons. Premièrement, la principale contrainte pesant sur la portée des revendications des brevets réside dans l'état de la technique dans le domaine concerné.[13] Les secteurs récents tendent à présenter un état de la technique moins abondant que les secteurs plus établis. Deuxièmement, personne n'a sans doute de connaissances suffisantes sur un domaine de recherche récent au moment du dépôt de la demande de brevet pour se rendre compte qu'une revendication est large. De façon plus pernicieuse, la société déposant la demande de brevet peut être consciente que la demande est exagérément générale, alors que les examinateurs du brevet peuvent ne pas le percevoir.

Complexité. Le secteur des biotechnologies est relativement complexe en comparaison avec la plupart des autres secteurs. En outre, cette complexité passe pour s'accroître aussi bien du point de vue du nombre de revendications figurant dans les demandes de brevet que de la difficulté de leur interprétation.[14] Cette complexité croissante peut faire que les examinateurs de brevets ont du mal à se tenir informés de l'évolution de la technologie.[15]

Rapidité d'expansion. L'ensemble du secteur se développe très rapidement et le nombre de brevets portant sur l'ADN a progressé en conséquence. Pour avoir une idée de cette croissance, on se reportera aux statistiques suivantes :

- Près de la moitié des récoltes mondiales de soja découle désormais du génie génétique.[16]

- En 1990, les pays de l'OCDE ont délivré au total quelque 1 900 brevets biotechnologiques. En 2001, les seuls États-Unis ont accordé plus de 5 000 brevets portant sur l'ADN, auxquels il faut ajouter les 1 223 brevets délivrés par le Japon.[17]

- De 1995 à 2001, l'Union européenne a enregistré un taux de croissance annuel moyen de 30 % de l'investissement de capital risque dans la biotechnologie.

- L'UE est suivie de près par les États-Unis dans ce domaine avec un taux de croissance de 27 %.[18]

il est possible que la croissance des demandes de brevets exerce une ponction sur les ressources des offices compétents et contribue par là-même à une détérioration de la qualité des brevets.

Applications. La majeure partie de la recherche biotechnologique est axée sur une application dans le secteur des soins de santé. La plupart des sociétés biotechnologiques qui effectuent ces travaux sont petites, privilégient fortement la recherche et n'ont que peu ou pas d'activité de commercialisation. Elles préfèrent constituer des partenariats avec des sociétés plus importantes, souvent des groupes pharmaceutiques, qui s'occupent de la commercialisation. La deuxième grande application de la recherche biotechnologique concerne l'agriculture, notamment les organismes et aliments génétiquement modifiés. L'organisation de cette composante du secteur biotechnologique est très différente, avec de très gros groupes agro-industriels effectuant l'essentiel des recherches et détenant la plupart des brevets.

- Près des deux tiers des plus de 300 entreprises biotechnologiques existant en France interviennent dans le secteur des soins de santé.[19]

- Selon une enquête récente menée aux États-Unis, près des trois quarts des entreprises travaillant dans les biotechnologies ont indiqué que les applications pour la santé humaine constituent leur principal domaine d'activité touchant à la biotechnologie.[20]

Importance particulière des brevets. Les brevets jouent un rôle plus important de catalyseur de l'innovation biotechnologique que ce n'est le cas pour la plupart des autres types d'innovations.[21] Cela fait de la biotechnologie une exception au regard d'un *corpus* assez substantiel de travaux économiques empiriques qui se demandent si les brevets favorisent vraiment l'innovation.[22]

Un faisceau de facteurs contribue à expliquer cette importance relative des brevets dans le secteur des biotechnologies. L'un de ces facteurs pertinents est le fait que les entreprises ont tendance à être petites. Par exemple, les entreprises de moins de 50 salariés prédominent dans le secteur des biotechnologies au Canada et représentent près de trois entreprises sur quatre qui innovent dans ce domaine.[23] Aux États-Unis, une étude récente a montré que 57 % des entreprises intervenant dans le secteur des biotechnologies comptent 50 salariés au plus.[24] Ces petites sociétés ont naturellement tendance à présenter moins de projets technologiques à l'étude que les grandes entreprises.

Autre facteur, le développement de produits demande relativement longtemps dans le secteur des biotechnologies.[25] Si l'on y ajoute le moins grand nombre de projets à l'étude, cela fait que les petites entreprises biotechnologiques doivent souvent passer de nombreuses années sans enregistrer de recettes commerciales avant de trouver une idée gagnante (en d'autres termes, rentable). Les brevets valident et protègent leurs recherches pendant la phase de développement. Cela peut dès lors aider ces entreprises à trouver des financements pour leurs investissements, ainsi que des partenariats rémunérateurs qui leur permettent de continuer de travailler pendant leurs années de vaches maigres.[26] Le fait de détenir un portefeuille de brevets peut permettre à des jeunes pousses du secteur d'obtenir les financements dont elles ont besoin pour mettre la dernière main à leurs travaux et devenir des concurrents viables sur le marché.

Outils de recherche. Le secteur des biotechnologies se trouve à une phase de son développement où il génère plus d'informations qu'il ne peut actuellement en utiliser. De nouvelles entités génétiques apparaissent ou sont même créées chaque jour par des scientifiques qui dressent la carte du génome de divers organismes ou forment de nouveaux types de cellules. Le séquencement du génome d'une seule cellule humaine génère des dizaines de milliers de nouvelles entités (par exemple, des fragments du génome humain contenant une levure). Même une cellule bactérienne relativement simple, lorsque son séquencement est réalisé, amène la création de centaines de telles entités.[27] En d'autres termes, le séquencement du génome humain constitue simplement le point de départ de nouveaux projets génomiques. Il reste à effectuer un travail extraordinaire pour convertir ces informations en applications pratiques.[28] La tâche consistant à se frayer un chemin dans ce maquis de données nouvelles sans assistance ni orientation risque d'occuper des générations de scientifiques.

En conséquence, certaines sociétés biotechnologiques s'attachent moins au brevetage des produits en aval et plus à celui des outils d'aide à la recherche en amont, les « outils de recherche ». Ces outils de recherche ne donnent pas lieu à une large diffusion commerciale, mais pour nombre d'entre eux, ils aideront les inventeurs suivants à passer au crible les données de façon plus intelligente et donc à trouver et développer plus vite des innovations ultérieures.

Les inventeurs d'outils de recherche souhaitent naturellement récupérer une partie des bénéfices que leurs inventions rendent possibles. Pour autant, il peut s'avérer assez difficile d'attribuer une valeur à des licences d'utilisation d'outils de recherche. Tant que les inventeurs ultérieurs ne les utilisent pas, personne

ne peut être certain que ces outils contribueront à définir et développer des produits en aval remportant un succès financier. Même si un outil finit par faciliter un produit gagnant, au moment de l'octroi de la licence, il n'y a pas de moyen de savoir exactement quelle sera sa contribution à ce succès. Ce problème a amené les innovateurs ultérieurs du secteur des biotechnologies à adopter des techniques imaginatives de revendication de brevet et d'octroi de licence qui posent des problèmes épineux aux offices des brevets comme aux autorités de la concurrence. On reviendra plus loin sur deux de ces techniques – les mécanismes de revendication sur les inventions ultérieures et la rétrocession de licences – dans la Partie VI.B.

Interdépendance. Un aspect connexe réside dans le fait qu'une bonne partie des travaux de la biotechnologie dépend de technologies spécifiques appartenant à d'autres entreprises. En fait, ces travaux dépendent souvent des nombreuses inventions brevetées contrôlées par de nombreuses sociétés différentes. En conséquence, les biotechnologies sont mûres pour un problème de « maquis de brevets » ou de blocage par les biens privatifs, dans lequel l'innovation à venir risque d'être paralysée par la surabondance de la propriété intellectuelle. On reviendra sur ce phénomène dans la Partie IV.B. L'interdépendance entre les inventions met également en relief la nécessité de trouver un compromis entre les incitations que suscite un régime de propriété intellectuelle pour le premier inventeur et celles des inventeurs ultérieurs, et cette interdépendance fait que les biotechnologies sont plus susceptibles que d'autres secteurs de voir des brevets aux revendications inutilement larges décourager l'innovation.

4. Qualité et étendue des brevets, et craintes d'un blocage par les biens privatifs dans le secteur des biotechnologies

Le secteur des biotechnologies est relativement nouveau, complexe et en mutation rapide. Des préoccupations relatives à la qualité des brevets se sont exprimées dans de tels secteurs, ce qui signifie que des brevets peuvent parfois être délivrés pour des technologies qui ne répondent pas aux critères officiels de nouveauté, de caractère distinctif et d'utilité. Certains observateurs ont également affirmé que l'étendue des revendications des brevets dans ces secteurs est excessive ; en d'autres termes, même si les inventions elles-mêmes sont probablement éligibles à la protection des brevets, les revendications qui leur sont associées sont formulées en termes trop généraux ou ambigus.[29] Cette section du présent document traitera de la façon dont la qualité et l'étendue des brevets peuvent affecter l'innovation et la concurrence dans le secteur des biotechnologies. Elle abordera ensuite la question de savoir si ces problèmes de qualité et d'étendue des brevets ont abouti à un problème de blocage par les biens privatifs pour évoquer les moyens envisageables pour y remédier.

4.1 Comment la facilité de la délivrance des brevets et l'étendue des brevets affectent l'innovation et la concurrence

Idéalement, on n'accordera un droit découlant d'un brevet (et la puissance sur le marché que cela peut induire) que si, et seulement si, il est nécessaire pour encourager l'innovation couverte par ce droit. Cette question de type « que se passerait-il s'il n'y avait pas... » ne définit certes pas de norme pratique opérationnelle, mais c'est celle qu'il faut poser sur le principe.[30] Les critères officiels de caractère distinctif, de nouveauté et d'utilité peuvent être comme des substituts du test « que se passerait-il s'il n'y avait pas... ».

C'est une caractéristique curieuse de la délivrance des brevets et de l'étendue des brevets que de pouvoir tout à la fois exercer des effets positifs et négatifs sur l'innovation et la concurrence. Ces incohérences peuvent être source de frustration pour les pouvoirs publics face au constat que le réglage des différents leviers politiques à leur disposition en matière de délivrance des brevets et d'étendue des brevets aboutit à des résultats imprévisibles.

Comme nombre d'effets positifs et négatifs de la délivrance des brevets et de l'étendue des brevets sont analogues, le présent document abordera ensemble ces deux aspects. Pour commencer par les effets positifs, plus il est facile d'obtenir un brevet en général et plus ses revendications peuvent être larges, plus la rémunération que pourra attendre un innovateur potentiel de l'innovation qu'il envisage, aura tendance à être importante. De toute évidence, plus la rémunération attendue est forte, plus l'inventeur sera porté à s'engager dans l'innovation.

En outre, dans la mesure où la facilité de la délivrance des brevets et l'étendue des brevets amènent les concurrents à investir plus dans la R-D de façon à inventer autour des brevets, la souplesse des normes peut effectivement favoriser l'innovation et donc affecter positivement la concurrence comme le bien-être des consommateurs. Autre solution, les concurrents peuvent choisir de se retirer du marché du détenteur du brevet pour investir au contraire sur un marché entièrement nouveau, ce qui amène des innovations qui ne se seraient peut-être pas produites s'il n'y avait pas eu le brevet sur le premier marché.

En ce qui concerne maintenant les effets négatifs, une chose est également claire : plus il est facile d'obtenir des brevets et plus leur étendue est large, plus le nombre de brevets délivrés tendra à s'accroître et plus ils seront étendus (jusqu'à un point de saturation). Ce processus accroît lui-même la probabilité que le simple fait d'entrer sur le marché déclenche un procès en contrefaçon de brevet. En conséquence, plus les normes des brevets seront souples, plus on risque de voir des produits susceptibles d'être compétitifs constituent des contrefaçons. Or, les procès dans ce domaine sont onéreux et demandent du temps. La souplesse des normes de délivrance des brevets et d'étendue des brevets accroît donc le risque que représente l'entrée sur le marché et tend à réduire la concurrence en conséquence.

Lorsque l'on réfléchit au préjudice que la souplesse des normes de délivrance des brevets peut porter à la concurrence, il convient de rester conscient que la protection offerte par un brevet va au-delà des termes précis qui ont été retenus pour décrire une invention. Les brevets englobent au contraire l'idée ou le concept qui se trouve en arrière-plan de ce qui est exprimé dans les revendications, si tant est qu'on puisse le déduire de la formulation de ces revendications. Les brevets accordent donc des droits exclusifs, non seulement sur une invention particulière, mais aussi sur d'autres inventions qui sont réputées fonctionnellement équivalentes.

La souplesse et la portée plus grande de la délivrance des brevets accroît en outre la difficulté, le coût et le risque de l'innovation marginale en répandant la crainte de la contrefaçon. Cela tend à réduire l'investissement dans l'innovation pour deux raisons. Premièrement, le titulaire du brevet, satisfait de la position de force que lui confère le brevet, risque de ne pas ressentir la nécessité d'investir dans de nouvelles innovations en soi. Deuxièmement, les innovateurs ultérieurs sont plus susceptibles de devoir obtenir une licence d'utilisation du brevet initial avant de pourvoir tirer profit de leurs travaux.[31] L'identification des brevets nécessaires et le paiement de leur utilisation absorbent des ressources précieuses. Ces ressources sont gaspillées lorsque des brevets immérités ou rédigés en termes trop généraux sont délivrés en raison d'une politique de délivrance des brevets laxiste. En fait, une politique souple de délivrance de brevets pourrait aboutir, au moins en théorie, à une situation dans laquelle il y a tant d'éléments interdépendants qui sont brevetés que les fonds et le temps nécessaire pour identifier et acquérir tous les droits de licence nécessaires découragent, voire bloquent les innovations ultérieures dans le domaine de recherche.[32] Le domaine des biotechnologies, avec sa tendance à créer des brevets sur les outils de recherche et à s'appuyer sur ces brevets, est particulièrement vulnérable à cette menace.

De plus, si la politique des brevets est si souple qu'elle aboutit à des brevets injustifiés ou de portée trop générale, les consommateurs seront dans certains cas privés des avantages de la concurrence sans percevoir pleinement la contrepartie qu'une invention brevetable est supposée apporter. De fait, les entreprises biotechnologiques ont indiqué qu'elles évitaient parfois certains domaines de recherche dans lesquels elles auraient travaillé si ces domaines semblent être couverts même par des brevets douteux.[33]

Autre cas de figure, elles peuvent d'abord éliminer le risque en payant des droits de licence. Toutefois, si le brevet ne méritait pas au départ d'être accordé, ces droits de licence faussent à la fois l'incitation à innover et le coût en dernier ressort de toute invention ultérieure.

Encadré 2. La portée excessive des brevets affecte-t-elle l'innovation biotechnologique ?

À n'en pas douter, des brevets biotechnologiques de très large portée ont parfois été approuvés, mais cela ne semble pas avoir eu beaucoup d'effets sur les transferts de technologie ou l'innovation dans le secteur des biotechnologies. Dans certains cas, les titulaires de brevets ont ouvert un accès facile à leur propriété intellectuelle moyennant des redevances raisonnables. Dans d'autres, les tribunaux ont invalidé les brevets trop larges. De plus, il est devenu plus difficile d'obtenir des brevets biotechnologiques aux revendications larges, à tout le moins aux États-Unis. On retiendra trois exemples pour illustrer ces propos.

En 1980, l'Université Stanford a obtenu un brevet sur la méthode de manipulation génétique connue sous le nom de technique de Cohen-Boyer.[34] Les revendications de ce brevet allaient au-delà de la technique elle-même, puisqu'elles couvraient tout organisme recombinant créé à l'aide de la technique, même si ces organismes et leurs utilisations possibles n'avaient pas été spécifiquement identifiés. Cette technique a été largement utilisée pour créer toute une série de nouveaux produits biotechnologiques et, à proprement parler, tous ces produits relevaient du brevet de Stanford. La validité du brevet n'a pourtant jamais été contestée sur le plan juridique, parce qu'il a donné lieu à un large octroi de licences à des conditions raisonnables.[35]

Vingt ans plus tard, Human Genome Sciences (HGS) a obtenu un brevet portant sur un gène dont la fonction était initialement inconnue. La demande indiquait que ce gène était utile en tant que réactif pour la recherche ou de matériel de diagnostic. D'autres scientifiques ont découvert par la suite que la séquence d'ADN brevetée par HGS codait en fait le récepteur CCR5, qui est utilisé par le virus VIH pour infecter une cellule. Cet événement a largement fait craindre que le brevet d'HGS ne bloque la recherche sur le SIDA. Jusqu'ici, ces craintes ne paraissent pas fondées. HGS a accordé plusieurs licences de recherche pour de nouveaux médicaments contre le VIH et ne prévoit pas d'empêcher les chercheurs universitaires de mener des travaux sur le CCR5 sans licence.[36]

Toujours en 2000, l'Université de Rochester a obtenu un brevet pour une méthode d'inhibition sélective d'un enzyme, le COX-2, par « un composé non stéroïdien ». La demande de brevet ne divulguait cependant pas ce composé, ne donnait aucun moyen d'en identifier un ni d'indication que l'université avait même connaissance d'un tel composé. Néanmoins, une fois le brevet délivré, l'université s'en est immédiatement servi pour engager un procès pour contrefaçon à l'encontre de plusieurs groupes pharmaceutiques qui fabriquaient des médicaments utilisant des composés non stéroïdiens pour inhiber le COX-2. Cette décision a eu des répercussions spectaculaires. En février 2004, une cour d'appel a décidé que non seulement il n'y avait pas contrefaçon, mais encore que l'absence d'identification par l'université d'un composé prévu par sa méthode invalidait le brevet pour manque de description.[37]

Il ne s'agit certes que d'exemples, et non pas d'observations empiriques systématiques, mais il tendent à montrer que les brevets aux revendications trop larges n'ont pas d'impact considérable sur l'innovation – à tout le moins pour le moment. En outre, les offices européens, japonais et américains des brevets ont collaboré sur des études relatives à l'étendue admissible des brevets et aux éléments nécessaires pour étayer les revendications. Ces études montrent par exemple que les demandes de brevet sur des séquences partielles de gènes ne donnant pas d'informations convenables sur l'utilité ou la fonction de l'invention se voient refuser la protection des brevets.[38] Les États-Unis ont également durci les conditions de délivrance de brevets de matériel génétique dont la demande ne serait pas accompagnée de connaissances d'une utilisation spécifique, substantielle et crédible d'un gène donné et de ses protéines.[39]

Pour aggraver encore les choses, lorsque les pouvoirs publics accordent des brevets trop facilement, les inventeurs ultérieurs risquent davantage d'avoir besoin d'obtenir des licences complémentaires auprès d'une multitude de détenteurs de droits de propriété. Lorsque ces détenteurs de droits de propriété disposent d'une puissance sur le marché, ils ont tendance à facturer des droits de licence globalement supérieurs à ce qu'ils feraient s'ils intervenaient en tant qu'entité unique. Ce phénomène est désigné par le terme « empilement de redevances ». Ce n'est en fait rien d'autre que le problème connu des monopoles verticaux successifs qui renchérissent les prix et limitent la production plus sensiblement que ce ne serait le cas si un monopole unique verticalement intégré contrôlait tous les facteurs.[40]

Un autre problème spécifique posé par la délivrance des brevets facile peut se manifester dans des secteurs comprenant un groupe relativement restreint de grands intervenants (comme l'agro-industrie). En l'occurrence, cela peut donner lieu à des stratégies de thésaurisation de brevets à la fois inefficientes et éventuellement anticoncurrentielles. En pareille situation, des entreprises accumulent les brevets pour empêcher l'entrée sur leur marché ou à titre de levier contre d'autres intervenants susceptibles d'engager des procès pour contrefaçon à leur encontre. On reviendra plus en détail sur ce phénomène dans la partie VI.C.2.

La difficulté pour les pouvoirs publics tient à la quasi impossibilité de quantifier la valeur nette de l'innovation qui va être acquise ou perdue s'ils optent pour un durcissement de la politique des brevets, ou au contraire à la solution consistant à ne rien faire ou à assouplir cette politique.

4.2 Existe-t-il un problème de blocage par les biens privatifs dans les biotechnologies ?

Voilà plusieurs années, la crainte que les normes de délivrance des brevets ne soient pas assez strictes a fait dire à certains qu'il y avait des circonstances où les brevets pouvaient en fait décourager l'innovation et non l'encourager. Le principal argument avancé était alors que si des éléments complémentaires sont couverts en trop grand nombre par les droits de propriété intellectuelle, ils risquent d'être tous sous-utilisés au point d'aboutir à une « tragédie du blocage par les biens privatifs ».[41] Dans les secteurs confrontés à ce problème, les entreprises ont des difficultés à innover, car tout ce qu'elles inventent va probablement dépendre d'un maquis de droits de propriété intellectuelle détenus par une multitude de parties. L'identification et l'obtention de toutes les licences nécessaires deviennent donc onéreuses et demandent du temps, avec d'autant plus de risques de procès. Si le problème est particulièrement grave, la majeure partie ou la totalité des DPI ne seront pas exploités et le rythme de l'innovation en souffrira.

Les biotechnologies semblent compter parmi les secteurs qui sont exposés au problème de blocage par les biens privatifs. Premièrement, on a observé une prolifération des brevets, notamment en ce qui concerne les outils de recherche en amont qui favorisent la découverte et l'efficacité des produits en aval. Deuxièmement, les brevets sont détenus par un grand nombre d'intervenants sur le marché. Troisièmement, les universités participent également à cette prolifération, car elles déposent elles aussi un nombre croissant de brevets sur les outils de recherche qu'elles inventent. Quatrièmement, il est possible que les entreprises accumulent des DPI en biotechnologie à des fins défensives, pas tant parce qu'elles souhaitent utiliser elles-mêmes ces DPI, mais parce qu'elles entendent s'en servir comme monnaie d'échange lors de négociations avec d'autres entreprises qui détiennent des DPI qu'elles convoitent. Tout cela suffit-il pour autant à créer un problème de blocage par les biens privatifs dans les biotechnologies ?

La lecture des comptes rendus des auditions conjointes de la Federal Trade Commission et du Department of Justice des États-Unis, qui se sont tenues en 2002 sur le thème « Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy » montre qu'il s'agit uniquement d'une préoccupation théorique, pour le moment du moins.[42] Cela peut s'expliquer par le fait que les inventeurs ont réussi à obtenir des accords de licence équitables, qui leur permettent de poursuivre leurs

travaux tout en leur apportant des incitations suffisantes pour les mener à terme. Cela peut aussi venir du fait que les biotechnologies restant un secteur relativement nouveau, il y existe encore de vastes domaines de travail dont la recherche est encore absente. Cette possibilité est étayée par deux études récentes, l'une allemande, l'autre américaine, qui démontrent que les sociétés de biotechnologie ont tendance à éviter les domaines de recherche qui déboucheront inévitablement sur des brevets dépendants.[43] On pourrait faire valoir qu'il s'agit d'un résultat négatif, car cela montre que la prolifération des brevets décourage la poursuite de l'innovation. Mais on pourrait aussi en conclure que le système de protection des brevets produit précisément l'effet attendu en encourageant les entreprises à orienter leurs ressources vers des travaux novateurs.

L'étude allemande conclut que les brevets sur les outils de recherche n'ont pas eu d'effet visible ni sur le rythme ni sur le coût de la recherche biotechnologique en Allemagne.[44] Ces résultats sont en grande partie conformes aux conclusions de l'étude américaine, qui démontre que « selon la grande majorité des sondés, aucun projet de recherche digne d'intérêt n'a jamais été bloqué en raison de problèmes de propriété intellectuelle liés aux recherches antérieures, » et que la « découverte de médicaments n'a pas été entravée de manière substantielle » par l'augmentation du nombre des brevets sur les outils de recherche. De l'avis des auteurs, les effets sur l'innovation sont dans l'ensemble atténués par la capacité des entreprises et des organismes de recherche à trouver ce qu'elles qualifient de « solutions opérationnelles » aux problèmes soulevés par la propriété intellectuelle. La concession de licences, les inventions autour des brevets, le fait de s'en remettre de manière informelle à une exemption au titre de la recherche tout en commettant une contrefaçon technique, ainsi que les contestations devant les tribunaux sont autant de solutions opérationnelles.[45]

L'étude américaine a effectivement trouvé des éléments montrant que le processus de négociation de l'accès à l'arsenal croissant des outils de recherche brevetés diffère la poursuite de l'innovation et que les brevets sur les diagnostics génétiques nuisent à la recherche universitaire.[46] Cela étant, comme le soulignait Richard Epstein, « la hausse considérable et durable du taux de demandes de brevets sur le génome ne concorde pas avec l'idée que les nouveaux brevets étranglent l'innovation, mais aboutirait plutôt à la conclusion inverse ».[47] En somme, bien que la majeure partie des éléments disponibles ne témoigne d'aucun blocage par les biens privatifs à ce jour, les risques qu'un tel blocage se produise demain existent bel et bien.

4.3 Impact de l'exemption de l'utilisation expérimentale sur l'innovation et sur la concurrence

Une méthode permettant de compenser une partie des effets d'un blocage par les biens privatifs consiste à exempter de la responsabilité pour contrefaçon les utilisations purement expérimentales des technologies brevetées, par opposition aux utilisations purement commerciales. En fait, même s'il n'existe pas encore de blocage par les biens privatifs, la question de l'existence d'une exemption des utilisations expérimentales revêt une importance toute particulière dans les secteurs comme les biotechnologies, où les outils de recherche représentent une part substantielle des brevets accordés. Les fondations, les universités ou les entreprises qui se consacrent à la recherche souhaitent parfois utiliser une invention brevetée simplement pour vérifier qu'elle fonctionne réellement conformément au descriptif du brevet. Elles peuvent aussi vouloir l'utiliser pour essayer de trouver d'autres applications ou pour voir si elle leur donne des idées pour d'autres projets de recherche. Autrement dit, dans certaines circonstances, un brevet peut faire l'objet d'une contrefaçon technique, mais sans que le « contrevenant » commette cette contrefaçon dans le dessein de faire et de vendre des reproductions des travaux du détenteur du brevet. De plus, cette contrefaçon technique se traduit parfois par des innovations ultérieures qui améliorent le bien-être des consommateurs.

Il y a là un véritable défi pour les pouvoirs publics. Comment peuvent-ils, en effet, garantir aux titulaires de brevets une protection suffisante contre des comportements parasitaires et nuisibles aux incitations, sans interdire pour autant la recherche qui est inoffensive – et de fait souvent utile ?

La plupart des systèmes nationaux de protection des brevets instaurent une exception à la responsabilité pour contrefaçon de brevets pour l'utilisation à des fins « expérimentales » ou « de recherche » de technologies brevetées. L'article 11.2 de la loi allemande sur les brevets de 1981, par exemple, dispose que les droits attachés à un brevet ne s'étendent pas aux actions menées dans un objectif expérimental lié au domaine de l'invention brevetée. Nombre d'autres pays européens ont adopté des lois similaires. L'article 69.1 de la loi japonaise sur les brevets comporte une exemption légale en vertu de laquelle les droits attachés à un brevet ne peuvent pas s'étendre à la recherche expérimentale. Toutefois, elle ne définit pas ce qu'est une « expérience ».[48] Dans d'autres pays, il n'existe pas d'exemption légale, mais celle-ci est inscrite dans la *common law* appliquée par les tribunaux.

L'exemption de l'utilisation expérimentale a permis à des chercheurs universitaires, entre autres, d'utiliser des innovations brevetées à des fins non commerciales. Cette politique paraît sensée, car elle favorise le développement continu du savoir sans décourager les inventeurs privés d'innover.

Le problème est que les universités ne limitent pas toutes leurs activités à la recherche fondamentale. Nombre d'entre elles obtiennent, vendent et concèdent sous licence des droits de propriété intellectuelle et si elles étaient autorisées à utiliser gratuitement les DPI de tiers, elles pourraient le faire sous couvert d'investigations scientifiques afin de développer leurs propres inventions à but lucratif. Il n'est donc pas surprenant que certains tribunaux aient adopté une interprétation stricte de l'exemption, en soulignant qu'elle ne couvre que les « actions menées pour se distraire, satisfaire sa propre curiosité ou pour des investigations strictement philosophiques ».[49] Dans l'affaire *Madey v. Duke University*, le tribunal a statué que l'exception que constitue l'utilisation expérimentale :

> n'exonère aucunement les comportements relevant des activités légitimes du contrefacteur présumé, indépendamment de toute implication commerciale. À titre d'exemple, les grandes universités de recherche… approuvent et financent fréquemment des projets de recherche n'ayant sans doute aucune application commerciale quelle qu'elle soit. Néanmoins, ces projets servent incontestablement les objectifs commerciaux légitimes de l'établissement, notamment la volonté de former et d'éclairer des étudiants et enseignants travaillant sur ces projets.[50]

Dans les juridictions où l'exemption de l'utilisation expérimentale peut être plus facilement invoquée, les entreprises peuvent aussi tenter de tirer parti de cette exemption. Dans l'industrie pharmaceutique, par exemple, des concurrents peuvent vouloir réaliser des tests sur un médicament qui a été breveté pour une application donnée afin de savoir s'il peut avoir d'autres applications utiles. D'autres concurrents pourraient utiliser l'exemption pour réaliser des tests sur leur propre version d'un médicament breveté de manière à obtenir l'autorisation officielle de mise sur le marché dès l'expiration du brevet.[51]

Dans de tels cas, l'exemption se justifie de plusieurs manières. Dans le premier cas, l'inventeur a déjà été récompensé par un brevet pour une application et il a intérêt à trouver toutes les autres applications possibles susceptibles de générer des bénéfices. Pourtant, l'inventeur ne peut pas, pour une raison quelconque, identifier concrètement les autres applications. Si elles existent, il ne semble pas judicieux ou nécessaire d'empêcher les autres de les identifier et de les mettre sur le marché durant la vie du brevet initial. Dans le deuxième cas, la concurrence joue aussi vite que possible, mais l'inventeur initial continue de bénéficier de toute la période de protection légale à laquelle il a droit sur le marché.

En fait, l'exemption de l'utilisation expérimentale a été défendue par des tribunaux allemands dans ces deux objectifs.[52] On peut considérer, néanmoins, que l'Allemagne fait preuve d'une relative souplesse

à cet égard par rapport à certains de ses voisins. Le Royaume-Uni et la Suède, par exemple, considèrent que les essais cliniques sur des substances brevetées constituent une contrefaçon.

5. Les rôles possibles des autorités de la concurrence dans l'élaboration et l'application de la politique de protection de la propriété intellectuelle

Les thèmes évoqués jusqu'à présent amènent une question fondamentale : quel doit être le rôle des autorités de la concurrence au regard de la propriété intellectuelle ? Parmi les possibilités figure la participation à l'élaboration d'une politique de protection de la propriété intellectuelle, à sa mise en œuvre et à l'application du droit de la concurrence aux activités commerciales touchant à la propriété intellectuelle. Les autorités doivent à tout le moins appliquer le droit de la concurrence aux domaines liés d'une manière ou d'une autre à la propriété intellectuelle. Par exemple, il serait difficile de défendre une décision revenant à ne pas contester la fusion des composantes d'un duopole pour la simple raison que chacun d'entre eux détient un portefeuille de brevets. Ces brevets ont en effet pu être à l'origine de la concurrence, qui serait éliminée par un tel accord. Plusieurs autres types de comportements potentiellement anticoncurrentiels concernant la propriété intellectuelle sont évoqués plus loin dans la Partie VI.

La seule alternative consiste donc à décider s'il faut laisser l'élaboration et l'application de la politique de protection de la propriété intellectuelle aux législateurs et aux offices de la propriété intellectuelle ou s'il faut y prendre part. Les autorités de la concurrence peuvent-elles apporter des contributions susceptibles d'améliorer le système de protection de la propriété intellectuelle ? Est-ce souhaitable ? Avant de traiter directement de ces questions, il est logique de se pencher sur certains mécanismes de résolution des problèmes d'ores et déjà en place sur les marchés des DPI.

5.1 Comment les intervenants privés peuvent-ils régler des problèmes de propriété intellectuelle ?

Dans le secteur privé, les parties en présence peuvent accepter, contester ou contourner l'existence et la portée des DPI de bien des manières.

- **Concéder une licence**. Il va de soi que les parties peuvent négocier une licence d'utilisation de DPI. Cette méthode peut résoudre les problèmes de blocage, mais de ce fait, les concessionnaires peuvent être soumis à des pratiques de prix supra concurrentielles et éventuellement à des conditions d'octroi de licence restrictives. Si la validité ou la portée des DPI est suspecte, cela peut poser un problème du point de vue de la politique de la concurrence.

- **Demander un réexamen.** Si la licence ne constitue pas une solution viable, les parties ont la possibilité de demander un réexamen des brevets délivrés par les offices spécialisés de la plupart des pays. L'issue favorable d'une contestation peut avoir pour effet de limiter la portée du brevet, voire d'obtenir sa révocation. Les règles de procédure concernant de telles démarches imposent parfois, cependant, de démontrer que le processus d'examen a posé un problème concret. À titre d'exemple, les contestataires peuvent être tenus d'apporter la preuve que certaines techniques antérieures importantes n'ont pas été prises en compte précédemment, au lieu d'affirmer tout simplement qu'un brevet n'est pas valable ou trop étendu.

- **Porter l'affaire devant les tribunaux**. De plus, dans certains cas, les parties en présence peuvent faire appel aux tribunaux.[53] Ces recours ont cependant tendance à être très onéreux et à prendre du temps ; en outre, leur issue est imprévisible. On estime que contester devant les tribunaux un brevet dans le domaine des biotechnologies peut prendre deux ou trois ans et coûter de cinq à sept millions de dollars des États-Unis.[54] De plus, certains procès en annulation de brevets posent des problèmes de recours collectifs ; en effet, alors qu'une seule société supporte

les dépens de la contestation, d'autres sociétés peuvent bénéficier de l'annulation. La combinaison de ces facteurs rend peu intéressantes les contestations financées à titre privé, en particulier pour les plus petites entreprises qui sont très répandues dans les biotechnologies.

- **Constituer un groupement de brevets**. Les groupements de brevets représentent une autre solution et ils peuvent permettre d'échapper en grande partie, voire entièrement à un maquis de brevets.[55] À ce jour, il n'est guère démontré que des groupements de brevets se constituent dans le secteur des biotechnologies.

- **Inventer autour des brevets**. Par ailleurs, les parties peuvent inventer autour des brevets. Dans les diagnostics traditionnels, par exemple, une société peut breveter un kit de tests pathologiques. Ultérieurement, une autre entreprise peut contourner le brevet en concevant un kit totalement différent et plus performant pour détecter la maladie. Il est impossible, toutefois, d'inventer autour de quelque chose d'unique et d'essentiel, et les codes génétiques peuvent correspondre à cette description. Par conséquent, si une société détient un brevet sur un gène et une méthode permettant de détecter sa présence ou sa mutation, aucun concurrent ne sera en mesure de développer un autre test pour ce gène sans contrefaçon.[56]

- **Se domicilier à l'étranger**. Pour certaines entreprises, se soustraire aux DPI en se domiciliant à l'étranger est parfois la solution la plus intéressante – mais habituellement, ce sont uniquement les groupes pharmaceutiques bénéficiant d'une solide assise financière, et non les entreprises de plus petite taille, qui peuvent faire ce choix.

- **Utiliser le brevet uniquement à des fins expérimentales**. S'en remettre à l'exception/exemption de l'utilisation expérimentale est une autre possibilité. Néanmoins, cette tactique n'est peut-être pas très utile pour les entreprises ayant des visées commerciales et, de toute façon, elle semble de moins en moins pouvoir s'appliquer, du moins aux États-Unis.

- **Contrefaire.** Si toutes les autres méthodes échouent, les parties peuvent tout simplement décider de courir le risque d'un procès et de contrefaire le brevet. La contrefaçon peut être difficile à déceler, notamment pour ce qui est des outils de recherche, car elle se fait derrière les portes closes des laboratoires.[57] Cela étant, cette méthode ne serait certainement pas encouragée par les autorités de la concurrence.

- **Créer une association de connaissance à but non lucratif**. Enfin, les entreprises peuvent s'allier pour créer des associations qui mettent volontairement leurs inventions dans le domaine public, échappant ainsi tout bonnement au système de protection de la propriété intellectuelle. Voir l'exemple de l'encadré 3. Néanmoins, les consortiums comme le SNPC ne sont pas courants. Cela s'explique probablement par le fait que les intérêts des entreprises concordent trop rarement pour donner naissance à de telles entités. On constate donc que chacune des stratégies énumérées ci-dessus présente des inconvénients de taille. Si nous supposons dès lors que le secteur privé ne peut pas résoudre tous les problèmes de concurrence liés à la facilité de la délivrance des brevets ou à l'étendue excessive des revendications de brevets, nous sommes en droit de revenir à la question de savoir si, à quel moment et de quelle manière, les autorités de la concurrence doivent s'impliquer dans ce processus.

Encadré 3. Le Consortium SNP (SNPC)

Le Consortium SNP est une fondation à but non lucratif créée en vue de fournir au public, sans restriction de DPI, une carte de première qualité des SNP du génome humain. Les SNP (*Single Nucleotide Polymorphisms*) sont des polymorphismes nucléotidiques, qui sont des variations naturelles de la séquence d'ADN chez l'homme. Selon les prévisions, la carte devrait permettre a) d'identifier des gènes spécifiques en cause dans certaines pathologies, ce qui faciliterait la découverte de nouveaux moyens d'intervention dans le processus de la maladie, b) de développer de nouveaux tests de diagnostic et c) de créer de nouveaux traitements « personnalisés » capables de prendre en compte d'infimes variations génétiques de façon à prévoir la réaction du patient au traitement. Le SNPC a été créé par un organisme caritatif de recherche médicale, 11 groupes pharmaceutiques et technologiques de premier plan et plusieurs centres universitaires de recherche. Doté d'un budget initial de 45 millions de dollars, il avait pour mission de développer jusqu'à 300 000 SNP distribués de façon homogène dans le génome humain. Il a fini par découvrir 1,5 million de SNP.[58]

Pourquoi le SNPC a-t-il vu le jour ? Ses membres espéraient que leur collaboration déboucherait plus rapidement sur une carte de première qualité, compte tenu du partage des risques financiers et de l'absence de doublons dans les activités menées, que si chaque société avait entrepris de développer seule sa propre carte de SNP.[59] Au-delà de cette brève réponse, il y a sans doute là une leçon de grande portée sur le système de protection des brevets. Premièrement, tous les travaux du SNPC ayant été menés alors même qu'il n'y avait pas d'incitations relatives à la propriété intellectuelle, il semble que le système de protection des brevets récompense de manière excessive certains types de recherche. Deuxièmement, la mission du SNPC indique que le système de protection des brevets risque en fait de freiner les avancées biotechnologiques, du moins dans certaines circonstances (dans le cas présent, bien en amont du processus de recherche). On pourrait en déduire que le SNPC a été constitué pour accélérer le processus d'identification des SNP afin de pouvoir les divulguer (et donc les rendre évidents), empêchant ainsi quiconque de les breveter et de contraindre les membres du consortium à acquitter des frais de licence pour les SNP. En allant plus loin, le fait que le SNPC ait recueilli cinq fois plus d'informations que prévu montre que de telles collaborations peuvent s'avérer particulièrement fructueuses et apporter une large contribution à la société sans recourir de quelque manière que ce soit au système de protection des brevets.

5.2 Quelques implications possibles des autorités de la concurrence, leurs avantages et inconvénients

5.2.1 Le rôle de conseil

Les autorités de la concurrence bénéficient d'un avantage comparatif en matière d'identification et d'analyse des effets anticoncurrentiels de brevets trop étendus ou non valides. De toute évidence, les autorités de la concurrence pourraient améliorer l'équilibre entre les DPI et la concurrence en conseillant les offices des brevets sur les éventuels effets anticoncurrentiels de décisions influant sur l'étendue et l'ambiguïté de brevets. De même, les offices des brevets pourraient apporter de précieux conseils juridiques et techniques sur la propriété intellectuelle aux autorités de la concurrence qui enquêtent sur des affaires dans ce domaine.

Cet échange d'informations pourrait prendre la forme de conclusions et d'avis d'application générale, comme ceux qu'émet la U.S. Federal Trade Commission (FTC) après les auditions conjointes réalisées avec le Department of Justice (DOJ) sur la politique de la concurrence et les brevets. Le rapport de la FTC contient des propositions concrètes pour améliorer la qualité des brevets et minimiser l'impact anticoncurrentiel du système des brevets. Ces recommandations s'adressent au Congrès, aux tribunaux, ainsi qu'au Patent and Trademark Office.[60]

À l'inverse, l'échange d'informations pourrait être spécifique à un cas donné, l'autorité de la concurrence intervenant en tant que conseiller auprès de l'office des brevets. Une telle intervention pourrait se faire soit à la demande de l'office des brevets, soit à l'initiative de l'autorité de la concurrence, qui pourrait demander à l'office des brevets de réexaminer un brevet douteux. En outre, les autorités de la concurrence pourraient jouer un rôle plus actif dans les poursuites judiciaires relatives à des brevets

présentant d'importantes ramifications en termes de concurrence en intervenant en tant qu'« *amicus curiae* » (tiers prêtant son assistance au tribunal) et elles pourraient, à ce titre, présenter au tribunal des exposés succincts concernant l'impact des affaires examinées sur le bien-être des consommateurs.

En dernier lieu, les autorités de la concurrence pourraient s'efforcer de promouvoir la connaissance et l'application des principes économiques au niveau des organismes de protection de la propriété intellectuelle. Ayant elles-mêmes profité d'une démarche similaire il y a de nombreuses années déjà, les autorités de la concurrence seraient bien placées pour faire accepter une telle approche.

5.2.2 Traiter les problèmes d'étendue et de validité au moment de l'examen du brevet.

La première étape où les autorités de la concurrence sont susceptibles d'intervenir dans le processus de délivrance d'un brevet se situe juste après le dépôt de la demande, lorsqu'il faut décider de son approbation. Si les autorités de la concurrence étaient impliquées à ce stade, elles pourraient contribuer à éliminer les brevets non valides ou à limiter les revendications trop étendues susceptibles de poser des problèmes de concurrence.

Cela étant, il semble n'y avoir que très peu d'arguments en faveur de cette approche. Une question déterminante à cet égard est de savoir pourquoi les autorités de la concurrence devraient être impliquées dans l'évaluation de la validité et de l'étendue de brevets, alors que le personnel de l'office des brevets a, de toute évidence, plus d'expérience en la matière. En fait, on peut supposer que les examinateurs de brevets sont plus compétents à la fois sur le droit des brevets et la technologie concernée. De même, ni les autorités de la concurrence, ni les offices des brevets ne peuvent déterminer l'étendue optimale d'un brevet et, des deux, ce sont les offices des brevets qui pourraient être plus à même de déterminer l'équilibre entre les incitations favorables aux innovations initiales et ultérieures.

En outre, demander l'approbation des autorités de la concurrence ralentirait le processus de délivrance d'un brevet. Cela risquerait d'atténuer l'incitation à innover et de retarder les avantages découlant du brevet, comme la diffusion d'informations technologiques et la facilitation d'accords de licence favorisant la concurrence.

Par ailleurs, le fait d'être impliquées dans toutes les décisions d'approbation de brevet surchargerait les autorités de la concurrence. La grande majorité des brevets ne pose aucun problème de concurrence.[61] Et en serait-il autrement, peu d'organismes chargés de la concurrence, voire aucun, n'auraient les ressources nécessaires pour assumer ce niveau de responsabilité, d'autant que les offices des brevets eux-mêmes ont déjà des difficultés à s'acquitter des tâches qui leur incombent.[62] En dernier lieu, même si les autorités de la concurrence disposaient des ressources nécessaires, il est loin d'être certain que les problèmes de concurrence posés par un brevet seraient perceptibles au moment du dépôt de la demande, notamment dans des secteurs aussi innovants et complexes que les biotechnologies.

5.2.3 Contester les brevets douteux par le biais d'une procédure judiciaire

Plutôt que d'essayer de traiter les brevets non valides ou trop généraux susceptibles de poser des problèmes de concurrence dès le stade de l'examen de la demande, les autorités de la concurrence pourraient intervenir après l'octroi du brevet en le contestant devant un tribunal.

L'un des avantages de cette approche est qu'elle éviterait aux autorités de la concurrence d'assumer la lourde tâche d'étudier un nombre considérable de brevets dès leur examen préalable. En outre, on aura ainsi eu plus de temps pour observer l'impact concret des brevets. Cela améliorerait la qualité de la décision de savoir si un brevet nuit ou est susceptible de nuire à la concurrence.

Un autre avantage de la procédure judiciaire est que les décisions de justice créent des précédents. En d'autres termes, les autorités de la concurrence interviendront directement dans l'élaboration du droit et de la politique des brevets, et pas seulement par des décisions ponctuelles. De plus, lorsqu'un organisme public assume la responsabilité d'aller en justice pour contester la validité d'un brevet, cela résout le problème de recouvrement que rencontrent les entreprises privées.

Du côté des inconvénients, on peut penser que les offices des brevets devraient seuls pouvoir juger de la validité et de l'étendue de brevets, dans la mesure où ce sont eux qui sont impliqués les premiers dans le processus. Si un autre organisme public intervient pour invalider un brevet ou réduire son étendue après que ce brevet a été approuvé par l'office des brevets, cela accroît l'incertitude quant à la rémunération des inventeurs. Or, cela peu avoir pour effet involontaire de freiner l'innovation.

Le problème posé par cet argument, du moins en ce qui concerne l'étendue excessive, est que les offices des brevets peuvent ne pas prendre conscience immédiatement de l'étendue réelle des revendications liées à un brevet. Cette situation est d'autant plus envisageable avec des inventions dans les secteurs technologiques complexes ou nouveaux, comme les biotechnologies.[63] Plusieurs années peuvent s'écouler avant que quelqu'un ne prenne conscience qu'un brevet de biotechnologie a été formulé dans des termes trop généraux. Par exemple, une société peut obtenir des droits d'usage pour un gène donné avant que l'on ne se rende compte de l'importance de ce gène. Si ce gène s'avère jouer un rôle crucial dans une maladie grave et que le brevet couvre, de manière générale, « tous les usages diagnostiques » du gène, cette société aura alors le contrôle de DPI d'une grande valeur, sans pour autant avoir identifié, et encore moins conçu, leurs applications les plus importantes. La rémunération qu'elle en tire pourrait être difficile à justifier.

Par conséquent, il peut être souhaitable de disposer d'un filet de sécurité, rôle que pourrait jouer le droit de la concurrence. Si, rétrospectivement, un brevet est manifestement non valide ou trop étendu et que ce brevet a contribué à un comportement anticoncurrentiel illicite, les autorités de la concurrence devraient pouvoir contester ce brevet devant un tribunal.

6. Les problèmes d'application du droit de la concurrence

Dans une économie de plus en plus fondée sur les connaissances, il est quasiment certain que les autorités de la concurrence vont être confrontées à des affaires de DPI et qu'elles devront, à terme, prendre des mesures afin de limiter l'utilisation de ces droits. Du moins en théorie. Les DPI n'impliquent pas une immunité totale vis-à-vis du droit de la concurrence. Après tout, le principal objectif du droit des brevets est d'encourager l'avancée et la propagation des connaissances scientifiques, pas d'enrichir les détenteurs de brevets.[64]

Cette partie du document explore quelques-uns des comportements liés à la propriété intellectuelle que les autorités de la concurrence peuvent rencontrer. Bien qu'il y ait d'autres comportements qui ne sont pas analysés ici, on s'attachera aux questions examinées ci-après parce qu'elles sont parmi les moins bien définies du point de vue de leurs conséquences pour la propriété intellectuelle et la politique de concurrence.

6.1 Hypothèses

La concession de licence favorise généralement la concurrence. La concession de licence sur des brevets est un moyen de diffuser des technologies faisant l'objet d'un droit exclusif auprès d'un plus grand nombre d'entités innovantes. Les licences permettent également aux entreprises de se concentrer sur leurs points forts en s'appuyant sur d'autres entreprises pour les technologies complémentaires. Elles constituent en outre un moyen pour les entreprises de tirer parti de technologies qu'elles ne peuvent pas utiliser elles-

mêmes, tout en encourageant de nouveaux investissements dans l'innovation. La concession de licence peut également être un moyen d'épuiser le potentiel de revenu d'une invention. Si le brevet a plus d'applications que l'inventeur ne peut en exploiter, l'inventeur peut tout de même profiter d'une partie au moins des bénéfices potentiels en octroyant une licence pour l'invention à d'autres entreprises.

De plus, la concession de licence peut également être un bon moyen pour les inventeurs de partager les risques. Lorsque le succès commercial d'une invention est incertain, les inventeurs peuvent transférer une partie du risque lié à sa commercialisation en octroyant une licence à d'autres intervenants pour qu'ils se chargent de la commercialisation à leur place ou pour qu'ils s'associent à leurs travaux.[65]

Il est important de distinguer les relations horizontales et verticales. La concession de licence sur des DPI crée habituellement un lien entre deux éléments complémentaires. Les transactions qui impliquent des éléments complémentaires sont essentiellement verticales parce qu'elles facilitent le progrès tout au long de la chaîne de production. Les transactions complémentaires peuvent être verticales, même si le concessionnaire et le cédant sont par ailleurs en concurrence pour la fabrication de produits utilisant la propriété intellectuelle sous licence.[66] Cela étant, la concession de licence sur un DPI peut quelquefois présenter des caractéristiques manifestement horizontales, comme lorsque qu'une société octroie une licence tout en exigeant que tous les DPI ultérieurs créés par le concessionnaire lui soient rétrocédés afin de parer à toute retombée que pourrait avoir une amélioration apportée par le concessionnaire en termes de concurrence.

Certaines autorités distinguent explicitement les concessions de licence horizontales et verticales, et cette distinction est importante, car les accords horizontaux sont fondamentalement plus problématiques du point de vue de la concurrence. Le Règlement d'exemption par catégorie en faveur du transfert de technologie (ECTT) de l'UE, contrairement au texte antérieur de 1994, établit une distinction entre les accords de licence horizontaux et verticaux pour évaluer les restrictions imposées dans le cadre d'accords de licence.[67] La législation américaine établit de façon générale la même distinction.[68]

6.2 Comportement bilatéral potentiellement anticoncurrentiel en matière de concession de licence

Groupements de brevets. Lorsque des brevets détenus par au moins deux parties sont concédés en licence de façon groupée, ces parties forment un groupement de brevets. Souvent, les membres d'un groupement de brevets attribuent ou accordent une licence exclusive sur leurs DPI à une entité distincte, qui contrôle alors la concession de licence sur le portefeuille de brevets aux membres du groupement ou, s'il s'agit d'un groupement « ouvert », à une tierce partie.[69] Les modalités de ces accords sont variables. Les membres du groupement peuvent être autorisés à utiliser l'ensemble des DPI gratuitement ou contre le versement de redevances. En outre, il existe de nombreuses façons de répartir les revenus issus de la concession de licences générés par le groupement et la gestion du groupement peut faire intervenir divers mécanismes de vote ou de veto.

Le rôle que les groupements de brevets sont susceptibles de jouer dans le secteur des biotechnologies a fait l'objet d'une attention considérable dans les publications spécialisées. Selon certains auteurs, eu égard aux problèmes posés par l'empilement de redevances, le blocage par les biens privatifs ou toute autre situation où les droits liés à des brevets sont susceptibles de faire obstacle à la poursuite de la R-D, les groupements de brevets présentent des avantages considérables et devraient par conséquent être encouragés. Aux États-Unis, par exemple, selon un document publié par le U.S. Patent and Trademark Office, les groupements de brevets pourraient aider le secteur des biotechnologies en atténuant les risques liés aux brevets créant des situations de blocage et au blocage par les biens privatifs ; en réduisant les coûts de transaction liés à la concession de licence ; en permettant aux entreprises de partager les risques de R-D ; et en institutionnalisant l'échange d'informations techniques non couvertes par des brevets.[70]

D'autres se sont demandés si les groupements de brevets permettraient de résoudre les problèmes qui se posent sur le marché des inventions génétiques. Dans une récente étude de l'OCDE, par exemple, les répondants d'une enquête allemande, à savoir les représentants de diverses entreprises pharmaceutiques et biotechnologiques, de centres de recherche en génétique et d'organismes publics de recherche, n'ont pas estimé que les groupements de brevets ou les accords de concession réciproque de licences contribuaient à élargir l'accès aux inventions génétiques. Selon eux, en effet, il est trop difficile de mesurer la valeur des contributions apportées par chacune des parties dans le cadre de l'accord.[71] Des observateurs ont identifié plusieurs caractéristiques propres au secteur des biotechnologies susceptibles de limiter l'intérêt des groupements de brevets et d'expliquer pourquoi ils ne sont pas (encore) très utilisés.[72]

6.2.1 Les préoccupations suscitées par les groupements de brevets en termes de concurrence

Même si l'utilité des groupements de brevets pour le secteur de la biotechnologie est contestable, les autorités de la concurrence pourraient avoir à traiter des accords de regroupement dans ce secteur à l'avenir. Il est généralement admis que les groupements de brevets profitent à la fois aux détenteurs et aux utilisateurs de DPI, à condition que ce groupement se limite aux brevets complémentaires ou de nature à créer un blocage. Dans ce cas, les groupements de brevets peuvent faciliter l'intégration de technologies complémentaires, réduire les coûts de transaction, faciliter la suppression des situations de blocage par des brevets et éviter des procès en contrefaçon de brevet.[73] Mais on s'accorde également à penser que les groupements de brevets présentent des risques pour la concurrence à plusieurs égards :

- *Réduction de la concurrence sur les marchés technologiques horizontaux* : tout d'abord, lorsque les technologies regroupées ne sont pas des compléments mais des substituts (ne créant pas de blocage), les groupements de brevets peuvent constituer un accord horizontal qui élimine la concurrence entre des technologies qui existeraient s'il n'y avait pas d'accord de groupement. Par exemple, de tels regroupements pourraient devenir de simples dispositifs d'entente sur les prix sous couvert d'accords de licence.[74] Les groupements de brevets peuvent également nuire à la concurrence en incluant des brevets non valides et en limitant les risques de contestation de la validité des brevets, prolongeant ainsi des droits exclusifs et un pouvoir de marché qui ne sont pas légitimés par la politique de protection de la propriété intellectuelle.

- *Facilitation des collusions sur les marchés de produits en aval* : ensuite, les groupements de brevets sont susceptibles de réduire la concurrence horizontale sur les marchés en aval. Si le groupement normalise un intrant du marché en aval et que les redevances sont élevées par rapport au coût de fabrication total du produit en aval, la collusion entre les entreprises en aval devient plus facile. Cette éventualité est particulièrement préoccupante lorsque les membres du groupement participent également au marché en aval, car cela induit une incitation à créer un groupement en vue d'imposer les prix sur ce marché.

- *Exclusion de technologies concurrentes :* les groupements sont susceptibles d'exclure des technologies qui ne font par partie du groupement, mais qui sont en concurrence avec les technologies regroupées. Cela peut arriver, par exemple, si les concessionnaires estiment qu'il est plus commode de signer un seul accord portant sur l'ensemble des technologies regroupées que de chercher des technologies de rechange pour conclure des accords distincts.

- *Réduction des incitations à l'innovation* : les accords de groupement peuvent nuire à l'innovation en réduisant les incitations à inventer d'autres technologies à partir de celles qui sont regroupées, ou en réduisant les incitations favorisant des inventions ultérieures (ce qui peut se produire si les membres d'un groupement sont tenus de concéder une licence à ce dernier pour les inventions ultérieures, par exemple).

1. La section suivante présente le cadre juridique élaboré par deux autorités de la concurrence pour traiter ces questions. Il ressort de cette présentation que si les cadres sont similaires, ils ne semblent cependant pas rigoureusement identiques.

6.2.2 Politiques destinées à régler les problèmes de concurrence dans les cas de groupement de brevets

Lignes directrices européennes

Les nouvelles lignes directrices européennes abordent dans le détail la question des critères utilisés pour évaluer les effets sur la concurrence des groupements de brevets.[75] La Commission souhaite principalement s'assurer que les brevets ainsi regroupés soient des compléments et non des substituts. Les lignes directrices établissent que l'inclusion, au sein d'un groupement de brevets, de technologies de substitution constitue sans doute un manquement à l'article 81(1), alors même que les conditions d'une exemption au titre de l'article 81(3) ne peuvent probablement pas être réunies.[76]

Si elle se montre stricte sur le critère de complémentarité des brevets regroupés, la Commission semble légèrement plus souple sur l'éventuelle existence de substituts, en dehors du groupement de brevets. (Selon les termes des lignes directrices, les technologies n'ayant aucun substitut en dehors du groupement de brevets sont qualifiées d'« essentielles »). Tout en admettant le risque que certains groupements de brevets pour des technologies non essentielles puissent évincer des technologies de tiers en dehors du groupement de brevets, la Commission indique qu'elle s'efforcera de vérifier au cas par cas si l'inclusion de technologies non essentielles peut avoir des effets d'éviction.[77]

La « position » du groupement de brevets sur tout marché pertinent est le principal facteur permettant d'évaluer les effets d'éviction, cette position dépendant, peut-on supposer, de considérations comme le degré de satisfaction de la demande en aval par les technologies regroupées. Parmi les autres facteurs pris en compte par la Commission figurent toutes les raisons d'inclure les technologies non essentielles pour favoriser la concurrence et ce, que les cédants des licences conservent ou non la liberté de concéder leur technologie individuellement et la faculté de se procurer des licences distinctes, plutôt qu'un lot.

Dans ses lignes directrices, la Commission souligne par ailleurs la nécessité pour les cédants de pouvoir octroyer des licences individuelles en dehors du groupement de brevets. En outre, les rétrocessions de licence ne doivent pas être exclusives afin de ne pas limiter l'incitation à innover. De plus, les groupements de brevets ne doivent pas être conçus pour permettre d'échanger des informations sensibles sur le plan concurrentiel. Les lignes directrices européennes semblent également prohiber les clauses de non contestation et requièrent, dès lors que la validité d'un brevet faisant l'objet d'un octroi de licence est contestée, que le droit de résiliation de la licence soit limité à la technologie du cédant qui est propriétaire du brevet contesté. Cette condition devrait atténuer le risque de contestation.

Lignes directrices américaines et Business Review Letters du Department of Justice (DOJ)

Les lignes directrices américaines n'exposent pas en détail l'analyse à laquelle les autorités de la concurrence devraient se livrer sur la question des groupements de brevets. Elles énumèrent, en termes assez généraux, les avantages concurrentiels potentiels des accords de groupement de brevets,[78] ainsi que les effets anticoncurrentiels possibles desdits groupements. Parmi ces effets, on compte les ententes sur les prix et les limitations de production sans gains correspondants d'efficience, l'effet dissuasif des clauses de rétrocession de licence sur l'innovation, ainsi que – surtout en cas de puissance sur le marché – l'éviction de tiers n'ayant pas accès au groupement de brevets.[79]

Plusieurs Business Review Letters[80] du DOJ ayant trait aux groupements de brevets dans le contexte de la définition de normes examinent en détail les restrictions qui peuvent être nécessaires pour minimiser les risques anticoncurrentiels associés à ces groupements.[81] Même si elles sont très factuelles, ces lettres constituent pour beaucoup une référence utile pour former un groupement de brevets dans le respect du droit de la concurrence. Les commentateurs ont identifié les restrictions et les critères suivants à prendre en compte à cette fin :

- les brevets au sein d'un groupement doivent être valides et ne pas être parvenus à expiration ;
- les brevets du groupement doivent être *essentiels* ;
- les redevances doivent être minimes par rapport au coût de fabrication total des produits en aval incorporant la technologie mise en commun dans le groupement ;
- l'octroi de licence ne doit faire aucune discrimination entre les différentes personnes intéressées ;[82]
- chaque détenteur de licence doit être autorisé à concéder sa technologie en dehors du groupement de brevets ;
- l'accès à des informations sensibles en matière de concurrence doit être limité ;
- les clauses de rétrocession de licence ne doivent pas limiter l'incitation à innover.[83]

Les deux premiers critères portent sur certains problèmes de concurrence affectant les marchés technologiques. Outre l'obligation fondamentale de validité des brevets regroupés, un élément primordial entrant dans l'évaluation des groupements de brevets par le DOJ est leur caractère « essentiel » . Par définition, les brevets « essentiels » n'ont pas de substituts et une licence est nécessaire pour chacun d'entre eux afin de respecter la norme. »[84] Par conséquent, la condition d'être essentiel implique d'une part que les brevets regroupés soient mutuellement complémentaires (condition interne), et d'autre part qu'aucun d'entre eux n'ait de substitut en dehors du groupement (condition externe). Cette condition est justifiée comme suit :

> La limitation du portefeuille à des brevets techniquement essentiels, par opposition aux brevets qui sont simplement avantageux, permet de garantir que les brevets en portefeuille ne se font pas concurrence et que la licence issue du portefeuille n'évince pas, du fait du regroupement de brevets non essentiels,. des options d'application concurrentes [.][85]

Il peut être difficile de déterminer dans quels cas les brevets respectent ou non la condition d'être « essentiel ». Pour les groupements technologiques visés dans les Business Review Letters du DOJ, des experts extérieurs ont été chargés d'identifier les brevets qui pouvaient être qualifiés d'essentiels et ont donc été inclus dans le groupement et ceux qui devaient en rester exclus. Les experts sont également intervenus durant l'exploitation du groupement.[86]

Il n'est pas surprenant que ce bref tour d'horizon des politiques européenne et américaine sur les groupements de brevets ait fait ressortir une égale rigueur des autorités de la concurrence des deux juridictions en ce qui concerne l'interdiction des groupements de brevets faisant intervenir des technologies de substitution. Il est concevable que des exigences strictes de complémentarité puissent augmenter les risques anticoncurrentiels quand les groupements sont formés dans un secteur comme celui des biotechnologies, dans lequel la portée des brevets et/ou des applications en aval de la technologie sous licence peut ne pas être connue des détenteurs de droits au moment où ils envisagent la constitution d'un

groupement de brevets.[87] En fin de compte, les lignes directrices européennes semblent principalement s'intéresser aux éventuels effets horizontaux des groupements de brevets entre les membres du groupement et paraissent plus souples que les lignes directrices américaines en ce qui concerne les effets d'éviction (verticaux) impliquant la technologie de tiers.[88]

Ayant évalué les effets sur la concurrence des groupements de brevets, Lerner et Tirole ont souligné que la distinction entre compléments et substituts constitue certes une première étape utile pour en déterminer le caractère anticoncurrentiel, mais que les inventions brevetées sont rarement de parfaits compléments ou substituts . De plus, les liens entre les brevets peuvent évoluer avec le temps, dans la mesure où les brevets peuvent donner naissance à de nouveaux produits qui se trouveront en concurrence en aval.[89] Dans certains accords de groupements de brevets, il pourrait donc être difficile de s'en tenir à une stricte distinction entre les brevets complémentaires et les brevets de substitution.

Contrats de licence sur les inventions ultérieures. Les contrats de licence sur les inventions ultérieures évaluent les redevances sur la base des recettes générées par un produit en aval, qu'il soit ou non fabriqué à l'aide de la technologie faisant l'objet de la licence. Par exemple, la technologie sous licence peut permettre d'identifier et de développer le produit, sans aucunement entrer dans sa fabrication ou sa commercialisation. Il s'agit là d'un scénario typique sur le segment des outils de recherche du secteur des biotechnologies au sein duquel les contrats de licence sur des inventions ultérieures procurent aux sociétés en aval l'accès à des plates-formes de recherche brevetées moyennant des redevances sur de futurs produits qui ne constitueraient pas une contrefaçon du brevet en amont. L'exercice par une société de ses droits de brevet pour tirer profit d'un autre produit que celui breveté doit-il constituer un manquement au droit de la concurrence ? Pourquoi une société en aval consentirait-elle à un tel accord ?

Premièrement, il faut prendre en compte que les contrats de licence sur des inventions ultérieures peuvent, à certains égards, favoriser la concurrence. Ainsi peut-il être parfois extrêmement difficile d'établir ce qu'est un droit de licence équitable. Ce problème d'évaluation est davantage susceptible de survenir quand il s'agit de contribuer à inventer des produits en aval plutôt que de les fabriquer. Si un problème survient, c'est qu'au stade de l'octroi de la licence, il est difficile de déterminer :

a. si la technologie brevetée pourra un jour conduire à l'invention en aval d'un produit remportant un succès financier ;
b. quel succès ce produit remportera ;
c. quelle part de ce succès, s'il advient, pourra être attribué à la technologie en amont.

Cette incertitude peut provoquer bien des controverses sur la valeur réelle d'une invention. En fait, même si un produit remportant un succès est ultérieurement développé, la part de la technologie en amont dans ce succès sera toujours matière à discussion.

Les redevances sur les inventions ultérieures offrent une solution au problème de l'évaluation du brevet en amont en indexant simplement les droits de licence aux recettes générées par le(s) produits(s) en aval du concessionnaire de la licence quel que soit, en définitive, le lien entre ces deux éléments. Cet accord facilite par conséquent l'octroi de licences qui n'aurait pu intervenir sans cela.

De plus, la signature d'un contrat de licence sur les inventions ultérieures libère le concessionnaire du règlement de droits anticipés. Dans cette optique, le contrat constitue un instrument de financement qui pourrait être privilégié par les jeunes sociétés biotechnologiques de petite taille et pauvres en trésorerie, en mettant à leur disposition une technologie qui serait, sans cela, financièrement hors de leur portée.

D'un autre côté, les contrats de licence sur des inventions ultérieures ne sont pas sans risque. Par exemple, s'il est clair, dès le début d'un tel accord, que les redevances seront tirées des recettes générées

par un produit n'ayant absolument aucun rapport, le contrat semble plus discutable puisqu'il exploite la puissance du brevet pour engranger des bénéfices sur un marché n'ayant aucun lien avec celui-ci. De fait, ces accords peuvent constituer une forme d'abus de brevet.[90]

Le règlement ECTT ne s'appliquerait à un contrat de licence sur des inventions ultérieures que si ce contrat fait référence à un produit destiné à être fabriqué sous ladite licence.[91] Il n'est pas tout à fait clair jusqu'à quel point la référence au produit doit être détaillée pour que le règlement ECTT puisse s'appliquer. Il est cependant assez probable qu'au moment de la signature de licences portant sur des outils de recherche biotechnologiques, les parties ne pourront souvent pas identifier le produit que le concessionnaire développera, ce qui exclurait l'application du règlement ECTT.[92]

Aux États-Unis, le fait de subordonner l'octroi d'une licence au versement de redevances sur des inventions non brevetées constitue techniquement une forme d'abus de brevet.[93] Les tribunaux ont toutefois autorisé de telles licences quand les parties y souscrivent volontairement à leur convenance mutuelle,[94] ce qui peut être l'exception qui confirme la règle.

Les lignes directrices américaines ne traitent pas directement des contrats de licence sur des inventions ultérieures, même si elles contiennent des termes qui pourraient permettre d'en contester la légalité en raison de leur caractère exclusif. En effet, selon les lignes directrices :

> L'exclusivité peut être garantie par une clause d'exclusivité figurant dans la licence ou par toute autre disposition telle que les clauses relatives à la rémunération ou à d'autres incitations économiques. Ces restrictions peuvent avoir des effets anticoncurrentiels en excluant l'accès des concurrents à des intrants essentiels, ou en augmentant le coût à payer pour les obtenir, ou bien en favorisant les ententes pour augmenter des prix ou réduire la production, mais elles peuvent aussi stimuler la concurrence.[95]

En ce qui concerne les accords de licence sur les inventions ultérieures conclus entre non-concurrents et qui n'entrent pas dans le champ du règlement ECTT, les lignes directrices européennes précisent que la Commission vérifiera si le taux des redevances basées sur des produits n'incorporant pas la technologie sous licence produit des effets d'éviction, ce qui tend à montrer que l'approche de la Commission s'apparentera à celle des lignes directrices américaines.[96] En ce qui concerne les accords passés entre concurrents, les lignes directrices européennes donnent à penser que la Commission pourra adopter un raisonnement plus restrictif, et, de manière générale, considèrera les accords de redevances basés sur des produits non couverts par la technologie sous licence comme une restriction caractérisée à la concurrence. Aux termes des lignes directrices, toutefois, ces accords peuvent bénéficier d'une exemption particulière si la restriction est considérée comme indispensable pour qu'une concession de licence favorisant la concurrence puisse être conclue.[97] Ce raisonnement semble pouvoir englober les contrats de licence sur les inventions futures conclus dans le secteur biotechnologique, dans les cas notamment où il peut être démontré que l'accord constitue le moyen le plus efficace de régler les problèmes d'évaluation et qu'il n'est pas destiné à restreindre la liberté du concessionnaire à utiliser sa propre technologie ou celle de tiers.

Les lignes directrices japonaises adoptent une même approche, qui s'intéresse principalement aux effets d'éviction potentiels.[98]

On pourrait certainement opposer qu'interdire complètement les contrats de licence sur les inventions ultérieures découragerait l'innovation car, sans eux, les inventeurs en amont ne pourraient tirer suffisamment profit du produit de leur imagination pour rentabiliser les investissement nécessaires. On pourrait également objecter qu'une interdiction contraindrait tout simplement les parties à rechercher d'autres moyens de valoriser la technologie en amont. Autrement dit, quand la volonté est là, il y a toujours un moyen.

Du moins, quand la volonté est suffisamment forte, on trouve toujours un moyen. C'est le principe suivi par les grandes sociétés pharmaceutiques dans leurs négociations avec les concepteurs d'outils de recherche en amont qui, parfaitement conscients du potentiel financier des médicaments vedettes en aval, privilégient de plus en plus les contrats de licence sur les inventions ultérieures pour leurs outils. Toutefois, les groupes pharmaceutiques s'y opposent souvent âprement, car ils préfèrent verser des droits fixes en avance que céder des parts sur des recettes en aval susceptibles d'atteindre des milliards. Quand les concepteurs d'outils se montrent réticents à percevoir des droits en avance, on a pu voir des sociétés pharmaceutiques aller très loin pour éviter d'avoir à payer le moindre droit de licence pour l'outil concerné. Grâce à leurs trésors de guerre généralement considérables, elles ont les moyens de délocaliser à l'étranger leurs activités pour y tester leurs propres médicaments candidats sur des cibles de gène brevetées. Elles peuvent aussi créer une séquence d'ADN suffisamment différente de celle brevetée par le concepteur d'outils pour éviter toute contrefaçon, mais suffisamment similaire pour pouvoir servir de cible de médicament.[99]

Ceci nous ramène à notre point de départ, et donc à nous demander pour quelle raison les autorités cherchent à restreindre, voire bannir les contrats de licence sur les inventions ultérieures (du moins pour les créateurs d'outils du secteur biotechnologique). Si les « victimes » supposées de ces licences peuvent réussir à s'en passer, celles-ci ont-elles vraiment un impact sur l'innovation ?

Les grandes sociétés pharmaceutiques ne sont certes pas les seules à utiliser les outils de recherche biotechnologiques. D'autres entreprises de biotechnologie y ont aussi recours mais, en ce qui les concerne, les faits ne semblent pas vraiment militer en faveur d'une intervention. Ces entreprises disposent de bien moins de ressources financières que les groupes pharmaceutiques. Elles sont donc davantage susceptibles de conclure des contrats de licence sur les inventions ultérieures.[100] En effet, non seulement, elles ne possèdent souvent pas la solidité financière qui leur permettrait d'engager par avance les sommes permettant de ne pas céder à la volonté des innovateurs en amont de conclure ce type de contrats, mais elles manquent aussi souvent des fonds leur permettant d'effectuer en avance le moindre versement important. Pour elles, ces accords constituent un mode de financement les autorisant à utiliser une technologie brevetée sans la payer, sauf si, et jusqu'au moment où, elles développent elles-mêmes un produit générant des recettes. Dans ce contexte, ces accords semblent donc être propices à l'innovation car les concessionnaires les concluent volontairement et les préfèrent dans les faits à des règlements monétaires intervenant dès le début de la période couverte par la licence.

Les rétrocessions (grant-backs). Elles interviennent lorsque, à titre de condition à la concession d'une licence pour une technologie, le détenteur d'un brevet exige des concessionnaires qu'ils lui rétrocèdent les droits d'exploitation pour toute technologie qui en découle et que les concessionnaires font breveter. Parfois, le détenteur d'un brevet demandera même aux concessionnaires de lui accorder une licence exclusive ou une cession pure et simple des droits.

Les rétrocessions, comme de nombreux contrats de licence, produisent toute sorte d'effets qui ne vont pas forcément dans le même sens. Elles peuvent permettre des transactions pour la concession de licences contribuant à des transferts efficients de technologie qui auraient pu ne pas avoir lieu autrement. Par exemple, une rétrocession peut se substituer aux droits de licence, donnant aux concessionnaires disposant de peu de capitaux un moyen de financer la technologie. Par ailleurs, les rétrocessions peuvent servir à protéger le cédant du danger d'une amélioration de sa technologie par un concessionnaire concurrent, qui le chasserait du marché. En outre, les rétrocessions peuvent renforcer les incitations en amont pour les innovateurs à créer de la propriété intellectuelle que d'autres trouvent utiles. De plus, les rétrocessions permettent au cédant et au concessionnaire de partager les risques et les avantages de l'innovation ultérieure.

Dans le secteur des biotechnologies, les rétrocessions sont souvent utilisées lorsque le concessionnaire est une entité à but non lucratif qui ne crée pas de produits commercialisables tout en étant susceptible de créer de la propriété intellectuelle.[101] Ce peut être le cas, par exemple, d'une fondation de recherche ou d'une université. Pour ces catégories de concessionnaires, un contrat de licence sur les inventions ultérieures n'aiderait sans doute pas le cédant, mais une rétrocession permet de tirer un certain profit de la transaction. Aux États-Unis, où l'exception de l'utilisation expérimentale devient plus stricte,[102] les chercheurs travaillant dans un but non lucratif vont sans doute s'en remettre de plus en plus aux rétrocessions pour obtenir les licences dont ils n'avaient auparavant pas besoin.

Cela étant, certaines rétrocessions peuvent avoir des conséquences anticoncurrentielles. Elles peuvent par exemple étendre le contrôle initial de l'inventeur sur un produit à d'autres produits ultérieurs, y compris des produits qui auraient pu autrement constituer des substituts concurrents. Ce problème est, bien entendu, le plus aigu lorsque la rétrocession impose l'attribution de droits de propriété intellectuelle ultérieurs. En outre, les rétrocessions limitent l'intérêt pour les concessionnaires de mener des recherches ultérieures car tout ce qu'ils inventent qui vaut la peine d'être breveté devra être partagé avec le cédant ou lui être entièrement cédé. En revanche, lorsque le concessionnaire est un organisme à but non lucratif, son programme de recherches risque moins d'être menacé par une rétrocession.

L'adoption d'une politique de la concurrence uniformément rigoureuse vis-à-vis des rétrocessions irait à l'encontre du but recherché. Tout d'abord, il faut établir une distinction entre les licences non exclusives, les licences exclusives (dans le cadre desquelles l'inventeur ultérieur conserve des droits sur son invention) et les cessions (dans le cadre desquelles il ne conserve aucun droit). Le risque de préjudice à la concurrence est moindre lorsque les licences sont non exclusives. En fait, ces licences peuvent favoriser la concurrence, car elles permettent à plusieurs sociétés d'utiliser la technologie ultérieure. Ensuite, si les autorités de la concurrence voulaient s'opposer à toutes les rétrocessions, elles favoriseraient probablement des refus inefficients d'accorder des licences.[103]

On peut obtenir un meilleur résultat global en exemptant les rétrocessions à des structures à but non lucratif et en autorisant d'autres rétrocessions sous réserve qu'elles n'attribuent pas au cédant initial des droits sur des produits ultérieurs, ni une licence exclusive sur de tels produits. Cette politique dissiperait les craintes des cédants de perdre leur part de marché au profit des concessionnaires, tout en laissant aux concessionnaires au moins quelques incitations à innover.

Le Règlement d'exemption par catégorie des accords de transfert de technologie de l'Union européenne donne à penser que la Commission a adopté une approche plus permissive vis-à-vis des rétrocessions exclusives que ce n'était le cas dans le précédent Règlement. Ce nouveau Règlement adopte une position neutre à l'égard des rétrocessions exclusives et des clauses d'attribution rétroactive de droits relatives aux améliorations qui sont jugées séparables, autrement dit des améliorations qui peuvent être utilisées sans contrefaire la technologie initiale ayant fait l'objet d'une licence. Ces rétrocessions exclusives ou les attributions rétroactives de droits sont « exclues », ce qui signifie qu'elle ne font l'objet ni d'une exemption par catégorie, ni d'une interdiction aux termes du Règlement.[104] Les lignes directrices européennes expliquent que l'évaluation consistant à vérifier si les rétrocessions ou attributions rétroactives de droits restreignent ou non la concurrence dépend d'une diversité de facteurs, dont l'importance de la technologie sous licence, l'existence de réseaux parallèles d'accords de licence avec des obligations comparables ou des concessions réciproques de licence assorties de rétrocessions.[105]

Les lignes directrices de la Japan Fair Trade Commission (JFTC) semblent avoir une approche un peu plus stricte. Comme elles le précisent en effet, étant donné que « ...il n'y a habituellement pas de justification raisonnable pour que le détenteur d'une licence impose pareille condition, il y a très peu de chance que cela entre dans la catégorie des pratiques commerciales déloyales et soit contraire à la Loi contre les monopoles."[106]

Selon le § 5.6 des lignes directrices américaines, les effets anticoncurrentiels des rétrocessions ne sont jugés probables que si (1) le cédant de la licence et le concessionnaire se seraient trouvés autrement en concurrence dans le domaine de la recherche-développement et si (2) le cédant de la licence est en position de force sur le marché.[107]

En définitive, le choix de la rigueur que doivent adopter les pouvoirs publics vis-à-vis des rétrocessions (comme des licences sur les inventions ultérieures, d'ailleurs) dépend de leur préoccupation première : motiver l'innovation en amont ou bien en aval. Accorder plus d'attention à l'innovation en amont entraîne logiquement l'adoption d'une politique plus permissive vis-à-vis des rétrocessions et des licences sur les inventions ultérieures. Mettre l'accent sur l'innovation en aval, en revanche, aboutit à une politique plus restrictive.

Une raison pour encourager les innovateurs en aval est que la recherche en amont coûte généralement moins et reçoit davantage de subventions publiques que les travaux en aval. Bien des découvertes majeures effectuées en amont dans le domaine de la recherche biomédicale ont été financées par les pouvoirs publics. On peut donc se demander s'il faut amplifier les incitations destinées à l'innovation en amont. En fait, Eisenberg attire l'attention sur des signes témoignant d'ores et déjà que ces incitations sont peut-être déjà trop importantes.[108] Dans le même article, cependant, elle rappelle aux lecteurs que les droits sur les inventions ultérieures et les rétrocessions apportent une solution aux problèmes d'évaluation, constituent un mode de financement extrêmement utile pour de nombreuses sociétés de biotechnologie et universités qui manquent de fonds et donnent aux innovateurs en amont la motivation financière dont ils ont besoin pour transférer leur technologie à d'autres. Eisenberg conclut par conséquent que « dans ce marché en pleine évolution, il semble peu judicieux repousser les limites de la loi antitrust pour exclure le recours à de telles conditions dans les contrats de licence. »[109]

Restrictions sur les prix. Le contrôle du prix que le concessionnaire peut facturer pour des produits utilisant la technologie sous licence est une pratique qui est contraire aux termes des lignes directrices de l'Union européenne, du Japon et des États-Unis. La pratique des prix imposés empêche l'application du Règlement d'exemption par catégorie des accords de transfert de technologie de l'Union européenne.[110] Les prix imposés étant qualifiés de restriction injustifiable, il est peu probable qu'ils puissent donner lieu à une exemption individuelle.[111] Selon le Règlement sur le transfert de technologie, « l'article 1 et l'article 2(2) ne s'appliquent pas lorsque... une partie a un pouvoir limité de détermination des prix, des composantes des prix ou des rabais pour les produits sous licence. »[112] Selon les lignes directrices japonaises, « imposer des restrictions sur les prix de revente de produits brevetés au Japon » est une pratique qui sera considérée « très probablement comme faisant partie des pratiques commerciales déloyales ».[113] Selon les lignes directrices américaines, « les administrations publiques appliqueront la règle de l'interdiction *per se* à l'encontre des prix imposés dans le contexte de la propriété intellectuelle »[114], mais elles limiteront également le traitement *per se* aux cas pour lesquels on ne peut attendre de la restriction « qu'elle contribue à une intégration de l'activité économique de nature à apporter des gains d'efficience. »[115]

Cette mise en garde des États-Unis est significative car les restrictions imposées par le cédant aux décisions de prix des concessionnaires concernant la technologie sous licence ne produisent généralement pas d'effets anticoncurrentiels plus importants que ce ne serait le cas en l'absence de toute licence. Le principe d'un brevet est que l'on peut déterminer le prix des produits sous licence. On voit mal comment les consommateurs pourraient tirer parti d'une interdiction des restrictions sur la détermination des prix des concessionnaires si cela a pour seule conséquence d'inciter les détenteurs de brevet à refuser d'accorder des licences. Un tel refus pourrait facilement signifier que l'on renonce aux gains d'efficience que pourrait apporter une combinaison des DPI et de ressources complémentaires détenues par les concessionnaires potentiels. La politique la plus judicieuse pourrait donc être d'autoriser les restrictions sur les licences qui aboutissent à plus de concurrence que ce ne serait le cas en l'absence de toute licence.[116]

Autres catégories de licences restrictives. Il existe d'innombrables moyens de restreindre la concurrence dans les clauses d'une licence de propriété intellectuelle. Certains sont plus faciles à reconnaître que d'autres. Du côté le plus simple du spectre, on trouve les licences qui dictent le prix qu'un concessionnaire peut facturer pour un produit qui n'utilise pas la technologie sous licence ou qui interdit le recours à la technologie sous licence à l'expiration du brevet.

Vers le milieu du spectre, on trouve les licences qui restreignent probablement la concurrence, mais qui, pour une raison ou une autre, n'obligent pas les candidats à les contester en invoquant le droit de la concurrence. Imaginons, par exemple, une société dont on a constaté qu'elle contrefaisait le brevet d'un concurrent. Le concurrent accepte un règlement à l'amiable, mais seulement à des conditions qui fragilisent considérablement la capacité du contrefacteur à rester concurrentiel. Plus particulièrement, le détenteur du brevet en position dominante peut demander à son concurrent d'accepter de ne pas fusionner avec une autre entreprise donnée pendant deux ans. Dans le cas où la fusion aurait engendré un puissant concurrent face au détenteur de brevet en position dominante, les autorités de la concurrence peuvent-elles intervenir et annuler l'accord ?

Dans la pratique, avant que les autorités apprennent l'existence de l'accord, mènent leur enquête, obtiennent une date de jugement, contestent le cas et obtiennent une décision, au moins deux ans se seront probablement écoulés, autrement dit les autorités de la concurrence ne peuvent pas faire grand chose. Mais sans entrer dans cette considération, que se passe-t-il si le défendeur avance de manière assez plausible que s'il n'y avait pas eu d'accord à l'amiable, la décision de justice et les préjudices financiers en résultant auraient affaibli le contrefacteur encore plus que les conditions de l'accord à l'amiable ? Un choix réaliste en l'occurrence semble être de ne pas contester cette pratique.

Un peu plus loin dans le spectre, on trouve des accords de licence qui peuvent être soit légaux, soit illégaux, selon la situation concernée. Par exemple, une licence peut prévoir des conditions imposant aux concessionnaires de continuer à verser des redevances après l'expiration du brevet. Cela peut de toute évidence constituer un moyen illégal de prolonger les avantages du brevet si les redevances sont calculées en fonction d'une utilisation de l'invention après l'expiration du brevet.[117] Cependant, si les redevances sont fonction des ventes qui se sont produites pendant la durée de vie du brevet, mais que tout ou partie des sommes effectivement versées le sont après son expiration, cela semble un moyen inoffensif de financer des droits légitimes que le concessionnaire n'a peut-être pas été en mesure de régler antérieurement. Par ailleurs, si les redevances sont fonction de ventes qui ont eu lieu après l'expiration du brevet, mais sont censées compenser l'utilisation de l'invention en question avant l'expiration du brevet, elles peuvent être aussi permises.[118]

6.3 Comportement potentiellement anticoncurrentiel en matière de concession de licence

Refus unilatéral d'octroi de licence. Ce comportement peut être particulièrement dommageable dans le secteur des biotechnologies dont l'activité dépend en grande partie des technologies brevetées en amont. Cantonner l'accès à ces technologies peut avoir des effets importants sur l'innovation ultérieure et, dans certains cas, sur la concurrence. Cela ne signifie cependant pas que les refus unilatéraux de concession de licence doivent toujours être considérés comme une violation du droit de la concurrence.

Il y a près d'un siècle, la Cour Suprême américaine jugeait que le refus d'un détenteur de brevet de concéder une licence sur un brevet ne pouvait constituer le fondement d'une plainte pour pratique anticoncurrentielle.[119] Au fil des ans, un certain nombre d'affaires sont survenues et se sont accompagnées de comportements annexes suffisants pour justifier la limitation, voire la suppression du droit d'exclusion initialement octroyé avec le DPI.[120] Le principe selon lequel le simple refus unilatéral de licence en matière de propriété intellectuelle se trouve hors de la portée du droit de la concurrence a toutefois perduré aux États-Unis.[121]

La Cour de justice des Communautés européennes a statué, au contraire, qu'un guide de télévision qui faisait l'objet de droits d'auteur représentait un service essentiel et a imposé une obligation de licence.[122] Il a été confirmé assez récemment dans un autre cas de droits de reproduction que le refus d'une firme dominante d'octroyer une licence pouvait être illégal dans certaines circonstances. Dans l'affaire IMS, la Cour a statué :

> Il ressort de cette jurisprudence que, pour que le refus d'une entreprise titulaire d'un droit d'auteur de donner accès à un produit ou à un service indispensable pour exercer une activité déterminée puisse être qualifié d'abusif, il suffit que trois conditions cumulatives soient remplies, à savoir que ce refus fasse obstacle à l'apparition d'un produit nouveau pour lequel il existe une demande potentielle des consommateurs, qu'il soit dépourvu de justification et de nature à exclure toute concurrence sur un marché dérivé.[123]

La Cour a clairement stipulé que l'obligation relative au « marché dérivé » ne concernait pas un marché distinct au regard du droit de la concurrence. Il suffit plutôt que l'on puisse identifier deux stades de production différents et interconnectés dans lesquels le produit en amont représente un élément indispensable pour le produit en aval que le concurrent souhaite produire et fournir. Il apparaît que, dès lors qu'un concurrent a besoin d'accéder à la propriété intellectuelle pour produire un bien, l'obligation du marché dérivé est satisfaite. Les obligations que le refus d'octroi de licence exclue *toute* concurrence et que le tiers doive chercher à fabriquer un nouveau produit constituent des exigences limitant quelque peu la portée potentielle du jugement. Malheureusement, la Cour n'a pas expliqué dans quels cas le refus de licence pouvait se justifier, laissant ainsi sans réponse une question importante.

On peut se demander quels effets ce jugement aura sur les cas survenant dans le secteur des biotechnologies dans l'Union européenne. Il se pourrait bien que, sur des marchés caractérisés par le dynamisme du développement de nouvelles technologies et de nouveaux produits, le refus de licence n'entraînera que rarement l'exclusion de tous les concurrents, d'autant plus si cette exclusion doit se produire sur une durée importante. De plus, on peut estimer que les investissements considérables nécessaires pour mettre au point une technologie brevetée constituent une justification objective à un refus de licence.

À bien des égards, l'obligation de licence est un instrument tentant pour les autorités de la concurrence, notamment lorsqu'elles sont confrontées à une société en position dominante. Garantir l'accès à la propriété intellectuelle peut assurer l'ouverture relativement rapide du marché aux concurrents. et permettre l'innovation ultérieure qui s'était trouvée bloquée par le refus de licence de la société dominante.

Cela étant, contraindre un détenteur de DPI d'octroyer des licences lui retire dans une certaine mesure le contrôle sur son invention qui a été l'une de ses motivations initiales pour inventer. De fait, si le droit de la concurrence empêchait de manière générale les détenteurs de DPI de refuser l'octroi de leurs licences, il proscrirait précisément le même comportement que celui autorisé par les lois sur la propriété intellectuelle et affecterait donc l'incitation à innover.

De plus, si une firme dominante est obligée de concéder des licences sur sa technologie, ses concurrents ne seront plus autant incités à investir pour réaliser des inventions autour du brevet original. Des améliorations qui auraient ainsi pu être faites risquent donc d'être perdues.

L'un des inconvénients majeurs de l'obligation de licence, c'est quelle nécessite au moins une certaine implication des autorités de la concurrence et des tribunaux – ou des deux – dans la définition des conditions de la licence, voire dans la supervision de son exécution dans la pratique. Sans cette implication, le cédant pourrait imposer des conditions équivalant à un refus virtuel de licence. Les autorités de la

concurrence comme les tribunaux pourraient trouver fastidieux d'avoir à s'impliquer immédiatement, puis pendant toute la durée des pratiques d'octroi de licence.[124]

Il est toutefois utile de tenter d'identifier certains types de refus unilatéraux de licence pouvant justifier une intervention. D'emblée, il semble clair qu'aucun refus unilatéral de licence en matière de propriété intellectuelle n'est réputé avoir un effet anticoncurrentiel d'un point de vue juridique sauf si le détenteur du DPI possède une certaine puissance sur le marché. De plus, en raison du risque d'affecter les incitations à innover en limitant le droit des détenteurs de DPI à conserver pour eux-mêmes la propriété intellectuelle, les défenseurs doivent avoir la possibilité de démontrer que leur refus de licence a eu des retombées favorables sur la concurrence.

Une possibilité consiste à cibler les situations où une société refuse sélectivement sa licence à certains concurrents, mais pas à d'autres. Ce comportement ne justifie toutefois pas toujours une intervention des autorités de la concurrence, car le droit de choisir qui exclure est inhérent au brevet. De plus,

> quand il est question de licences de propriété intellectuelle, il existe des raisons encore plus importantes pour les autorités que normalement de ne pas imposer l'obligation de non-discrimination dans le choix des concessionnaires. . . . Si un détenteur de DPI a un jour concédé une licence sur un droit et se voit contraint par là-même de mettre ses licences à la disposition de tous les intervenants dans des conditions largement équivalentes, cela aura pour effet probable de décourager de manière générale l'octroi de licences. Cela reviendrait certainement à interdire les licences exclusives qui constituent le meilleur moyen de tirer le plus grand profit d'un droit de propriété intellectuelle.[125]

Il semble également utile de traiter séparément les situations dans lesquelles le brevet concerne un outil dont la licence a été accordée à un certain nombre de fabricants d'outils de recherche concurrents qui en dépendent ou auquel font appel leurs produits et le détenteur du brevet décide soudain de ne pas renouveler la licence. Il pourrait s'agir du scénario le plus convaincant pour attaquer un refus de licence en vertu du droit de la concurrence. Ce comportement est particulièrement préjudiciable car il encourage les concessionnaires concurrents à absorber les coûts irrécupérables en se fiant à une licence octroyée, puis en ôtant soudain toute valeur à leurs investissements.

Outre les cas dans lesquels il est démontré que la propriété intellectuelle constitue un service essentiel ou bien qui consistent pour la firme à utiliser sa propriété intellectuelle sur un marché pour monopoliser un autre marché, il n'est pas facile de trouver un exemple de refus unilatéral de licence de propriété intellectuelle dont on puisse considérer, de manière générale, qu'il justifie une condamnation, que ce soit du point de vue de la plupart des commentateurs ou en vertu du droit de la concurrence en vigueur dans la plupart des pays,. Une cour d'appel américaine a souligné récemment que dans sa juridiction au moins, il n'existait pas de « cas référencé où un tribunal aurait jugé comme un manquement à la concurrence un refus unilatéral de céder ou de concéder un brevet sous licence ».[126]

Thésaurisation de brevets. Il existe au moins deux types de thésaurisation de brevets. L'un se produit quand une firme obtient des brevets non seulement pour des processus et des produits qu'elle à l'intention d'utiliser et de commercialiser mais également sur un large éventail de processus et de produits concurrentiels qu'elle a l'intention de laisser inexploités afin d'empêcher les autres sociétés de les utiliser légalement. L'objectif est alors d'acquérir ou de protéger une puissance sur le marché. On pourrait appeler cela la « stratégie globale ». Un autre type de thésaurisation de brevets se fait jour quand une firme accumule des brevets qu'elle n'a pas l'intention d'exploiter commercialement, mais que ses concurrents sont susceptibles de contrefaire. L'objectif de cette stratégie est de servir de monnaie d'échange vis-à-vis des concurrents dont elle pourrait déjà contrefaire déjà les brevets et de dissuader l'entrée sur le marché de sociétés ne disposant pas d'un « empilement » de brevets aussi considérable. Cette stratégie peut être appelée « stratégie de détente ».

Ces deux stratégies soulèvent de nombreuses interrogations du point de vue du droit de la concurrence. Elles sont sources d'inefficiences car les firmes dépensent des ressources pour créer des inventions qu'elles n'utilisent pas. De plus, la stratégie globale peut permettre d'acquérir et de protéger la puissance de marché et la stratégie de détente de conforter la position des titulaires de brevets au sein d'un oligopole restreint. Il est intéressant de noter que ces deux stratégies sont plus faciles à mettre en oeuvre et davantage susceptibles d'être jugées nécessaires quand les normes de délivrance des brevets sont les plus souples.

6.3.1 Stratégie globale

Cette stratégie représente un moyen simple d'acquérir ou de préserver la puissance sur le marché et si possible, une position dominante. Il n'est pas aussi simple de déterminer si elle devrait être illégale.[127]

La plupart des pays européens et plusieurs autres pays ont adopté des dispositions législatives et réglementaires en faveur de l'obligation de licence qui pourraient s'appliquer contre une firme ayant recours à une stratégie globale. Dans ces juridictions, si une société ne fait pas usage de son brevet, un tribunal peut l'enjoindre de concéder son brevet sous licence à une personne qui en fera usage.[128]

Un argument en faveur de cette approche est qu'elle ne semble pas engendrer le risque de priver la société des avantages de la technologie inutilisée, puisque cette technologie n'était pas utilisée de toute façon. En fait, elle aurait probablement l'effet inverse. Les titulaires cesseraient de s'abriter derrière des brevets leur assurant certes une protection mais inutilisés, laissant à d'autres le soin de développer et d'utiliser ces technologies, ce qui favoriserait une intensification de la concurrence sur le marché.

En revanche, en remontant un peu plus loin dans le temps du point de vue d'un titulaire, on constate que, si les autorités de la concurrence ont une propension à lutter contre les stratégies globales, elles risquent de décourager l'innovation qui a abouti au produit que l'entreprise *utilise*. Cela peut se produire si une entreprise reconnaît qu'elle ne peut pas construire autour de son invention une muraille de propriété intellectuelle inutilisée qui lui permettrait d'acquérir et de maintenir un monopole. Partant, l'invention initiale a une valeur attendue plus faible.

Ces arguments reposent sur des analyses fondamentalement divergentes des incitations nécessaires pour pénétrer un marché. Le premier argument part du principe que les concurrents estiment qu'il vaut la peine d'entrer sur un marché par le biais de licences ou la mise au point de propriétés intellectuelles concurrentes, même s'il faut pour cela faire concurrence au titulaire des brevets. Le second argument pose l'hypothèse que même le titulaire n'aurait pas fait son entrée sur le marché s'il n'avait pu y détenir un monopole.

Les autorités de la concurrence peuvent évaluer la probabilité d'entrée sur un marché. Elles peuvent raisonnablement décider de ne pas intervenir contre une société qui utilise une stratégie globale si elles estiment que personne ne serait entré sur ce marché de toute façon. Cela laisserait toutefois penser que le titulaire se comporte de façon irrationnelle, puisque si personne n'est susceptible d'entrer sur un marché sauf à y détenir un monopole, pourquoi prendre la peine d'accumuler autant de brevets ?

Un autre aspect est que le titulaire détient déjà un brevet pour l'invention qu'il utilise, ce qui constitue en soi l'incitation que les pouvoirs publics considèrent comme suffisante pour encourager l'innovation. C'est le prix que la société est prête à payer en échange des avantages que présente l'invention. Mais les systèmes de brevets ne sont pas conçus pour garantir des monopoles. Si le brevet en lui-même ne suffit pas à encourager une entreprise donnée à innover, cela ne signifie pas nécessairement que la société doive tolérer une plus grande restriction de la concurrence afin de garantir que le titulaire acquière et maintienne un monopole.

Il n'est cependant pas facile de discerner la solution à ce débat. Par exemple, on peut revenir sur l'argument selon lequel tous les autres disposaient des mêmes chances que le titulaire d'acquérir ces brevets inutilisés et ils ne l'ont pourtant pas fait. En outre, lorsque la Cour suprême des États-Unis a décidé que le refus pur et simple d'un détenteur de brevet de concéder une licence sur ce brevet ne saurait légitimer des poursuites au nom du droit de la concurrence, elle en est arrivée aux mêmes conclusions concernant le refus d'utiliser des brevets.[129] Par conséquent, certaines autorités de la concurrence au moins devront identifier d'autres pratiques anticoncurrentielles avant d'engager des procédures contre des entreprises qui obtiennent des brevets dans le seul but de les remiser.

6.3.2 La stratégie de détente.

Lorsque la plupart des brevets d'un secteur sont entre les mains de quelques entreprises sur un marché à structure oligopolistique, il est possible que, d'un point de vue technique, toutes ces entreprises contrefassent leurs brevets respectifs. Par conséquent, il peut en découler une situation de concession réciproque implicite de licences. Chacune des entreprises renonce à poursuivre les autres pour contrefaçon de crainte que ces dernières n'engagent en représailles des procès en contrefaçon tout aussi légitimes. Ainsi, plutôt que de bouleverser le *statu quo*, les parties peuvent s'entendre tacitement sur la contrefaçon de leurs brevets respectifs tant que personne ne s'en plaint. Les titulaires peuvent également conclure un accord explicite de concession réciproque de licences, mais avant d'ouvrir les négociations, ils n'en voudront pas moins disposer d'une « puissance de feu » en termes de propriété intellectuelle au moins équivalente à celle des autres parties.

Par conséquent, il y a une incitation à obtenir des brevets simplement parce que des concurrents sont susceptibles de les contrefaire.[130] Cohen, Nelson et Walsh ont constaté ce phénomène dans le cadre de leur enquête menée en 2000 auprès de quelque 1 500 directeurs de centres de R-D américains, enquête indiquant que dans les secteurs de produits complexes, les brevets étaient couramment utilisés pour

> … devenir ou rester un concurrent (c'est-à-dire un « acteur ») majeur dans un secteur, souvent par la constitution d'importants portefeuilles… [L]es entreprises n'acquièrent pas des brevets dans le seul but de protéger leur propre technologie, mais aussi pour prendre leurs rivaux en otage en contrôlant une technologie dont ceux-ci ont besoin… La rançon demandée par l'entreprise est soit l'accès formel à une technologie concurrente par le biais d'une concession réciproque de licences, soit au moins la possibilité de mener des travaux similaires à ceux de ses concurrents sans être poursuivie en justice… En conférant un accès non exclusif à un marché dans ces conditions, les brevets sont moins un instrument permettant à une entreprise de percevoir des rentes directement engendrées par ses inventions brevetées (par leur commercialisation ou la concession de licences), qu'un instrument pour s'approprier une partie des rentes oligopolistiques générées par les nouvelles technologies de tous les titulaires.[131]

La stratégie d'accumulation de brevets dont des concurrents ont besoin renforce le *statu quo* au sein d'un oligopole en faisant en sorte qu'une entreprise détienne suffisamment de DPI représentant une menace pour décourager les autres entreprises d'engager des poursuites. Si la facilité avec laquelle on peut obtenir des brevets favorise également le partage de rentes oligopolistiques, les autorités de la concurrence devraient normalement l'examiner, à tout le moins, d'un œil suspicieux. Si, en revanche, la solution de rechange à l'oligopole est un marché dominé seulement par une ou deux entreprises qui ont été capables de respecter des normes de délivrance des brevets strictes, on pourrait préférer le scénario de l'oligopole et de la facilité d'obtention des brevets. Malheureusement, même en cas de souplesse des conditions de délivrance des brevets, du temps et de l'argent sont gaspillés pour l'acquisition de brevets à des fins de marchandage, dans la mesure où ces brevets ne promeuvent pas l'introduction de nouveaux produits qui n'auraient pas été fabriqués sans brevet.

En outre, dans un environnement où les conditions de délivrance des brevets sont souples, des entrants potentiels sont susceptibles d'être quasiment exclus du marché. S'il est probable que ces entrants contrefassent un ou plusieurs brevets détenus par les titulaires, il est moins probable qu'ils arrivent équipés d'une lourde artillerie de propriété intellectuelle leur permettant d'instaurer une stratégie de détente face aux portefeuilles considérables des titulaires. Les entrants peuvent par conséquent avoir le sentiment qu'ils risquent fortement des poursuites, ce qui rend leur entrée sur le marché plus difficile que pour des entreprises qui sont arrivées sur le marché plus tôt et en sont devenues un acteur majeur.

Une autre option peut être de chercher à obtenir les licences nécessaires des titulaires mais, si les entrants doivent ajouter ce coût à ceux projetés et à l'issue incertaine de leurs propres investissements de R-D, ils pourraient considérer cette solution comme irréalisable. En dernier lieu, même si les entrants prennent le risque de supporter le coût supplémentaire lié à l'obtention de licences, ils seraient quand même tenus de partager avec les titulaires les profits supra concurrentiels provenant de leurs innovations, ce qui constitue un facteur dissuasif supplémentaire à l'entrée sur le marché.[132]

On peut être tenté d'ignorer les problèmes posés par la stratégie de détente, du moins sur le segment de la santé publique du secteur biotechnologique, dans la mesure où on n'y a pas observé d'évolution vers une structure de marché oligopolistique. Cela étant, la prolifération de brevets laisse craindre l'émergence d'une telle stratégie.[133]

Les autorités de la concurrence ont-elle le pouvoir ou le devoir d'intervenir dans ces circonstances ? Une possibilité serait de recourir au droit de la concurrence pour permettre aux entrants de se défendre contre des poursuites en contrefaçon lorsque la technologie nécessaire fait déjà l'objet de l'octroi d'une licence (explicitement ou implicitement) entre les principaux concurrents d'un secteur concentré, mais qu'elle n'est pas proposée à des conditions raisonnables à d'autres entreprises. Cette approche suscite néanmoins un débat similaire au précédent concernant la stratégie globale.

7. Conclusion

Idéalement, la politique de concurrence en matière de propriété intellectuelle dans le secteur de la biotechnologie devrait pouvoir s'appuyer sur une conception bien arrêtée de la façon d'attribuer des droits de brevet tout au long du processus allant des recherches initiales au produit fini, de manière à favoriser une création rentable d'innovations utiles mises sur le marché. Ce défi est considérable, non seulement du fait de la complexité du secteur, mais également en raison de la sensibilité des mécanismes d'incitation à l'innovation, qui évoluent souvent dans plus d'une direction en réaction à chaque brevet et changement de la politique de la concurrence. Un renforcement de la protection des brevets et de la liberté d'action pour les inventeurs en amont, par exemple, les encouragerait à innover, mais tendrait également à décourager la R-D en aval.

Par conséquent, lorsqu'elles envisagent des mesures concernant la propriété intellectuelle, le plus sage pour les autorités de la concurrence serait de se concentrer sur des domaines qui a) ne sont pas influencés par l'évolution les incitations évoquées précédemment ou b) présentent un déséquilibre si manifeste que les types d'incitations qui doivent êtres renforcées, même au détriment des autres, apparaissent clairement. Dans la catégorie a), on peut inclure une grande partie des initiatives que les autorités de la concurrence peuvent prendre dans une optique de conseil, comme faire mieux comprendre et appliquer les principes économiques, ou organiser des réunions régulières avec des dirigeants d'offices des brevets afin de discuter de problèmes de politique en matière de propriété intellectuelle et de concurrence.

Un exemple simple de la catégorie b) consiste à poursuivre devant les tribunaux les parties à un accord de contrefaçon de brevet, parce que cet accord fait de deux concurrents fabriquant des outils de recherche les participants à un dispositif d'entente sur les prix. On peut penser que cela aurait pour effet de

réduire les incitations à l'innovation pour les fabricants d'outils en amont, mais comparé au coût d'une tolérance à l'égard des ententes sur les prix et au frein qu'elles représenteraient pour les utilisateurs de ces outils en aval, le bon choix de la politique à adopter est facile à identifier. Un autre exemple dans la catégorie b) consiste à poursuivre devant les tribunaux le cédant d'une licence en position dominante qui cherche à obtenir des redevances dans le cadre d'un contrat de rétrocession sur tous les articles produits en aval par le détenteur de la licence, alors qu'il est relativement facile de déterminer quels articles en aval utilisent ou non la technologie du cédant.

Les autorités de la concurrence auront inévitablement à traiter des cas intermédiaires où la marche à suivre n'est pas aussi évidente. Dans ces cas, il est probablement préférable de pêcher par excès de prudence et d'éviter d'intervenir en raison de l'ampleur du préjudice causé à long terme par une réduction involontaire des incitations à innover.

NOTES

1. Un gène contient des informations héréditaires encodées sous forme d'acide désoxyribonucléique (ADN) et il est situé à un emplacement spécifique d'un chromosome dans le noyau d'une cellule.

2. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

3. Rapport de l'OCDE aux ministres, *Patents and Innovation: Trends and Policy Challenges* (2004), pp. 11-13, 22.

4. Un génome est l'ensemble complet de l'ADN d'une cellule ou d'un organisme.

5. Voir notamment le site web de Geron Corporation at www.geron.com/.

6. Rapport de l'OCDE aux ministres, *Patents and Innovation: Trends and Policy Challenges* (2004), p. 22 ; Ronald Hirshhorn and Jock Langford, *Intellectual Property Rights in Biotechnology: The Economic Argument*, document préparé pour le Comité consultatif canadien de la biotechnologie sur la propriété intellectuelle en biotechnologie et le brevetage des formes de vie supérieures, (2001), disponible à l'adresse http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/vwapj/IPPHL_integrated_summary_f.pdf/$FILE/IPPHL_integrated_summary_f.pdf, pp. 18-19.

7. Japanese Fair Trade Commission, *Guidelines for Patent and Know-how Licensing Agreements under the Antimonopoly Act* (30 juillet 1999), disponible à l'adresse http://www2.jftc.go.jp/e-page/guideli/patent99.htm (ci-après, les "Lignes directrices japonaises") ; United States Department of Justice and Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* § 2.0 (6 avril 1995), disponible à www.usdoj.gov/atr/public/guidelines/ipguide.htm (ci-après, les "Lignes directrices américaines") ; Communications de la Commission, Lignes directrices relatives à l'application de l'article 81 du traité CE aux accords de transfert de technologie, JO C101/2 (2004) (ci-après, les "Lignes directrices de la Commission ").

8. Frank H. Easterbrook, "Ignorance and Antitrust," in Antitrust, Innovation, & Competitiveness 82, 122-23 (Thomas M. Jorde & David J. Teece, eds. 1992); *accord* F.M. Scherer & David Ross, Industrial Market Structure and Economic Performance 613 (3d ed. 1990).

9. Edmund Kitch, *Elementary and Persistent Errors in the Economic Analysis of Intellectual Property*, 53 Vanderbilt Law Review 1727, 1729-38 (2000).

10. Lignes directrices américaines, § 2.0 (1995).

11. Rebecca S. Eisenberg, *Reaching Through the Genome*, 50 Advances in Genetics, pp. 210, 211 (2003).

12. *Id*. p. 212.

13. *Id*. p. 218.

14. OCDE, *Genetic Inventions, Intellectual Property Rights and Licensing Practices* (2002), en anglais uniquement, pp. 38, 65.

15. *Voir* FTC Report (2003), Chap. 1, p. 34 (un membre du groupe a noté que le temps dont dispose les examinateurs de brevets aux États-Unis était « de toute évidence inadapté compte tenu de la complexité et de la difficulté des brevets biotechnologiques »).

16. OCDE, *An Overview of Biotechnology Statistics in Selected Countries* (Document de travail de la DSTI 2003/13), DSTI/DOC (2003)13, en anglais uniquement, p. 21.

17. OCDE, *Genetic Inventions, Intellectual Property Rights and Licensing Practices* (2002), pp. 33-38.

18. OCDE, *An Overview of Biotechnology Statistics in Selected Countries* (STI Document de travail de la DSTI 2003/13), DSTI/DOC (2003)13, en anglais uniquement, p. 19.

19. *Id*. p. 39.

20. *Id*. p. 69.

21. Joshua Gans, David Hsu & Scott Stern, *When Does Start-Up Innovation Spur the Gale of Creative Destruction?*, 33 Rand Journal of Economics (2002) (les brevets sont relativement plus efficaces pour protéger les DPI dans le secteur des biotechnologies que dans d'autres secteurs); F.M. Scherer, *The Economics of Human Gene Patents*, 77 Academic Medicine 1348, 1353-54 (2002) (qui note que les éléments disponibles ne vont pas tous dans le même sens, mais conclut que « pour que les investissements en vue du développement de nouvelles thérapies pharmaceutiques ou biologiques, il semble clair que disposer de la protection d'un brevet est la plupart du temps assez important. »). Les brevets jouent un rôle inhabituellement prédominant dans l'innovation pharmaceutique. *Voir* Wesley M. Cohen, Richard R. Nelson & John P. Walsh, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not), National Bureau of Economic Research*, Working Paper No. 7552 (2000) (qui conclut que les brevets sont particulièrement importants pour l'innovation dans le secteur pharmaceutique) ; Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 Management Science 173 (1986) (qui observe que l'absence de protection par les brevets n'aurait eu que peu ou pas d'effet sur l'innovation pour la plupart des entreprises de la plupart des secteurs à l'exception de la pharmacie).

22. Dans de nombreux secteurs, les sociétés attribuent un rang modeste aux brevets dans la liste des facteurs dont elles tiennent compte lorsqu'elles décident d'investir dans la R-D. Les sociétés ont tendance à penser que d'autres mesures, comme maintenir le secret sur leurs travaux et s'efforcer de tirer un net avantage d'être le ^premier à prendre l'initiative, sont plus efficaces que les brevets pour protéger les bénéfices que l'on peut tirer des inventions. Cohen, Nelson & Walsh (2000) pp. 1-2 & note 2.

23. OCDE, *An Overview of Biotechnology Statistics in Selected Countries* (Document de travail de la DSTI 2003/13), DSTI/DOC (2003)13, en anglais uniquement, p. 28.

24. United States Department of Commerce, *A Survey of the Use of Biotechnology in U.S. Industry* (October 2003), disponible à l'adresse http://www.technology.gov/reports

25. FTC Report (2003), Chap. 3, p. 16.

26. Joshua Gans, David Hsu & Scott Stern, *When Does Start-Up Innovation Spur the Gale of Creative Destruction?*, 33 Rand Journal of Economics (2002); OECD, *Genetic Inventions, Intellectual Property Rights and Licensing Practices*, (2002) at 47; F.M. Scherer, *The Economics of Human Gene Patents*, 77 Academic Medicine 1348, 1353-54 (2002).

27. OCDE, *Biological Resource Centers: Underpinning the Future of Life Sciences and Biotechnology* (2001).

28. Francis Collins, *et al.*, *A Vision for the Future of Genomics Research: A Blueprint for the Genomic Era*, 422 Nature 835 (24 avril 2003).

29. OCDE, Rapport aux ministres, *Patents and Innovation: Trends and Policy Challenges* (2004), p. 8, 23 ; FTC Report (2003), Chap. 2, 3.

30. FTC Report, Chap. 4, pp. 6-8.

31. Bien entendu, si des normes de **délivrance des brevets** laxistes permettent facilement non seulement d'obtenir un brevet original dans un domaine donnaée, mais aussi d'obtenir des brevets ultérieurs dont on peut dire qu'ils empiètent sur le champ d'application du brevet original, ces effets peuvent être compensées et les inventeurs ultérieurs peuvent être enhardis. La question de savoir quels seront les effets produits dépende de celle de la soupklesse relative des normes de **délivrance des brevets** (nouveauté, non-évidence et utilité).

32. *Voir* Partie IV.B. à propos du « blocage par les biens privatifs ».

33. Josh Lerner, *Patenting in the Shadow of Competitors*, 38 Journal of Law and Economics 463, 465, 489-490 (1995) (le coût des procès décourage les sociétés biotechnologiques de prendre des brevets dans des domaines dans lesquels leurs rivales en détiennent déjà).

34. La manipulation génétique est une technique qui consiste à attacher un gène à un autre fragment d'ADN pour créer une nouvelle mollécule. Elle sert souvent à introduire l'ADN d'un organisme dans un autre, ce qui aboutit à un micro-organisme ou une cellule génétiquement modifié ou un animal « transgénique ».

35. Eisenberg (2003), at 219.

36. OCDE, *Genetic Inventions, Intellectual Property Rights and Licensing Practices* (2002), p. 13.

37. *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 916-919, 927 (Fed. Cir. 2004).

38. Office européen des brevets, Japan Patent Office, et United States Patent and Trademark Office, Trilateral Project B3b, Mutual understanding in search and examination, Report on Comparative study on biotechnology patent practices (2001), available at www.jpo.go.jp/saikine/tws/report/B3b_report_pdf/B3b_reachthrough_text.pdf ; toutes ces études sont disponibles sur le site www.jpo.go.jp/saikine/tws/sr-3.htm.

39. *Voir* U.S. Patent and Trademark Office, *Utility Examination Guidelines* (2001), disponible à l'adresse www.uspto.gov/web/offices/com/sol/notices/utilexmguide.pdf

40. Joseph J. Spengler, *Vertical Integration and Antitrust Policy*, 58 Journal of Political Economy 357 (1950); Carl Shapiro, *Navigating the Patent Thicket*, in 1 Innovation Policy and the Economy 119, 123, 149 (Adam Jaffe, Josh Lerner, Scott Stern, eds., 2001).

41. Michael A. Heller and Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 Science 698 (1998).

42. Les comptes rendus sont disponibles à l'adresse www.ftc.gov/opp/intellect/. Les auditions se sont déroulées sur 24 jours en 2002. Plus de 300 panélistes, dont des représentants du secteur des entreprises, des inventeurs indépendants, des professionnels de premier plan dans les domaines de la concurrence et des brevets, ainsi que des universitaires de renom, y ont participé.

43. OCDE, *Genetic Inventions, Intellectual Property Rights and Licensing Practices* (2002, en anglais uniquement), pp. 47, 51.

44. *Id.* p. 47.

45. John P. Walsh, Ashish Arora, & Wesley M. Cohen, *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, in Patents in the knowledge-based Economy (Wesley M. Cohen and Stephen A. Merrill, ed. 2003), pp. 285-286.

46. *Id*. p. 286.

47. Richard Epstein, *Steady the Course: Property Rights in Genetic Material*, John M. Olin Law & Economics Working Paper, No. 152, The Law School of the University of Chicago (2003), p. 19, disponible sur www.law.uchicago.edu/Lawecon/index.html.

48. L'exemption a été votée en 1909. Katsuya Tamai a fait valoir, du moins à cette époque, que l'exemption de l'utilisation expérimentale était parfaitement justifiée. Au début des années 1900, le Japon était encore un pays en développement. Il devait être en mesure de procéder à des études rétrotechniques des inventions brevetées sans crainte d'une action en justice, pour pouvoir les utiliser afin de développer de nouvelles technologies. Katsuya Tamai, *The Experimental Use Exception: A Japanese Perspective*, Symposium, Reconciling Competing Interests in Intellectual Property, University of Washington Center for Advanced Study and Research on Intellectual Property (juillet 2002), disponible sur www.law.washington.edu/casrip/. Ce raisonnement tend à montrer que l'exemption n'est peut-être plus nécessaire dans le Japon d'aujourd'hui.

49. *Madey v. Duke University*, 307 F.3d 1351, 1362 (Fed. Cir. 2002).

50. *Id*.

51. Heinz Goddar, *The Experimental Use Exception: A European Perspective*, Symposium, Reconciling Competing Interests in Intellectual Property, University of Washington Center for Advanced Study and Research on Intellectual Property (juillet 2002), disponible sur http://www.law.washington.edu/casrip/

52. *Voir Clinical Trials I*, 130 BGHZ 259, 1996 GRUR 109, 1997 IIC 103, 1997 RPC 623 (1995) (l'utilisation d'un médicament breveté dans des expériences, y compris des essais cliniques, dans l'intention de trouver des indications autres que celle qui est brevetée, ne constitue pas une contrefaçon du brevet) ; *Clinical Trials II*, 135 BGHZ 217, 1997 NJW 3092, 1998 RPC 423, *affirmed*, GRUR 2001 p. 43 *et seq*. (2001) (les essais cliniques sont autorisés lorsqu'ils visent à obtenir des données nécessaires pour l'agrément d'un produit à des fins d'utilisation clinique, même s'il s'agit de la même indication que celle du produit breveté).

53. Aux États-Unis, par exemple, les concurrents n'ont pas le droit de demander à un tribunal d'annuler un brevet, à moins que le titulaire du brevet ne les ait menacés d'entamer des poursuites. Cette règle accroît le risque d'entrée sur des marchés protégés par des brevets, le détenteur des DPI pouvant attendre que le nouveau venu ait assumé les coûts irréversibles nécessaires pour prendre pied sur le marché avant d'intenter un procès en contrefaçon. En revanche, cette règle présente l'avantage de réduire les occasions, pour les concurrents, de harceler les détenteurs de DPI par des tracasseries judiciaires.

54. FTC Report (2003), Ch. 3, III.

55. Dans un groupement de brevets, plusieurs parties s'accordent pour mettre leurs brevets en commun, ce qui facilite l'octroi de licences, aux parties elles-mêmes ou à des tiers, de toutes les technologies nécessaires pour développer de nouveaux produits. Voir la Partie VI.B.1. pour plus de précisions sur les groupements de brevets.

56. Cela s'est produit pour deux gènes brevetés par Myriad Genetics, BRCA1 et BRCA2. Les femmes porteuses d'une mutation de BRCA1 ou BRCA2 ont sept fois plus de risques de développer un cancer du sein que celles dont les gènes BRCA1 et BRCA2 sont normaux. Myriad détient les droits exclusifs des tests de diagnostic pour les mutations de BRCA1 et BRCA2. Ses concurrents ne peuvent pas inventer

légalement autour du brevet de Myriad, car tous les tests qu'ils sont susceptibles de créer porteraient nécessairement sur le gène breveté.

57. OCDE, *Genetic Inventions, Intellectual Property Rights and Licensing Practices* (2002), p. 47.

58. *Voir* le site web du SNPC, sur http://snp.cshl.org/about/ ; *voir aussi* le communiqué de presse de Wellcome Trust en date du 15 avril 1999 concernant le SNPC, à l'adresse http://www.wellcome.ac.uk/en/1/awtprerel0499n123.html

59. Communiqué de presse de Wellcome Trust (15 avril 1999), à l'adresse http://www.wellcome.ac.uk/en/1/awtprerel0499n123.html

60. United States Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003), ci-après, le « Rapport de la FTC ». Ce rapport se fonde sur des auditions conjointes réalisées en 2002 par la FTC et le DOJ sur 24 jours.

61. Rapport de la FTC, chapitre 5, p. 1 et note 2 (sachant que la plupart des demandes de brevet impliquent des revendications de portée économique restreinte et que, de fait, seul un faible pourcentage des brevets aboutit à une commercialisation).

62. Voir Mark Lemley, *Rational Ignorance in the Patent Office*, 95 Northwestern University Law Review 1495 (2001). M. Lemley estime qu'il n'est pas utile que l'office des brevets examine dans le détail chaque demande de brevet car, dans leur grande majorité, ces brevets ne sont jamais invoqués à l'encontre de concurrents. Du point de vue de la société, il est bien plus efficace que les tribunaux ne déterminent précisément la validité de brevets que dans les rares cas où il est nécessaire de faire valoir les droits attachés à un brevet face à des concurrents. Si le raisonnement de M. Lemley est correct et que les offices des brevets ne doivent pas examiner les brevets dans le détail, il n'y aurait, à plus forte raison, aucun intérêt à ce que les autorités de la concurrence le fassent.

63. Eisenberg (2003), pp. 218-219 et note 37 (sachant qu'il est courant que les inventions pionnières sur de nouveaux marchés obtiennent des brevets très étendus, car la principale contrainte qui pèse sur l'étendue des revendications liées au brevet est l'état antérieur de la technique dans le domaine concerné).

64. *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 511 (1917). *Voir également Sony Corp. of America v. Universal City Studios, Inc.*, 464 U.S. 417, 429 (1984) (« les privilèges de monopole susceptibles d'être octroyés par le Congrès ne sont ni illimités, ni conçus en premier lieu pour assurer un avantage privé particulier. L'octroi restreint de tels privilèges vise plutôt à atteindre un objectif d'intérêt public important. Il est censé motiver l'activité créative d'auteurs et d'inventeurs en leur assurant une rémunération spéciale et permettre au grand public d'accéder au produit de leur inventivité après expiration d'une période limitée de contrôle exclusif. »)

65. *Voir* Japan Fair Trade Commission, Guidelines for Patent and Know-how Licensing Agreements under the Antimonopoly Act (1999), p 1 ; Règlement (CE) N° 772/2004 concernant l'application de l'article 81, paragraphe 3, du traité à des catégories d'accords de transfert de technologie (également appelé Règlement d'exemption par catégorie en faveur du transfert de technologie, ci-après le « Règlement ECTT »), JO L 123/11 (2004), considérant (5).

66. Il convient toutefois de noter qu'aux termes des Lignes directrices américaines et du Règlement ECTT, les parties qui sont dans cette situation continueraient d'être considérées comme des concurrents aux fins de l'analyse de l'accord. Lignes directrices américaines § 3.3, p. 2; Règlement ECTT Article 1(1)(j), ainsi que les Articles 3(1) et 4(1).

67. Règlement ECTT, considérant (4). *Voir* Article 3 du Règlement ECTT (qui prévoit, dans le cas d'un accord de licence vertical, un relèvement du seuil de part de marché qui conditionne l'exemption). *Voir aussi* l'Article 4(1) du Règlement ECTT (les restrictions prohibées dans le cadre d'accords de licences conclus

entre concurrents) et l'Article 4(2) (les dispositions prohibées dans le cadre d'accords de licence verticaux). Les Lignes directrices européennes analysent plus en détail la distinction entre entreprises concurrentes et non concurrentes pp 26-33.

68. Lignes directrices américaines, § 3.3 (1995).

69. La concession réciproque de licences correspond à une généralisation du groupement de brevets fermé, dans le cadre duquel deux entreprises s'autorisent mutuellement à utiliser certaines technologies en respectant ce qui est, fondamentalement, un accord de réciprocité. Les questions soulevées en termes de concurrence par les accords de concession réciproque de licences sont similaires à celles analysées dans le texte en relation avec les groupements de brevets. Afin de limiter le volume du présent document, on se concentrera sur les groupements de brevets.

70. USPTO, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* (2000). *Voir également* Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, *in* 1 Innovation Policy and the Economy (A. Jaffe, *et al*. eds., 2001) ; Rapport de la FTC (2003), chapitre 3, pp. 27-28.

71. OCDE, *Genetic Inventions, Intellectual Property Rights and Licensing Practices* (2002), p. 48. Il est intéressant de constater qu'une association professionnelle du secteur biotechnologique s'est montrée particulièrement favorable aux groupements de brevets dans une contribution présentée devant la FTC et le DOJ. Rapport de la FTC, chapitre 3, p. 27.

72. On a constaté, par exemple, que l'absence de relations à long terme entre les entreprises et le manque d'homogénéité des intérêts des détenteurs de brevets diminuent la probabilité de création d'un groupement de brevets. Les incertitudes concernant la validité et l'étendue de brevets, ainsi que les problèmes d'évaluation, sont apparus comme des facteurs de nature à freiner la formation de groupements de brevets. *Voir par exemple* Arti K. Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 Northwestern University Law Review 77 (1999) ; *Comment: Evaluating the Use of Patent Pools For Biotechnology: A Refutation to the USPTO White Paper Concerning Biotechnology Patent Pools*, 19 Santa Clara Computer & High Tech. Law Journal 229 (2002).

73. Les Lignes directrices américaines, §5.5.

74. *Voir, par exemple*, U.S. Federal Trade Commission, *Summit Technology, Inc. and VISX, Inc*., communiqué de presse, 24 mars 1998, disponible sur http://www.ftc.gov/opa/1998/9803/eye.htm (annonçant une action exécutoire concernant un accord de concession réciproque de licences, l'accord faisant intervenir des technologies de substitution et ayant été conçu pour supprimer la concurrence entre les détenteurs de droits).

75. Le règlement ECTT ne porte pas sur les groupements de brevets. *Voir* Lignes directrices européennes §41.

76. Lignes directrices européennes §219.

77. Lignes directrices européennes §222.

78. Intégration de technologies complémentaires, réduction des coûts de transaction, élimination des positions de blocage et absence de coûteux litiges pour contrefaçon.

79. Les effets anticoncurrentiels des groupements de brevets sont considérés comme improbables sauf si l'accès à la technologie mise en commun dans le groupement est nécessaire pour être concurrentiel sur le marché en aval et si les membres du groupement possèdent collectivement une puissance commerciale sur le marché en aval. Dans ces circonstances, il convient de vérifier si les restrictions portant sur l'adhésion au groupement sont raisonnablement liées au développement et à l'exploitation efficients de la technologie mise en commun dans le groupement. De même, dans le cadre de l'examen des effets des rétrocessions de

licence, les lignes directrices européennes expliquent que la condition de rétrocéder pour un coût minimal les produits développés peut être préjudiciable à l'incitation à innover, mais aussi avoir pour effet de favoriser la concurrence. L'apparition d'effets anticoncurrentiels n'est probable que si les clauses de rétrocession portent sur un important segment de la recherche-développement potentielle sur un marché d'innovation. Lignes directrices américaines, art. 5.5.

80. Les Business Review Letters exposent l'intention actuelle du DOJ de ne pas engager d'action exécutoire contre les pratiques commerciales proposées exposées dans la demande de lettre d'intention (review letter), eu égard aux observations présentées et aux assurances données par le demandeur.

81. MPEG LA Business Review Letter (26 juin 1997) ; DVD 3C Business Review Letter (16 décembre 1998) ; DVD 6C Business Review Letter (10 juin 1999).

82. Notons, toutefois, que les Business Review Letters concernaient les groupements de brevets constitués en vue de créer des normes sectorielles, ce qui a pu justifier la condition d'accès non discriminatoire. Les lignes directrices américaines suggèrent que l'accès universel à la technologie mise en commun dans un groupement n'est pas nécessaire en soi pour chaque accord de groupement de brevets.

83. La liste s'inspire de Howard Morse, *Cross Licensing and Patent Pools, Legal Framework and Practical Issues*, 3 Antitrust and Intellectual Property 42 (2002).

84. DVD 6C Business Review Letter.

85. MPGE LA Business Review Letter.

86. Le rôle permanent de l'expert indépendant consistant à évaluer le caractère essentiel du brevet garantit très efficacement que les brevets en portefeuille sont des compléments et non des substituts. Les clauses correspondantes de l'Agreement Among Licensors [Accord entre cédants] semblent bien destinées à assurer que l'expert sera convoqué dès lors que se pose légitimement la question de savoir si un brevet donné fait ou non partie du portefeuille ; elle semble notamment destinée à limiter la probabilité d'une entente des cédants pour conserver en portefeuille des brevets qui ne sont pas valides ou essentiels ou pour proscrire l'admission au sein du portefeuille d'autres brevets essentiels. MPEG LA Business Review Letter.

87. Le présupposé fondamental que les brevets destinés à faire l'objet d'une licence au sein d'un groupement doivent être valides, peut constituer un autre problème important de respect du droit, pour les groupements de brevets biotechnologiques. Comme nous l'avons vu plus haut, il peut exister dans certains cas des incertitudes considérables quant à la validité des brevets biotechnologiques. L'un des commentateurs a demandé si le fait de rejoindre un groupement de brevets en supposant raisonnablement et de bonne foi que les brevets regroupés sont valides était suffisant pour protéger le groupement contre les risques de recours au titre du droit de la concurrence. Morse, *supra*, note 83. Il peut être aussi particulièrement important pour les groupements de brevets biotechnologiques de garantir que le groupement n'est pas utilisé aux fins de protéger les brevets non valides contre d'éventuelles contestations. Une clé de répartition des redevances peut être utilisé en vue d'inciter les autres cédants à exclure les brevets non valides. Il peut également être important de faire en sorte que les concessionnaires soient constamment incités à remettre en cause les brevets non valides, en autorisant, par exemple, une diminution des redevances dès lors qu'un brevet du groupement se révèle non valide. Les conditions prévues dans les lignes directrices européennes relatives aux clauses de non-contestation tentent de la même manière de préserver l'incitation des concessionnaires à remettre en cause les brevets non valides au sein du groupement.

88. Il peut très bien se trouver cependant que dans des cas réels, on aboutisse au même résultat, qu'il s'agisse des lignes directrices européennes ou des lignes directrices américaines. Les Business Review Letters du DOJ concernaient les groupements de brevets visant à établir des normes pour l'ensemble d'un secteur. Pour leur part, les lignes directrices européennes indiquent que, lorsque le groupement de brevets détient une position significative sur un marché pertinent, la Commission s'inquiétera des effets d'éviction

résultant de l'inclusion de brevets pour lesquels existent des brevets de substitution en dehors du groupement.

89. Josh Lerner & Jean Tirole, *Efficient Patent Pools*, American Economic Review, 94, 98 (juin 2004) ; Morse, *supra*, note 83 p. 399.

90. Supposons autrement que l'accord de revendication sur les inventions futures permette au concessionnaire d'utiliser une technologie donnée, et que celui-ci veuille utiliser cette technologie pour une part de sa production. Supposons encore qu'il existe pour cette technologie plusieurs produits concurrents qui ne soient pas des contrefaçons et que le concessionnaire souhaite les utiliser pour d'autres parties de sa production. Dans ce cas, l'accord de revendication sur les inventions ultérieures peut s'apparenter à un accord d'exclusivité si le concessionnaire doit verser au cédant des redevances sur chaque unité produite quelle que soit la technologie vraiment utilisée par lui. Le seul choix sensé pour le concessionnaire est d'utiliser la technologie du cédant soit pour toutes les parties de sa production soit pour aucune. Si le concédant est suffisamment dominant, utiliser sa technologie pour 100 % de la production peut être le seul choix viable. Pour déterminer si un accord d'exclusivité a un effet préjudiciable sur la concurrence, l'autorité compétente doit analyser des facteurs comme la puissance sur le marché de la partie qui l'impose, le degré d'éviction et la durée de l'accord.

91. Règlement ECTT, article 2(1).

92. Si les parties peuvent suffisamment identifier un produit contractuel, le Règlement ECTT s'appliquerait à un accord de licence prévoyant des redevances sur des inventions ultérieures entre parties non-concurrentes à condition que leurs parts de marché n'excèdent pas 30 %. Dans les accords conclus entre concurrents, les redevances calculées sur la base des recettes générées par les produits n'incorporant pas la technologie sous licence sont considérées interdites en vertu du Règlement ECTT. Lignes directrices européennes, §157.

93. *E.g.*, *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 135 (1969).

94. *Engel Industries, Inc. v. Lockformer Company*, 96 F.3d 1398, 1408 (Fed. Cir. 1996) ; *Bayer AG v. Housey Pharmaceuticals, Inc.*, 228 F. Supp.2d 467 (D. Del. 2002).

95. Lignes directrices américaines, art. 4.1.2 (1995).

96. Lignes directrices européennes, §160.

97. Lignes directrices européennes, §81.

98. Lignes directrices JFTC, chapitre 4(3)(2)(a).

99. Eisenberg (2003), p. 215.

100. *Id.*

101. *Id*. sous 214.

102. *Voir* Partie IV.C.

103. Herbert Hovenkamp, Mark D. Janis & Mark A. Lemley, IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law s. 25.2 au point 25-2 (2004).

104. Les lignes directrices donnent à penser que les rétrocessions et les cessions de technologie non exclusives ne seraient pas considérées comme une restriction de la concurrence et que, en toute circonstance, elles tireraient un bon parti du Règlement. Les rétrocessions et les cessions portant en principe sur la technologie

non séparable ne sont jamais considérées comme des restrictions de la concurrence. *Voir* Lignes directrices, §109.

105. Lignes directrices européennes, §110.

106. Lignes directrices de la JFTC, Partie 4(3)(5)(b).

107. Techniquement, les lignes directrices précisent que les effets anticoncurrentiels sont peu probables à moins que le cédant de la licence soit en position de force sur un marché de technologie ou d'innovation. Les « marchés de technologie » se composent de la propriété intellectuelle en question (par exemple la technologie sous licence) et ses proches produits de substitution — à savoir, les technologies ou les biens qui constituent des produits de substitution suffisamment proches pour limiter la position de force sur le marché au regard de la propriété intellectuelle en question. § 3.2.2. Un « marché d'innovation » est constitué par la recherche-développement pour produire une nouvelle propriété intellectuelle. § 3.2.3.

108. Eisenberg note l'exemple du Projet sur le génome humain financé par des fonds publics aux États-Unis, dans le cadre duquel les travaux nécessaires pour achever la séquence du génome humain étaient déjà bien avancés quand une société privée a entamé une course contre les pouvoirs publics jusqu'à la ligne d'arrivée. Le fait qu'une société privée consacre des ressources à un projet déjà sponsorisé par les pouvoirs publics, au lieu de se contenter d'accepter le don en amont et d'utiliser ses ressources pour des tentatives en aval, donne à penser que la recherche en amont a bénéficié de trop de contributions financières. Eisenberg (2003), pp. 227-228.

109. *Id*. pp. 228-29.

110. Article 4(1)(a)&(2)(a).

111. Lignes directrices européennes, §75.

112. Article 3(1).

113. Partie 1.3.(1).

114. § 5.2.

115. § 5.2.

116. En revanche, on peut facilement concevoir que ce type d'accord de licence puisse être une entente déguisée sur les prix. Imaginons qu'une Société A, qui détient une technologie brevetée pour laquelle il n'existe pour l'instant pas de concurrent, apprenne que la Société B envisage de lancer un produit concurrentiel qui ne soit pas une contrefaçon. Plutôt que de livrer concurrence au nouveau produit de B, A décide de maintenir des bénéfices supérieurs à ceux qui seraient proposés sur un marché concurrentiel, en partageant le marché avec B. Elle persuade B de renoncer au développement de son produit et de prendre à la place une licence pour la technologie de A. La licence contrôle le prix que B peut facturer pour le produit qu'il va maintenant lancer en utilisant la technologie de A. Ce prix est égal au prix que A facture actuellement pour son produit, autrement dit un prix de monopole. L'accord de licence est donc une mascarade pour une entente sur le partage d'un marché et sur les prix.

117. *Brulotte v. Thys*, 379 U.S. 29 (1964).

118. *Voir Bayer AG v. Housey Pharmaceuticals*, 228 F. Supp.2d 467 (D. Del. 2002). Dans ce cas, le tribunal a déclaré que le fait que le défendeur prélève des droits après expiration en fonction des ventes d'un médicament après expiration du brevet pour compenser l'utilisation, avant expiration du brevet, d'un outil

de recherche pour la découverte de médicaments, ne constituait pas une utilisation abusive de brevet. En d'autres termes, le tribunal a soutenu un type d'accord sur les droits relatifs à des inventions ultérieures.

119. *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 US 405, 426-30 (1908).

120. *Voir. par ex. American Cyanamid*, 72 F.T.C. 623, 684-85 (1967), *aff'd sub. nom. Charles Pfizer & Co.*, 401 F.2d 574 (6th Cir. 1968), *cert. denied*, 394 US 920 (1969) (brevets acquis par des pratiques déloyales) ; *Dell Computer Corp.*, 5 Trade Reg. Rep. (CCH) §24,054 (20 mai 1996) (le détenteur du brevet a acquis une puissance sur le marché en refusant, alors qu'il avait été explicitement enjoint de le faire, de divulguer un brevet contrôlant, à l'échelle du secteur, une norme qui n'aurait pas été adoptée si le brevet avait été divulgué).

121. Selon une décision récente de la Cour Suprême américaine, tout porte à croire que ce principe va perdurer. L'affaire *Verizon Communications v. Law Offices of Curtis Trinko* comporte un refus d'octroyer l'accès en dehors du contexte de la propriété intellectuelle, mais les termes employés sont si véhéments qu'elle aura nécessairement des implications sur le refus unilatéral de licence en matière de propriété intellectuelle. 124 S. Ct. 872 (2004). *Trinko* allègue que Verizon a bloqué l'accès d'un concurrent à la boucle locale de téléphonie de Verizon et aux équipements annexes. Le Tribunal a statué en faveur de Verizon, indiquant que les sociétés peuvent acquérir un pouvoir de monopole en constituant une infrastructure grâce à laquelle ils deviennent les seuls à pouvoir servir leurs clients. Contraindre ces sociétés à partager la source de leur avantage est en quelque sorte contradictoire avec la finalité sous-jacente du droit de la concurrence, dans la mesure où cela peut contribuer à dissuader la société en situation de monopole, son concurrent, ou les deux, à investir dans des équipements économiquement bénéfiques.

Id. p. 879. Le tribunal a donc conclu qu'il valait mieux préserver l'incitation à investir que d'exiger l'accès au marché pour favoriser la concurrence. Ce raisonnement s'appliquerait certainement avec d'autant plus de force en matière de propriété intellectuelle, le détenteur d'un brevet disposant d'un droit d'exclusion en vertu de la loi.

122. *Magill*, C-241/91 P (E.C.J. 1995).

123. Cas C-418/01, *IMS Health Care GmbH & Co. KG v. NDC Health GmbH & Co. KG*, Jugement du 29 avril 2004, ¶38.

124. Pour un examen assez approfondi des difficultés d'application et de supervision des recours portant sur l'obligation de licence, voir Richard Epstein, *Steady the Course: Property Rights in Genetic Material*, John M. Olin Law & Economics Working Paper, No. 152, The Law School of the University of Chicago (2003), pp. 29-34, disponible sur www.law.uchicago.edu/Lawecon/index.html ; *voir aussi Verizon Communications v. Law Offices of Curtis Trinko*, 124 S. Ct. 872, 879 (2004) (d'où il ressort que, pour imposer l'obligation d'accorder l'accès à, ou d'entretenir des relations commerciales avec, d'autres sociétés, les tribunaux devraient « agir en planificateurs centraux, en identifiant le juste prix, la quantité et d'autres conditions de la transaction – rôle qui ne leur correspond pas »).

125. *Voir* Hovenkamp, Janis & Lemley (2004), s. 13.2c pp. 13-7, 13-8.

126. *In re Independent Service Organizations Antitrust Litigation*, 203 F.3d 1322, 1326 (Fed. Cir. 2000).

127. En fait, le cas n'est pas simple quand la société utilise sa propre recherche pour mettre en oeuvre une stratégie globale. Si, en revanche, elle cherche à créer une muraille protectrice de brevets au moyen d'acquisitions, il est bien plus facile de conclure que cette pratique devrait être illégale.

128. *Voir par ex.*, Loi sur la concurrence, s. 32 (Canada) ; Loi sur les brevets 1999, s. 93 (Japon) ; Patents Act 1990 (Cth) [Loi sur les brevets 1990 (Commonwealth)], ss. 133, 163-167 (Australie) ; Patents Act 1977 [Loi sur les brevets 1977], ss. 48A, 48B (Royaume-Uni.).

129. *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 US 405, 426-30 (1908).

130. *Voir* Cohen, Nelson & Walsh (2000), pp. 19, 22, 25, 26.

131. *Id*. pp. 25, 26.

132. Cela étant, certains universitaires trouvent intéressante l'idée de limiter l'entrée dans des secteurs où de nombreuses entreprises détiennent des éléments brevetés d'une technologie commercialisable. Selon eux, parallèlement à l'augmentation du nombre d'entreprises dans ces secteurs, il devient de moins en moins probable qu'un produit soit commercialisé, car on assiste à une multiplication des cas d'accumulation de droits de licence atteignant un montant prohibitif, et de négociations avortées. Heller et Eisenberg (1998) ; Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and Patent Law*, 5 Journal of Economic Perspectives 29 (1991) ; Robert P. Merges et Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 Columbia Law Review pp. 839, 860-861 (1990).

133. Rapport de la FTC (2003), chapitre 2, p. 30 note 208 (d'après la déposition du Professeur John Barton).

ARGENTINA

1. The proper role of Competition Agencies in the patent process

- *For example, should competition agencies be involved in decisions concerning whether to award a patent, or concerning how to phrase the patent?*

No

- *Should competition authorities be allowed to challenge the validity of questionable patents that have already been granted?*

Yes, because they are the ones who may be involved in problems concerning overlapping of patents and their competition conflicts.

- *How can competition agencies, whose primary expertise is not in IP, effectively determine the scope and assess the validity of complex patents?*

Experience is obtained through time and research. If there are patent experts on many areas (industrial property agents, important companies, etc.) who have acquired knowledge, they can too. They should mainly be lawyers if they are to question the validity of patents. They ought in turn to be advised by technicians in the corresponding areas who may or may not be members of agencies for competition defence.

Companies that could be affected could also question the validity of patents. But there is a possibility that the damaged companies themselves may receive licences from the companies that affect them, and fearing to lose future licences, they may choose not to question them. In this case, it is a policy of companies that may be affecting the consumer, whereas if competition defence agencies are working, the consumer is being taken into account.

- *Should competition agencies simply establish good communication with IP agencies and play only an indirect role in the formulation and implementation of patent policy*?

In general terms yes.

2. Patent quality and Scope

We do not have experience with claims related to the quality and scope of patents, in particular, biotechnological ones.

However, in the SPLT treaty discussing the establishing of homogeneous criteria with regard to the way of carrying out the substance review, there are opposite stances. While, on the one hand, some countries propose a very light system of criteria for substantive analysis, at the same time enabling new types of invention to be added which are difficult to categorise in the system of patents (for example, business methods, etc.), other countries (Argentina, for example) aim at the analysis being more strict and at claims being restrictive enough to be understood.

It should be remembered that developing countries attending meetings do so using their own funds (which are sometimes not available) or invited by WIPO (which due to budgetary constraints does not have enough funds available for all countries to attend).

Probably, once the SPLT is achieved, together with the PLT and the PCT, the world patent will be sought by some countries. In fact, articles which refer to the PLT and the PCT are discussed in the SPLT.[1] Besides, there are WIPO studies linking the PLT, SPLT and PCT.[2]The world patent would, in principle, be handled by very few countries and although this has not yet been clarified, the problems concerning the validity of patents could be handled at the international rather than the domestic level, which would entail sovereignty being delegated in this matter.

It is easy to infer what will happen with patents in the world if those managing the offices in charge of substantive reviews have lax criteria.

Concerning the questions made as examples, as already reported, we do not have any news about problems. But we must clarify some items:

- Our office is very delayed in the consideration of biotechnological patents, so many patents which ought to have been put on the market, have not because of such delay.

- Our domestic market in the area of biotechnology is developing significantly. However, national submissions account for a very low percentage of the total Biotechnology patents (approximately 2%) and many biotechnological patents have not been put on the market yet.

Nevertheless, it may be assumed that if all conditions are fulfilled, there could be some problems (the same undergone by developed countries), although at present patentability conditions in the area of biotechnology in the Argentine Republic are more restrictive than in other countries (see manual of procedures on patents in the web page www.inpi.gov.ar).

3. The anticommons Problem

For the reasons stated above, we do not have evidence of this taking place, but also in accordance with the same report, there could be an overlapping (tangle) of patents that could lead companies not to request the declaration of invalidity of the patents but to obtain licences amongst themselves instead. This could not only discourage Research and Development but also increase the cost of the final product.

4. Exemptions

Our legislation grants an exception to the researcher.

The article 36 of the Argentine´s patent law (law 24.481), subparagraph a) indicates that the right granted by a patent shall not produce any effect against a third party who, privately or academically and not commercially, carries out purely experimental scientific or technological research, for testing or teaching purposes, manufacturing or using a product or a process which is equal to the one patented.

We understand that it is correct to use patents for research at an academic level (where it may currently be carried out with public, private or public-private funds) or privately. Whenever the purpose is to do research to attain new results, which may be subsequently patented, but not the use of an original invention in which the objective is commercial or of the results obtained until the concession of the new patent is granted.

In our view, it would be useful to unify the criteria at world level otherwise some countries would have handicap in their favour (countries allowing research to be carried out using the patent). On the other hand, allowing this kind of research techniques would enable further technical development, which would in turn lead to new patents and the preceding ones becoming obsolete.

5. Reach-through Licensing Agreements

It should first be remembered that the holder of a patent is required to exploit it.

It should also be remembered that import of the patented product satisfies the exploitation requirement. The holder of a patent has a specific period to exploit the patent, after which third parties may request mandatory licenses.

It should also be stipulated that after the granting of a mandatory license, if the patent cannot be exploited for reasons attributable to the holder (lack of information, etc.) it may be cancelled.

We also understand that the holder of a patent has the merit of having developed the invention. It is only reasonable that the inventor should be able to recover (or just make) money through his/her intellectual effort. The inventor often has no funds or does not know how to make the product, etc. As long as consistent with the law, it is reasonable for the inventor to get a royalty for the invention.

Blocking patents cause problems, although this again has to do with low-quality patents, with broad claims. These patents, as their name suggests, may make their holder obtain “royalties” on patents of little or no importance.

Patent pools

We have no experience in this respect.

However, there are two items to be taken into account:

- Does this patent package include blocking patents which collect royalties?
- If the parties to the pool are few, would this not constitute an oligopoly?

5.1 Unilateral refusals to License

Here we must find out the reasons for the patent holder refusing to grant a license:

- if the patent holder is supplying the market at reasonable prices, it is reasonable that he/she should refuse to grant a license;
- if the market is not being supplied, or if it is being supplied but insufficiently, or its prices are too high, under certain conditions, the laws should allow the granting of mandatory licences.

Some of the conditions may be:

- that such licence will last for a certain time (enough for the licensee to recover its investment);
- that it is not an exclusive patent (i.e. that it may be granted to other companies too);

- that the licences continue to exist although the holder has remedied the original situation which motivated the request for a mandatory licence;

- that licensees have the financial capacity, etc, to comply with the terms of the license granted, under penalty of fines, etc.

We understand this is a valid point for any technological area and not only for the biotechnology area.

NOTES

1. E.g., article 5 clause 1.

2. See document SCP/6/5

CANADA

Introduction

In recent years there has been increasing interest in how competition laws are applied to high technology sectors characterized by fast-paced innovation. Competition authorities have issued guidelines to explain how they will apply their competition laws to intellectual property ("IP"). The Canadian Competition Bureau issued its Intellectual Property Enforcement Guidelines (the "IPEGs") in September 2000.[1]

The IPEGs explain how the Bureau views the interface between IP and competition law, and given this view, how it would apply the various provisions of the *Competition Act* to situations involving IP. The guidelines deal with intellectual property generally and not just licensing. For example, mergers involving the acquisition of IP assets are addressed. Licensing or the sale of IP might be among the remedies that the Bureau may seek to remove competition concerns created by a merger.

Outline of the Paper

In this paper, the Competition Bureau's approach towards IP is described, with a focus on the treatment of unilateral refusals to license IP. First, is a brief history of the reasons for issuing the IPEGs. Second, is how the Competition Bureau interprets the interface between competition policy and IP. Third, some basic principles are presented which may be used in competition analysis relating to IP. Fourth, the Bureau's advocacy role with respect to the drafting and administration of IP law is briefly mentioned. Fifth, provides a detailed look at how the Bureau interprets and applies its unique competition legislation for remedying an undue lessening of competition as a result of a unilateral refusal to license IP. Finally, there is a brief conclusion.

1. The Motivation for Issuing the IPEGs

As IP becomes an increasingly important input and source of competitive advantage, businesses want to know how their conduct involving IP will be regarded under competition law. In Canada there has traditionally been limited overlap between intellectual property law and competition law practitioners. There was some uncertainty as to how competition law would be applied in cases involving intellectual property. The IPEGs are intended to clarify this interface and to minimize uncertainty to the extent possible by promoting compliance with the *Act*. In addition, they are also intended to mitigate any chilling effect on innovative behaviour that uncertainty concerning the status of conduct involving IP could potentially create.

2. The Interface of IP and Competition Law

Competition law and IP law do not operate in separate spheres. Rather, they both promote innovation and enhance welfare by fostering competition and efficiency in a dynamic sense. The IPEGs summarize this succinctly:

> "IP and competition laws are both necessary for the efficient operation of the marketplace. IP laws provide property rights comparable to those for other kinds of private property, thereby providing incentives for owners to invest in creating and developing intellectual property and encouraging the efficient use and dissemination of the property within the marketplace. Applying the Competition

Act to conduct associated with IP may prevent anti-competitive conduct that impedes the efficient production and diffusion of goods and technologies and the creation of new products. The promotion of a competitive marketplace through the application of competition laws is consistent with the objectives underlying IP laws."[2]

3. Basic Principles Behind the Enforcement Approach to IP

The IPEGs present some basic principles which may be used in competition analysis relating to IP. First, the same competition law analysis is applied to IP as to other forms of property. This does not mean that the unique characteristics of IP are not recognised and appropriately considered on a case-by-case basis. It does mean that although IP has unique characteristics, the application of competition law to IP does not require a fundamentally different competition law analysis.

Second, the right to exclude others from using one's property, including IP, does not usually create market power. There is no presumption that exclusive ownership of intellectual property creates market power in the antitrust context.

Third, licensing is generally viewed as being pro-competitive. A licensing agreement will not be considered anti-competitive unless it reduces competition substantially or unduly relative to that which would have likely existed in the absence of the license. Underlying this approach is the presumption that the exercise of an IP right is not considered anti-competitive in and of itself.

4. Policy Advocacy

The IPEGs make it clear that the Bureau's role extends beyond enforcement of the *Competition Act*. It also has a mandate to engage in policy advocacy on matters relating to competition. The Bureau may use its mandate to promote competition and the efficient allocation of resources to intervene in policy discussions and debates regarding the appropriate scope, definition, breadth and length of IP rights. The Bureau may also intervene in Federal Court and Superior Court cases when it believes it is important to bring a competition perspective to proceedings that will not be brought by the parties. In other proceedings, when the Bureau believes that IP rights could potentially be defined, strengthened or extended inappropriately, the Bureau may intervene to make representations concerning the scope of the protection that should be accorded IP rights.[3]

5. Approach to Unilateral Refusals to License IP - Section 32 Special Remedies

The Bureau has taken a somewhat unique approach to its analysis of refusal to licence. This is due to two reasons. First, there exists a provision in the *Competition Act*, section 32, which provides for special remedies when the exercise of a right under intellectual property law has resulted in an undue lessening of competition.

Second, jurisprudence in two IP cases before the Competition Tribunal has held that the mere exercise of the right to refuse to licence intellectual property is not an anti-competitive act. Competitive harm must stem from something more than just the mere exercise of that right. The two reasons are discussed further below.

5.1 Section 32 Special Remedies Provision[4]

Where the exercise of an IP right results in an undue lessening of competition, section 32 provides for the Commissioner of Competition to seek to have the Attorney General bring an application for a special remedy to the Federal Court. The remedies include declaring any agreement or license relating to the challenged right void, ordering licensing of the right (except in the case of trade-marks), revoking a patent,

expunging or amending a trade-mark, or directing that other such acts be done or omitted as deemed necessary to prevent the challenged use. The Federal Court would then balance the interests of the system of protection for IP (and the incentives created by it) against the public interest in greater competition in the particular market under consideration. In general, the Bureau would make an application when, in the Bureau's view, there is no appropriate remedy available under the relevant IP statute.

5.2 Jurisprudence

Two cases before the Competition Tribunal involving IP provided guidance on how to approach the issue of refusals to license IP. In its decision in *Tele-Direct*,[5] the Tribunal indicated that competitive harm must stem from something more than just the mere exercise of that right:

> "The respondents' refusal to license their trade-marks falls squarely within their prerogative. Inherent in the very nature of the right to license a trade-mark is the right for the owner of the trade-mark to determine whether or not, and to whom, to grant a license; selectivity in licensing is fundamental to the rationale behind protecting trade-marks. The respondents' trade-marks are valuable assets and represent considerable goodwill in the marketplace. The decision to license a trade-mark - essentially, to share the goodwill vesting in the asset - is a right which rests entirely with the owner of the mark. The refusal to license a trade-mark is distinguishable from a situation where anti-competitive provisions are attached to a trade-mark license."[6]

In the *Warner Music*[7] case, the Competition Tribunal held that the mere exercise of the intellectual property right was not an anticompetitive act:

> "The right granted by Parliament to exclude others is fundamental to intellectual property rights and cannot be considered to be anticompetitive, and there is nothing in the legislative history of section 75 of the *Act* which would reveal an intention to have section 75 operate as a compulsory licensing provision for intellectual property."[8]

2. The decisions in *Warner and Tele-Direct* suggested that there should be a distinction made between the general provisions of the *Competition Act* and the special remedies provision under section 32.

5.3 Distinction in the IPEGs between the General Provisions and Section 32

The general provisions of the *Competition Act* set out when it may be necessary for the Bureau to intervene in a business arrangement, including an arrangement involving intellectual property. Many provisions state that the Bureau must show that the conduct either substantially or unduly lessens or prevents competition.

The general provisions are applied when IP rights form the basis of arrangements between independent entities. This may be joint conduct between two or more firms coordinating their behaviour. The general provisions which could apply are conspiracy, bid-rigging, abuse of dominance (in the case of joint abuse), specialisation agreements and mergers. It can also involve conduct related to transfers of IP. The applicable general provisions here are the pricing practices provisions and those dealing with market restrictions; tying and exclusive dealing. Finally, there are refusals to licence which are more than a unilateral refusal. This can be through the acquisition of a controlling collection of IP rights.

The IPEGs outline the approach to the distinction made between the general provisions and the section 32 special remedies provision as follows:

- The mere exercise of an IP right is not cause for concern under the general provisions of the *Competition Ac*t. The Bureau defines the mere exercise of an IP right as the owner's right to unilaterally exclude others from using the intellectual property, including the right to use or not use the IP.

- The unilateral exercise of the intellectual property right to exclude does not violate the general provisions of the *Competition Act.* To hold otherwise would be inconsistent with the Bureau's underlying view that intellectual property and competition law are generally complementary.

- Joint conduct and transfers of IP rights are examples of situations in which any competitive harm that may result flows from something more than the mere exercise of the IP right. Systematic purchase of a controlling collection of IP rights would also be conduct which goes beyond the unilateral refusal to grant access to IP.

One of the benefits of organising the structure of the IPEGs around the distinction between the general provisions and section 32, is that it helps to emphasize that the mere exercise of an IP right does not raise an issue under the general provisions. Section 32 refers to remedies, not to any anticompetitive conduct. The general provisions are enforcement provisions which are triggered by anticompetitive conduct. It also helps to explain how the Bureau understands the exception to the abuse of dominance provisions which states in section 79(5) that an act engaged in pursuant only to the exercise of any right or enjoyment of any interest derived under IP is not an anti-competitive act.

The Bureau considers that the mere exercise of an IP right will be found to be anticompetitive in only rare situations. Consequently, the Bureau expects that it would apply for special remedies only in narrowly defined circumstances.[9] The determination involves a two-step analysis:

Step 1

- The Bureau establishes that the mere refusal has adversely affected competition to a degree that would be considered substantial in a relevant market that is different or significantly larger than the subject matter of the intellectual property.

- Normally step one would only be satisfied by the combination of these two factors:

  – the holder of the IP is dominant in the relevant market; and

  – the IP is an essential input or resource for firms participating in the relevant market - that is, the refusal to allow others to use the IP prevents other firms from effectively competing in the relevant market.

Step 2

- The Bureau establishes that invoking a special remedy would not adversely alter the incentives to invest in research and development in the economy.

6. Conclusion

Competition authorities should recognise the importance of IP in promoting innovation and dynamic competition in a knowledge-based economy while being vigilant for potentially anti-competitive consequences. The Competition Act contains a specific remedy for situations where an undue lessening of competition results from a unilateral refusal to license IP. The Bureau anticipates this remedy will be used

only in rare circumstances, such as when IP, combined with network effects, allows a competitor to gain market power.

APPENDIX I

SECTION 32, THE SPECIAL REMEDIES PROVISIONS OF THE COMPETITION ACT

Powers of Federal Court where certain rights used to restrain trade

32. (1) In any case where use has been made of the exclusive rights and privileges conferred by one or more patents for invention, by one or more trade-marks, by a copyright or by a registered integrated circuit topography, so as to
(*a*) limit unduly the facilities for transporting, producing, manufacturing, supplying, storing or dealing in any article or commodity that may be a subject of trade or commerce,
(*b*) restrain or injure, unduly, trade or commerce in relation to any such article or commodity,
(*c*) prevent, limit or lessen, unduly, the manufacture or production of any such article or commodity or unreasonably enhance the price thereof, or
(*d*) prevent or lessen, unduly, competition in the production, manufacture, purchase, barter, sale, transportation or supply of any such article or commodity,
the Federal Court may make one or more of the orders referred to in subsection (2) in the circumstances described in that subsection.

Orders
(2) The Federal Court, on an information exhibited by the Attorney General of Canada, may, for the purpose of preventing any use in the manner defined in subsection (1) of the exclusive rights and privileges conferred by any patents for invention, trade-marks, copyrights or registered integrated circuit topographies relating to or affecting the manufacture, use or sale of any article or commodity that may be a subject of trade or commerce, make one or more of the following orders:
(*a*) declaring void, in whole or in part, any agreement, arrangement or licence relating to that use;
(*b*) restraining any person from carrying out or exercising any or all of the terms or provisions of the agreement, arrangement or licence;
(*c*) directing the grant of licences under any such patent, copyright or registered integrated circuit topography to such persons and on such terms and conditions as the court may deem proper or, if the grant and other remedies under this section would appear insufficient to prevent that use, revoking the patent;
(*d*) directing that the registration of a trade-mark in the register of trade-marks or the registration of an integrated circuit topography in the register of topographies be expunged or amended; and
(*e*) directing that such other acts be done or omitted as the Court may deem necessary to prevent any such use.

Treaties, etc.
(3) No order shall be made under this section that is at variance with any treaty, convention, arrangement or engagement with any other country respecting patents, trade-marks, copyrights or integrated circuit topographies to which Canada is a party.
R.S., 1985, c. C-34, s. 32; R.S., 1985, c. 10 (4th Supp.), s. 18; 1990, c. 37, s. 29; 2002, c. 16, s. 4(F).

APPENDIX II

EXAMPLE 8: REFUSAL TO LICENSE A STANDARD

ABACUS and two other firms were the first to market a spreadsheet for personal computers. Electronic spreadsheet software was one of the applications that established personal computers as an essential tool for business. In the first five years, ABACUS out-sold its nearest competitor nearly two to one and its installed base (cumulative sales) grew to 50 percent. In the next two years, its annual market share grew to more than 75 percent and one of the other original firms left the market. At about the same time and after three years of programming, CALCULATOR introduced spreadsheet software that had a number of innovative features not found in ABACUS. However, CALCULATOR soon ran into financial difficulties despite the innovative features and a lower price. CALCULATOR approached ABACUS and requested a licence to copy the words and layout of its menu command hierarchy (for the purpose of this example assume that permission was required since ABACUS had valid IP rights in these works). With permission, CALCULATOR could have relaunched its product with an emulation mode and a key reader, which would have given CALCULATOR the ability to read ABACUS files and ensured compatibility between the two products. ABACUS refused to grant a licence and publicly announced that it would enforce its IP rights against CALCULATOR if it copied the ABACUS hierarchy. In light of this, several other prominent software makers announced that they were discontinuing their spreadsheet development programs.

An important characteristic of spreadsheets that determines their benefits to a purchaser is network effects. Network effects exist if the value of a product increases with the number of others who purchase compatible spreadsheets. Network effects for spreadsheets arise since the greater the size of the network (the installed base of compatible spreadsheets), the greater the number of individuals with whom files can be shared, the greater the variety of complementary products (utilities, software enhancements and macros), the more prevalent consulting and training services and the greater the number of compatible data files.

Analysis

Given the circumstances surrounding this case, ABACUS's refusal to license its IP would constitute a "mere exercise" of its IP rights and would, therefore, be subject to review only under section 32 of the *Competition Act*.

To establish whether ABACUS's refusal created an undue restraint of trade or lessened competition, the Bureau would determine whether the refusal adversely affected competition in a relevant market that was different or significantly larger than the subject matter of ABACUS's IP rights or the products or services which result directly from the exercise of such IP rights. In this case, competitive harm is alleged in the market for ABACUS-compatible spreadsheets.

Whether the relevant market is determined to be ABACUS-compatible spreadsheets depends on the extent and importance of network effects and switching costs. If network effects are important, consumers that have never purchased a spreadsheet may still purchase the more expensive ABACUS product. Consumers who are already on the ABACUS network may be locked in by the switching costs of joining a new

spreadsheet network (for example, their sunk investments in training, files and complementary products) and the loss in network benefits. If network effects and switching costs are material, then existing consumers are likely to stay and new consumers to choose ABACUS even if it is priced above competitive levels.

If the relevant market is determined to be ABACUS-compatible spreadsheets, then ABACUS would be the only producer and thus have 100 percent control of this market. If, in addition, entry barriers were found to be high, which is likely in an industry experiencing network effects, the Bureau would conclude that ABACUS is dominant. In determining whether the installed base of ABACUS contributes materially to entry barriers, the Bureau would consider the pace of innovation and the potential for a new technology to "leap-frog over" ABACUS despite its advantages (that is, its installed base and the switching costs). The Bureau would also endeavour to determine whether there are other efficient avenues for creating compatibility that would not infringe on the IP rights of ABACUS.

If the relevant market is determined to be ABACUS-compatible spreadsheets and the Bureau concluded that the relevant market was significantly larger than the subject matter of ABACUS's IP, and the products which result directly from the exercise of such IP rights, then the Bureau would likely conclude that ABACUS is dominant in the relevant market and that the IP is an essential input for firms participating in the relevant market. On this basis, ABACUS's refusal satisfies the first step of the Bureau's two-step analysis to determine whether it would seek to have an application brought under section 32.

In the second step, the Bureau determines whether ABACUS's refusal to licence its IP would adversely alter firms' incentives to invest in research and development in the economy. In this case, the facts suggest that it is possible that ABACUS's ability to impose incompatibility may have a chilling effect on the development of more advanced spreadsheets. In addition, the choice by ABACUS of the words and layout of its menu hierarchy was likely arbitrary and likely involved little innovative effort and had little value relative to other substitutes. In the absence of an installed base and switching costs, ABACUS's terms and menu hierarchy would be no better or worse than CALCULATOR's (or any other). It is only after consumers make sunk investments and adoption creates an installed base that ABACUS spreadsheets become the market or standard and that its choice of words and menu interface - required for compatibility with the ABACUS network - creates unintended and unwarranted market power, a situation that can be corrected through enforcement action under section 32. On this basis, the Bureau would likely conclude that a special remedy invoked under section 32 would restore incentives for other firms to engage in research and the development of competing compatible spreadsheet programs.

If the facts of the case suggest potential enforcement under section 32, the Bureau would seek a special remedy that would allow other spreadsheet firms to gain access to the words and layout of ABACUS's menu hierarchy.

NOTES

1. The guidelines are available at the Competition Bureau's web site at: http://competition.ic.gc.ca/epic/internet/incb-bc.nsf/en/ct01992e.html.

2. See, Section 3.4 of the IPEGs.

3. Section 125 of the Competition Act provides for the Commissioner, at the request of any federal board, commission or other tribunal or on her own initiative, to make representations to and call evidence in respect of competition, wherever such are relevant to the matter under consideration. Section 126 provides for powers to intervene before provincial boards, commissions or other tribunals, but only with the consent of the hearing body.

4. Section 32 is reproduced in Appendix 1.

5. *Canada, Director of Investigation and Research v Tele-Direct (Publications) Inc. and Tele-Direct (Services) Inc.* (1997), 73 C.P.R. (3d) 1 *Tele-Direct* involved the abuse provisions with regards to tying the sale of advertising services to advertising space in the Yellow Pages by Tele-Direct (Publications) Inc. and Tele-Direct (Services) Inc. The tie and a number of other acts were alleged to have had exclusionary effects on advertising agencies, advertising consultants and competing telephone directory publishers. In its decision, the Tribunal found that there was a tie of advertising space and services with respect to large local and regional advertisers and ordered a number of remedies. Additional background is provided in the Bureau's Annual Report for the year ending March 31, 1997 at: http://strategis.ic.gc.ca/pics/ct/icrepren.pdf.

6. *Canada, Director of Investigation and Research v Tele-Direct (Publications) Inc. and Tele-Direct (Services) Inc.* (1997), 73 C.P.R. (3d) 1, pg. 32.

7. *Canada, Director of Investigation and Research v Warner Music Canada Ltd. et al* (Competition Tribunal, 19 December 1997) 78 C.P.R. (3d) 321. In *Warner*, the Bureau made an application under the refusal to supply provisions of section 75, to the Competition Tribunal against Warner Music Group Inc. and WEA International Inc. for an order requiring the supply of music reproduction and sales licences to BMG Direct Ltd. on usual trade terms. The Warner companies were supplying licenses to the record club Columbia House, of which they owned 50 percent, while refusing to supply the new entrant, BMG. The Tribunal denied the application. Additional background is provided in the Bureau's Annual Report for the year ending at March 31, 1998 at: http://strategis.ic.gc.ca/pics/ct/stats98en.pdf.

8. *Canada, Director of Investigation and Research v Warner Music Canada Ltd. et al* (Competition Tribunal, 19 December 1997) 78 C.P.R. (3d) 321, pg.333.

9. A hypothetical example of a possible section 32 case is provided as Example 8 in the Bureau's IPEGs. This example is reproduced in Appendix II.

CHINESE TAIPEI

1. Introduction

This submission summarises Chinese Taipei's approaches toward dealing with the interface between competition policy and patent rights.

In general, Chinese Taipei is in the view that competition law and patent rights share common objectives to promote competition, innovation, and economic development on the one hand, and to benefit consumers with advanced and desirable products on the other. Conflicts between the two disciplines may arise, regarding how the rights of a legally protected patent shall be exercised in the interests of both patent protection and fair competition.

The Fair Trade Commission has yet to encounter any competition issue arising from the biotechnology industry. However, starting from 1999, the FTC has been involving with a case regarding the patent rights licensing practices in the recordable compact disc (the CD-R) technology market. This still pending case has been central to the FTC's efforts in balancing the benefits and disadvantages by granting patent rights.

2. Competition Policy and Patent Rights

2.1 The Proper Role of Competition Agencies in the Patent Process

What role should competition authorities play in the development of patent policy or in the patent granting process, if any? Should competition agencies be involved in decisions concerning whether to award a patent, or concerning how to phrase the patent? Should competition authorities be allowed to challenge the validity of questionable patents that have already been granted? How can competition agencies, whose primary expertise is not in IP, effectively determine the scope and assess the validity of complex patents? Should competition agencies simply establish good communication with IP agencies and play only an indirect role in the formulation and implementation of patent policy?

Under the current Patent Act and the Fair Trade Act, there is no room for the FTC to directly participate in the paten granting or phrasing process. The Patent Act is administered by the Intellectual Property Office under the Ministry of Economic Affairs. The IPO is staffed with legally qualified patent examiners whose main responsibility is to conduct substantive examination on patent applications for inventions.

Regarding the right to challenge the validity of granted patents, the Patent Act provides that any person with relevant evidence may institute a cancellation action with the IPO. The competition authority is not excluded from exercising this right, though, whether it can effectively challenge the scope and the validity of patents is the key issue.

In the CD-R technology market case which will be explained below, to determine whether the patents in question were complementary to or substitutes for each other, the FTC has had to recourse to an industrial technology research institute to conduct relevant researches. This task provided the FTC an

experience to use outside resources to determine the specific content, the scope, and the nature of patents while reviewing patent relevant cases.

2.2 Patent Quality and Scope

The biotechnology industry is relatively new, complex, and rapidly evolving. Concerns about patent quality and scope have been raised in such industries, meaning that patents may sometimes be granted for technologies that probably should not receive patents because they do not meet statutory criteria, while other inventions may be eligible but the patents themselves are worded too broadly or ambiguously. How does the level of patent quality affect competition in the biotechnology industry? How do overly broad or ambiguous biotechnology patents affect competition? In what ways does patent ambiguity (*i.e.*, difficulty in determining what a patent does and does not protect) make competition law enforcement more difficult? For example, does it matter that patent ambiguity might make it harder to determine the nature of competitive relationships between biotechnology companies?

The Patent Act defines the qualifications of patents in a broad way. Take the invention patent as an example, the term "invention" is defined as "a high-level creation of technical concept where natural rule is utilised". An invention which is "industrially applicable" and "not published, put into public use, or known to the public" prior to applying for patent may obtain a patent in accordance with the procedures set in the Patent Act. If an invention utilises "conventional technology or knowledge" known prior to application, and can be easily accomplished by persons with "ordinary knowledge in the relevant technology area," shall not be granted an invention patent.

It is easy to see how vague and uncertain those general descriptions are and how ample space is left for patent examiners' discretion. Chinese Taipei agrees that poor patent quality and ambiguously phrased patent might affect competition in various ways. There has been no empirical study conducted by the FTC on this subject up-to-date.

Patent ambiguity can make competition authority difficult to determine the nature of competitive relationships between companies. In reviewing whether a patent pool is pro-competitive or anti-competitive, competition authority needs to learn whether the patents included are essential to the production and there would be no substitutes in the pool. In the CD-R case, with help from outside experts, the FTC found that within the patent pool in question there did exist substitute patents and reached the conclusion that there was a collusion.

2.3 The Anticommons Problem

Does a proliferation of patents -- particularly with respect to patented biotechnological research tools that facilitate the discovery and production of downstream products -- lead to a "tragedy of the anticommons"? In other words, is there already such a tangled web of IP rights in biotechnology that companies face an inordinate burden when trying to develop products that depend on numerous supporting patents held by a multitude of other parties? If so, this would mean that patents may actually be discouraging innovation rather than promoting it. Have competition agencies observed an anticommons problem in any of their cases?

Under the patent thicket incurred by knowledge-based economy, a new technology product is very often involved with numerous patents. In practices, infringement charge usually does not appear during the research and development stage or at the beginning of the commercialisation of the products. Once a producer starts to really invest in and marketing a product, receives positive response and revenues from the market, then patent rights holders will gradually appear and demand for huge amount of royalty rate. If the payment is not satisfactory, infringement litigation and complaints to export countries' customs to bar

the products will then follows. This kind of situation is something typical for a technology importer like Chinese Taipei to deal with. The risk of patent thicket can bring enormous risk for industrial development.

2.4 Exemptions

From a competition policy standpoint, should there be exemptions to patent rights? For example, should universities have exemptions for the purpose of conducting research? What other exemptions should be permitted, and under what circumstances? Would it make sense to harmonise positions across national borders, assuming that some markets are worldwide? What effects would follow, if any, if exemption standards are divergent?

Chinese Taipei's Patent Act restricts the effect of an invention patent right to extend to where the invention is put into practice for research, educational or experimental purposes only, with no profit-seeking acts involved. The FTC believes this exemption tends to produce positive results in promoting innovation.

2.5 Reach-through Licensing Agreements

What are the competition policy implications of licensing agreements that involve royalties based on the revenue generated by a downstream product that the licensed technology only helped to identify and develop, but not to produce or sell? Should it be a violation of competition law for a company to use its patent rights to extract profits from something other than what it has patented?

Until now there has been no case received by the FTC that has pertained to the reach-through licensing agreements issue.

2.6 Patent Pools

Patent pools arise when patents held by two or more parties are licensed as a package. What are the positive and negative ramifications of patent pools for competition policy? Might they help to ameliorate an anticommons problem in the biotechnology industry? Which characteristics of patent pools are pro-competitive, and which are not?

Patent pools are particular useful tool under the patent thicket environment. Pooling arrangements can help patent owners to prevent potential infringement litigation, reduce costs of complex licensing negotiation, avoid waste of duplicate research inputs, and facilitate dissemination of knowledge, thereby encouraging utilisation of technologies and generating the pro-competitive effect.

Pooling of patents might have its down side under certain circumstances. Pooling arrangements might create market power to engage in harmful practices similar to what cartels might do, such as jointly determine price, limit the terms of quantity, technology, products, facilities, trading counterparts, or trading territory with respect to goods or services concerned, so as to hinder competition.

In its experience in dealing with the CD-R technology market, the FTC found the alleged pooling agreement contained patents that were not granted in Chinese Taipei, already invalid, substitutes for each other, and not essential to the production. That pool, considering its ability to affect the relevant market's function, also breached the Fair Trade Act in that it failed to apply for prior approval from the FTC. Such provision also authorises the FTC to set conditions to the patent pool. With deliberated consideration, the competition authority could reduce the potential breaches by the patent pools.

2.7 Unilateral Refusal to License.

How have the competition authorities analysed unilateral refusals to license, both in general and in the biotechnology sector? Does the biotech industry have any characteristics that distinguish it from other industries for purposes of this analysis? For example, does the fact that many biotechnology patents are granted for research tools rather than commercial products have any bearing on the analysis of unilateral refusals to license? What if the patent covers a tool that is relied upon by a range of competitive research instruments and products?

In reviewing unilateral refusal to license the FTC will take the licensors' market power, motivation, and practices in to account. The Fair Trade Act prohibits enterprise with certain market power to prevent other enterprises from competing by unfair means, or provide discriminatory treatment to trading counterparts without justification.

The Patent Act authorises the IPO may, upon request, grant to an applicant a compulsory licensing to practice the patent, if the patentee has committed competition restraint or unfair competition as confirmed through a judicial judgment or by the Fair Trade Commission. In the said CD-R case, the manufacturers already applied compulsory licensing request to the IPO. The IPO has not decide whether it should grant such application.

3. Regulations on Patent Licensing

The Patent Act is enacted to encourage, protect and utilise inventions and creations so as to spur the development of industries. To facilitate the fulfilment of such purpose, the Patent Act grants the patentee shall have the exclusive right to exclude other persons from manufacturing, selling, using, or importing the patented article for said purposes without the patentee's prior consent.

Not whatever the patentee does is deemed in the interest of patent protection, though. The Patent Act stipulates that an assignment or a licensing of an invention patent shall not take effect if the contract contains any of the following circumstances which will result in unfair competition:

- To prohibit or restrict the assignee from using any specific object or process not furnished by the assignor or licensor; and

- To require the assignee to purchase from the assignor products or raw materials not under patent protection.

Correspondingly the Fair Trade Act provides that its provisions shall not apply to any proper exercise of rights pursuant to the provisions of the Copyright Act, Trademark Act, or Patent Act. The FTC's interpretation of this provision is that consideration should be given to intellectual property right by providing that only the legitimate exercise of the rights shall be exempted from the application of the Fair Trade Act, otherwise the FTC should intervene to maintain a balance between the interest of the right-holders and the users.

The criteria used to determine whether patent right holders' practices is legitimate is the legislative purpose of the Patent Act, which reads as "to encourage, protect and utilise inventions and creations so as to spur the development of industries." If the exercise of rights is detrimental to the development of the industries concerned and harms the interests of consumers, the Fair Trade Act will then be applicable to such practices.

3.1 CD-R technology market case

In 1999, several CD-R manufacturers filed a complaint to the FTC, alleging that in 1996 the Koninklijke Philips Electronics N.V., Sony Corporation, and Taiyo-Yuden Co., Ltd. jointly formed a patent pool to monopolise the CD-R technology market, granted a package license to downstream manufacturers, and misused their market power to exploit the licensees concerned.

In conclusion of its investigation, the FTC found that Philips, Sony and Taiyo-Yuden were horizontal competitors in the CD-R manufacturing technology market through their ownership of technologies and patents related to that activity. By joint decision on the royalty rate and joint licensing of patents, the companies acquired monopolistic position in the CD-R technology license market in Chinese Taipei, unduly maintained the royalty rate, refused to provide licensees with important trading information regarding the license agreements, and prohibited licensees from objecting to the validity of the patents.

3.2 Package licenses

The alleged three companies respectively owned a number of patents with specifications related to the CD-R products and jointly set up the manufacturing standard, so called the Orange Book, of the CD-R production. In their joint licensing arrangement, Sony and Taiyo-Yuden licensed their patent rights exclusively to Philips, and then Philips bundled the rights together for licensing to other companies. Under the arrangement among the three companies, none of them can individually license their patents related to the CD-R products to any other company.

The patent pool owned all essential patents on CD-R production and thus monopolises the CD-R technology market. Manufacturing and sale of CD-R products around the world had to obtain licenses from the patent pool. The exclusive licensing from Sony and Taiyo Yuden to Philips and the single package license Philips provided to other companies made potential licensees not possible to negotiate and contract with individual licensor and obtain needed patents rather than all patents in the pool.

3.3 Royalty rate

The CD-R patent pool set the royalty rate at 3% of the net sales or a minimum of 10 Japanese Yen. The FTC found that the said royalty rate did not have a detrimental impact on manufacturers in 1996 when average selling price of per CD-R disc in the world market was 7 US dollars. With the rapid growth in global CD-R demand and production, by 2000, that price had dropped radically to less than 50 US cents. The 10 Yen minimum rate became the larger figure and amounted to nearly 17.8% of the net selling price of a disc. Licensing profits received by Philips in 2000 would amount to 20 to 60 times than that in 1997.

The royalty rate was then far more than the licensees can bear and cause heavy impact on this industry. Under this circumstance the licensees sought to re-negotiate the royalty rate with the Philips and was turned down all the time. Several smaller manufacturers had already been forced to withdraw from the market due to unable to cover the royalty rate. Other manufactures were also unable to raise retail prices to be profitable under severe competition in the world market. Concentration might increase once more manufactures leave the market and distort the CD-R market.

3.4 Information of patents

The CD-R patent pool gathered 109 patents as a single package to licensees and refused to provide specific contents, scopes, and validity periods of patents licensed. Philips also failed to demonstrate concretely the patents that licensees might be able to use in specific products and the scopes of such patents, merely listed the patent numbers and names of the patents at issue in the US and Japan instead. In

addition, the conditions Philips proposed to settle the complaint included prohibiting licensees from objecting to the validity of the patents in the pool.

It had been discovered that the CD-R patent pools granted technologies related to Pure CD-R and Hybrid CD-R both, while manufacturers only needed Pure CD-R patents. Philips owned only 5 patents on CD-R in Chinese Taipei but bundled its patents around the world in the pool, regardless whether the licensees need all of them. The investigation also found one of Philips' patents was substitute for one Sony patent, 5 patents were irrelevant to CD-R technology, and 12 patents were already invalid. The patent pool actually provided a shelter for invalid and unnecessary patents to be granted to licensees.

In its decision issued in 2002, the FTC concluded that the patent pool violated the Fair Trade Act in the following ways:

- the horizontal agreement among the alleged three companies which jointly set the royalty rate and conditions of licenses failed to apply for prior approval from the FTC;

- the improper maintenance of royalty rate which had adversely affect competition in downstream manufacturing market constituted misuse of monopolistic position; and

- the patent pool bundled valid, essential, complementary patents with invalid, unessential, substitute, and irrelevant patents to grant single package license to licensees constituted tying arrangement.

In compliance with the FTC's order, Philips, Sony and Taiyo-Yuden dissolved the patent pool and individually negotiated new license contracts with CD-R manufacturers. The latter two companies offered affordable royalty rate to licensees and entered into new contracts without disputes. Philips, on the other hand, still bundled all its patents regarding CD-R technology around the world to license and single-handedly raised up its royalty rate even higher than the previous patent pool's level.

The CD-R manufacturers filed another complaint to the FTC, alleging Philips continued to misuse its market power to set royalty rate through its patents essential to the CD-R manufacturing. The case is under review of the FTC now. In 2003, several CD-R manufacturers requested the IPO to grant compulsory licensing to practice Philips' patents on CD-R. The IPO is yet to make the decision.

3.4 The international development of the CD-R/RW case

While the FTC's decision was appealed to the Taipei High Administrative Court by Philips, Sony and Taiyo-Yuden and still pending there, it might be worthwhile to mention the international development of this case. In 2002 Philips filed a complaint to the United States International Trade Commission (the ITC), alleging that the above-mentioned CD-R and rewritable compact disc (the CD-RW) manufacturers violated the section 337 of the Tariff Act of 1930 in the importation into the US, the sale for importation, and the sale within the US after importation of certain recordable compact discs and rewritable compact discs by reason of infringement of certain claims of six US patents.

After extensive investigation and analysis conducted, in 11 March 2004, the ITC issued its determination that the US patents asserted by Philips are unenforceable for patent misuse, and has therefore found that there is no violation of the US Tariff Act of 1930. The ITC affirmed that the asserted patents are unenforceable for patent misuse, on the ground that the complainant's practice of mandatory package licensing constitutes a tying arrangement between licenses to patents that are essential to manufacture CD-R or CD-RW according to Orange Book standards and licenses to others patents that are not essential to that activities.

4. Conclusion

Patent rights are granted to encourage, protect and utilise inventions and creations, so as to spur the development of industries and generate welfare to the general public. While granting patent with certain legal protection, the competition authority is also required to carefully monitor and scrutinise the rights owners' practices, on a case-by-case basis. This is always a delicate issue and needs further exploration by all interested parties.

FRANCE

En France, le Code de la propriété intellectuelle promulgué en 1992 regroupe, d'une part les droits attachés aux brevets, aux marques et aux dessins et modèles sous l'appellation de droit de la propriété industrielle et d'autre part la propriété littéraire et artistique concernant les droits d'auteur et droits voisins ; cette distinction est importante car les règles de concurrence n'auront pas la même incidence selon que l'un ou l'autre de ces régimes sera concerné.

Les autorités de la concurrence ont toujours considéré que les restrictions concurrentielles pouvaient être justifiées par des contributions au progrès économique, notamment l'introduction de nouvelles technologies. Ces considérations permettent en particulier, aux droits de propriété intellectuelle de bénéficier d'un préjugé favorable car la nécessité d'une protection est évidente. A titre d'exemple, les brevets incitent à l'innovation et la recherche qui elle-même conduiront à la création de marchés futurs donc à l'émergence de rapports concurrentiels.

Dès lors, les règles de concurrence ne peuvent en aucun cas remettre en cause l'existence même du droit exclusif, mais ***elles interviennent afin d'en prohiber un exercice abusif***.

Dès 1955, c'est à dire la date de leur institution en France, les autorités chargées de contrôler le respect des règles de concurrence ont considéré que ces dernières s'appliquaient sans restriction aux accords portant sur les droits de propriété intellectuelle. Aujourd'hui, les règles de concurrence définies au Livre IV du Code de Commerce comportent des dispositions susceptibles de s'appliquer à la propriété intellectuelle et l'existence des droits de propriété intellectuelle ne fait pas obstacle à l'interdiction des pratiques anticoncurrentielles.

L'analyse prescrite par la majorité des économistes, afin de déterminer les axes généraux de mise en œuvre du droit de la concurrence par rapport à un problème posé par l'usage des droits de propriété intellectuelle, consiste à ***mesurer la réduction de concurrence existante induite par l'usage d'un droit de propriété intellectuelle sur les marchés de produits ou services existants et/ou innovants***. Dans le cas d'un usage abusif de ce droit, il appartient à l'autorité de concurrence de limiter les abus éventuels de détenteurs de droit.

L'objet de la table ronde de l'OCDE du 8 juin 2004 étant plus particulièrement de réfléchir sur les problèmes à l'interface du droit de la concurrence et de la propriété intellectuelle dans le domaine des biotechnologies, la présente note se concentre sur les cas d'application du droit de la concurrence par le Conseil de la concurrence dans le domaine des médicaments et produits pharmaceutiques.

S'agissant du marché pertinent notons que l'existence d'un brevet ne constitue pas en soi un monopole au sens du droit de la concurrence. Tout dépend en effet du marché examiné et des capacités de substitution des acteurs. Certes le pharmacien ne peut pas substituer un médicament sous brevet. En revanche le prescripteur choisit entre différents médicaments sans se préoccuper de leur situation au regard des brevets ; pour le médecin seuls les produits n'ayant pas d'équivalents thérapeutiques dans la situation clinique considérée sont en monopole. Il n'y a donc pas de concordance entre marché pertinent et brevet, et le marché pertinent doit être examiné au cas par cas..

S'agissant de la nature des abus, en matière de produits pharmaceutiques, comme pour les autres produits, deux types d'abus peuvent être identifiés dans la jurisprudence développée par le Conseil de la concurrence: les concertations et les abus de position dominante.

S'agissant de l'exploitation des droits de propriété intellectuelle, il est peu fréquent que des entreprises situées au même stade de la compétition économique soient amenées à se livrer à des pratiques concertées ; en revanche les ententes verticales entre les titulaires de ces droits et leurs licenciés font l'objet d'un examen plus systématique. Les accords de licence et de sous licence sont susceptibles de constituer des ententes restrictives de concurrence entre licenciés et sont de nature à porter préjudice aux entreprises tierces non licenciées.

Les règlements communautaires d'exemption et la jurisprudence, tant nationale que communautaire, permettent ***d'identifier les principales clauses de ces accords qui sont incompatibles avec le droit de la concurrence***.

Ainsi, sur la mise en œuvre de pratiques d'une entreprise en position dominante le Conseil s'est prononcé dans l'affaire Lilly France, en se referant à la jurisprudence communautaire. Une entreprise en position dominante et confrontée à l'arrivée d'un concurrent est en droit de se défendre ou de développer sa part de marché pourvu qu'elle demeure dans les limites d'un comportement normal et d'une concurrence légitime.

La jurisprudence du Conseil de la concurrence concernant l'application du droit de la concurrence a des cas impliquant le droit de la propriété intellectuelle a permis de traiter à la fois des problèmes permettant de mettre en évidence la position dominante, mettant en cause l'usage de droits exclusifs/brevets et, d'autre part, a conduit à rejeter les griefs d'ententes ou les demandes de mesures conservatoires lorsque ceci avait été invoqué ou sollicité par les auteurs de la saisine. On trouvera ci-après les principaux cas de jurisprudence rangés par catégorie de pratiques anticoncurrentielles. Pour la commodité de la présentation, chaque cas de jurisprudence est résumé succinctement à partir de l'ensemble des éléments d'ordre public et chaque décision étant disponible pour consultation sur le site *Internet* du Conseil de la Concurrence (**http/www.conseil-concurrence.fr**)

1. Abus de position dominante

1.1 Décision n°96-D-12 relative aux pratiques mises en œuvre par la société Lilly France dans le secteur des spécialités pharmaceutiques destinées aux hôpitaux.[1]

Au moment de l'expiration du brevet d'un médicament antibiotique pour le traitement des maladies à staphylocoque, la *Vancomycine*, la société Lilly France, filiale du groupe pharmaceutique nord-américain Lilly, a cherché à préserver sa position sur le marché de manière anticoncurrentielle. Cette action anticoncurrentielle a été mise en œuvre lors de la procédure de mise en concurrence lancée par les établissements hospitaliers français pour la fourniture de leurs pharmacies. Au moment des faits, Lilly France, producteur original, détenait le brevet et disposait jusqu'alors du monopole de la production et de la commercialisation de ce produit. Le pourcentage des ventes réalisées sur la Vancomycine en 1991 par Lilly France, c'est à dire 3 ans après l'expiration du brevet, était encore de 67.30 pour cent, avec un C.A. global de près de deux milliards de francs en France. Après l'expiration du brevet, deux entreprises ont commencé à développer la production d'équivalents génériques : le Laboratoire Lederlé et Dakota Pharm.

Au moment des faits, la société Lilly disposait d'un monopole de production et de commercialisation d'un autre médicament (pour le soin des maladies cardiaques), le *Dobutrex*, jugé indispensable par les hôpitaux pour de nombreux traitements.

A partir de la fin 1988, la société Lilly a proposé aux établissements hospitaliers des remises tarifaires importantes sur des spécialités dont elle détient le monopole, notamment le Dobutrex, à condition que ces établissements achètent également auprès d'elle de la *Vancomycine* [la vancomycine est la dénomination commune internationale, Vancocine est le nom de marque de la vancomycine de Lilly. Ce nom n'a pas

changé, et était Vancocin dans les pays anglo-saxons]. Au même moment, parallèlement, les tarifs de base sur le *Dobutrex* ont été augmentés.

Ces pratiques ont été considérées comme caractéristiques d'un abus de position dominante par le Conseil de la concurrence. En effet, elles visaient à empêcher les clients de Lilly France de se fournir en *Vancomycine* auprès de fournisseurs plus compétitifs et à limiter l'accès au marché de cette spécialité pour les sociétés Lederlé et Dakota-Pharm, au préjudice des acheteurs hospitaliers nationaux.

La société Lilly a, donc, été condamnée à une amende de 30 millions de francs. Cette décision du Conseil de la Concurrence a été confirmée par la Cour d'Appel de Paris. La Cour de Cassation a ensuite confirmé les deux décisions antérieures.

1.2 N° 99-D20 relatives à des pratiques constatées dans le secteur des implants et des substances viscoélastiques.[2]

La substance viscoélastique dénommée *Healonid* a été mise sur le marché par la société Pharmacia & Upjohn (Pharmacia). Ce produit a amélioré les conditions d'opération de la cataracte, dans lesquelles ils ont été utilisés d'une façon importante. Cette substance était soit vendue séparément par la société Pharmacia soit livrée à titre gratuit avec l'implant aux chirurgiens, afin de faire connaître ce produit. Par la suite, les autres fournisseurs de produits concurrents ont également utilisé ce dernier procédé commercial.

Le ministre chargé de l'économie a saisi le Conseil de la concurrence. Il reprochait tout d'abord à la société Pharmacia d'avoir eu recours à des procédés anticoncurrentiels consistant en des dons couplés à des ventes à l'égard de certains établissements de soins, et d'avoir opposé à certains de ses concurrents des refus de vente. Enfin la société Pharmacia était soupçonnée d'avoir conditionné la livraison de *Healonid* à la société Domilens, à la pratique de prix fixés à l'avance par elle[3].

En l'espèce, il s'agissait d'abord de circonscrire très précisément le marché concerné, de déterminer si la société Pharmacia détenait une position dominante sur ce marché, puis de rechercher si la société avait utilisé cette position dominante de manière abusive.

En droit français de la concurrence, comme dans la plupart des autres droits équivalents, le marché est défini comme « le lieu sur lequel se rencontrent l'offre et la demande pour un produit ou un service spécifique ». En l'espèce, le Conseil a estimé que la société Pharmacia ne détenait pas de position dominante sur le marché pertinent :

« …qu'ainsi, en dépit de la grande notoriété du Healonid et de la circonstance que ce produit était protégé par un brevet jusqu'en 1996, au cours de la période considérée, les parts détenues, en volume et en valeur, par la société Pharmacia sur le marché des substances viscoélastiques n'ont cessé de s'effriter et le nombre de nouveaux compétiteurs d'augmenter ;…. »[4]

Ces considérations ont été renforcées quand le Conseil s'est penché sur les prix, qui dans cette affaire, se sont stabilisés après une forte augmentation : « ….que cette hausse de prix peut s'expliquer par la pression croissante de la demande pour un produit particulièrement innovant et permettant une amélioration considérable des conditions d'opération de la cataracte…. »[5] .

Le Conseil a donc conclu que la société Pharmacia ne détenait pas sur le marché des substances viscoélastiques une position dominante lui permettant de s'abstraire de la pression concurrentielle et a rejeté l'application de l'art 8 de l'ordonnance du 1er décembre 1986.

Sur le second moyen, les accords entre Pharmacia et Domilens, le Conseil a estimé qu'il n'était pas établi qu'une entente de prix a existé, et par suite, qu'il ne pouvait être reproché aux sociétés Pharmacia et

Domilens de s'être livrées à une action concertée au sens des dispositions de l'article 7 de l'ordonnance du 1er décembre 1986.

1.3 N° 2001-D-23 relative aux pratiques de la société Abbott sur le marché des produits anesthésiques.[6]

La société Abbott détenait un brevet sur l'*isoflurane*, anesthésique gazeux et donc un monopole d'exploitation sur ce produit. Lorsque le brevet de ce produit est tombé dans le domaine public en 1992, plusieurs concurrents sont entrés sur le marché. Pour préserver sa position alors que sa part de marché faiblissait du fait de l'apparition de médicaments génériques, le laboratoire Abbott a adopté une nouvelle tarification à l'égard de plusieurs grosses centrales d'achat, comportant en particulier un système de remises de fidélité octroyées en cas d'exclusivité d'achat.

L'utilisation, par une entreprise en position dominante, de remises de fidélité destinées à empêcher les clients de changer de fournisseur, a été considéré comme particulièrement grave par le Conseil de la concurrence. Le Conseil a également pris en compte le fait que cette pratique vise à retarder l'entrée sur le marché d'un médicament générique dans un contexte difficile pour les dépenses publiques de santé.

Le Conseil s'est fondé sur une jurisprudence établie, notamment celle de Lilly France, précitée, afin de déterminer le marché pertinent : « ...il convient de tenir en compte à la fois des spécificités techniques de ce médicament et du comportement des médecins prescripteurs ». En ce sens, le Conseil a considéré qu'une spécialité pharmaceutique pouvait constituer un marché pertinent en termes de produit.

Le Conseil a considéré qu'Abbott avait abusé de sa position dominante sur le marché de l'isoflurane et a fixé une sanction de 2 millions de francs (304 898 euros).

1.4 Décision n° 03-D-35 relative à des pratiques mises en œuvre par les laboratoires Sandoz, devenues en 1997 Novartis Pharma SA, sur le marché de certaines spécialités pharmaceutiques destinées aux hôpitaux.[7]

Les laboratoires Sandoz, devenus en 1997 Novartis Pharma SA, fabriquent et commercialisent deux spécialités pharmaceutiques issues du même principe actif, Sandimmun et Néoral, [à l'époque des faits reprochés à Sandoz, seul Néoral était encore couvert par un brevet, mais il n'existait effectivement pas d'autres produits que ceux de Sandoz sur le marché]. Ces médicaments sont jugés par le Conseil indispensables et non substituables à d'autres spécialités pharmaceutiques. Les laboratoires Sandoz étaient donc en position de monopole sur le marché français de ces produits.

La société a mis en place un système de remises de fidélité jugée abusive par le Conseil. La pratique consistait à accorder des remises sur les produits indispensables, Sandimmun et Néoral, à condition que les hôpitaux achètent aussi d'autres spécialités de Sandoz, même si les hôpitaux pouvaient trouver ces spécialités moins chères chez les concurrents de Sandoz.[8]

Le Conseil a rappelé l'interdiction de tirer avantage de la position dominante détenue sur un marché donné pour développer sa position sur des marchés concurrentiels distincts par un système de remise sur ventes liées au détriment du libre jeu de la concurrence. En reprenant les conclusions de l'arrêt de la Cour de justice des Communautés européenne dans l'affaire Hoffmann-La Roche, le conseil rappelle que l'interdiction de telles pratiques est en effet justifiée dès lors qu'elles « ne reposent pas sur une prestation économique justifiant cette charge ou cet avantage, mais tendent à enlever à l'acheteur ou à restreindre dans son chef, la possibilité de choix en ce qui concerne ses sources d'apprivoisement et à barrer l'accès du marché aux autres producteurs. » Dans le cas d'espèce, il n'y avait aucune justification objective au système mis en place.

Le Conseil de la concurrence a sanctionné les laboratoires Sandoz pour abus de position dominante et leur a infligé une sanction pécuniaire de 7,8 millions d'euros.

NOTES

1. Décision n° 97-D-12 du Conseil de la Concurrence en date du 5 mars 1996 relative aux pratiques mise en œuvre par la société Lilly France dans le secteur des spécialités pharmaceutiques destinées aux hôpitaux, Dixième Rapport Annuel d'Activité du Conseil de la Concurrence, p.232-241. Voir aussi l'Arrêt de la Cour d'Appel de Paris (chambre économique et financière) en date du 6 mai 1997 relatif au recours formé par Lilly France SA contre la décision susnommée, publiée au Bulletin Officiel de la concurrence de la consommation et de la répression, des fraudes (BOCCRF) du 11 juin 1997. Voir l'Arrêt de la Cour de Cassation (chambre commerciale, financière et économique) en date du 15 juin 1999 relatif au pourvoi formé par la société Lilly France SA contre la même décision du Conseil de la concurrence, publiée au BOCCRF du 27 juillet 1999.

2. Décision n° 99-D-20 du Conseil de la Concurrence en date du 9 mars 1999 relative à des pratiques constatées dans le secteur d'implants et des substances viscoélastiques, 13ième rapport d'activité du Conseil de la concurrence, volume 1, p. 200-213. Voir aussi BOCCRF –B.O.S.P. N° 14 du mercredi 25 août 1999, p. 457.

3. Interdiction de « casser les prix » et Domilens devrait utiliser « les prix hauts » du marché.

4. Décision n° 99-D-20 du Conseil de la concurrence, p 13.

5. Ibid.

6. Décision n° 2001-D-23 du Conseil de la Concurrence en date du 10 mai 2001 relative aux pratiques de la société Abbott sur le marché des produits anesthésiques, 15ième Rapport Annuel d'Activité du Conseil de la concurrence, volume 1, p.229-244. Voir aussi BOCCRF N° 8 du jeudi 24 mai 2001, p. 499.

7. Décision n° 03-D-35 du Conseil de la concurrence en date du 24 juillet 2003 relative à des pratiques mise en œuvre par les laboratoires Sandoz, devenues en 1997 Novartis Pharma S.A., sur le marché de certaines spécialités pharmaceutiques destinées aux hôpitaux. Voit aussi BOCCRF N° 12 mercredi 8 octobre 2003, p. 731.

8. On notera ainsi que le Conseil a tenu compte du secteur particulier de la santé dans son évaluation de la gravité des pratiques.

JAPAN

1. Introduction

This paper discusses three main issues 1) approaches on competition policy regarding intellectual property rights, including patent rights, 2) some explanation on the exemption of intellectual property rights, including patent rights, from the application of the Antimonopoly Act (hereafter referred to as AMA), and 3) various approaches to competition issues in the biotechnology-related sector, with reference to the issues discussed in the report prepared by the study group of experts (published in June 2002 by the Japan Fair Trade Commission (JFTC)) entitled "Patent and Competition Policy in New Industries, With Focus on Business Model Patents and Biotechnology Patents" (hereinafter referred to as "Report").

2. Approaches to competition policy issues in relation to intellectual property rights, including patent rights

The patent system and the AMA have a common policy objective: industrial development through creation and ingenuity by enterprises and national economic growth. However, there is the risk that when the extent of protection of a patent right is broad, research and development could be discouraged and competition in a market could be distorted by way of exploiting the patent rights.

Therefore, to fully achieve the common objective of the above two systems, it seems necessary for the JFTC to step up its monitoring of anticompetitive behaviours in these fields to avoid the distortion of market competition that may be brought about by enhanced patent rights.

3. Exemptions

Sec. 21 of the AMA stipulates: "The provisions of this Act shall not apply to such acts recognisable as the exercise of the rights under the Copyright Act, the Patent Act, Utility Model Act, the Design Act or the Trademark Act." The entities exempted from the AMA under the provisions of Sec. 21 are not limited to universities and colleges alone. "The Guidelines for Patent and Know-how Licensing Agreements under the Antimonopoly Act" (published on July 30, 1999, hereinafter referred to as "Guidelines") provides an interpretation of the provisions of Sec. 21 and other sections related to IPR. The Guidelines say that Sec.21 was created to confirm the following two interpretations:

1. "Acts recognisable as exercises of rights" under the Patent Act, etc., are not subject to the AMA and shall not constitute violations of the AMA;

2. However, if acts looking like as "exercises of rights" under the Patent Act, etc. on its face, are considered to deviate from or contradict the purposes of the IPR system, i.e. to encourage innovation, they are not deemed "acts recognisable as the exercise of the IPR." For this reason, the AMA shall be applicable to them.

For instance, if an act on its face is considered to be an exercise of rights under the Patent Act, etc., but in reality is considered to be employed as part of a series of acts that constitute unreasonable restraint of trade (AMA Sec. 3) or private monopolisation (AMA Sec. 3), the said act is considered to deviate from or to contradict the purposes of the IPR system; i.e. to encourage innovation. For this reason, it is not

deemed an "act recognisable as the exercise of rights" under the Patent Act, etc., and is subject to the Antimonopoly Act.

In addition, if an act on its face is considered to be an exercise of rights under the Patent Act, etc., but is considered through the evaluation of its purpose, particular circumstances, and the extent of its impact on competition in a market to deviate from or to contradict the purposes of the IPR system, it is possible that the AMA would also apply, since it is not deemed an "act recognisable as the exercise of rights" under the Patent Act, etc.

4. Various approaches to competition issues, focusing on the biotechnology sector

The following sections discuss various approaches to competition issues focusing on the biotechnology sector, with reference to the issues presented in the Report.

4.1 Evaluation of biotechnology-related patents in terms of competition policy

The biotechnology-related sector is cyclical in the point of the relationship between investment made in research and development and patent rights: heavy investment is made in research and development in order to acquire patent rights, which are then licensed in order to generate revenues to cover the initial investment and hopefully provide further investment for the next similar cycle. The development of such patents and licenses increases incentives for research and development in this sector, which further increases competition in a market.

In developing new drugs based on the decoded human genome, the process flow from the upstream genetic analysis to the downstream production of components and compound drugs is often divided into several stages, each of which is undertaken by separate entities. A DNA-related patent granted to an invention originating upstream in the process, often having a function of a substance patent, has an extended scope of application including other uses, and there is often no alternative. A similar situation often arises with research tool patents. The more basic and universal such research tools may be, the more difficult it is for users to find alternatives.

The users of such patents might be obliged to obtain licenses even if conditions for the licenses demanded by the licensors are unreasonably high. In particular, if the holder of a certain patent with essential use in a downstream market refuses to grant licenses to downstream businesses, the latter would suffer greatly by being unable to use it, which would discourage downstream businesses from conducting related research and development.

Therefore, we believe it necessary to take a strict stance on aggressive licensing terms and conditions or refusal to license, etc., concerning genetic patents and tool patents, as such actions could interfere with the AMA.

4.2 Handling of violations of the AMA

4.2.1 Regarding an agreement to discontinue research work, etc.

Competing drugs makers may enter into an agreement to:

1. restrict individual research and development except subjects related to those designated for joint research and development, or

2. discontinue proprietary research and development, if started already, on similar subjects to those designated for joint research and development.

Further, if no joint research and development has been agreed upon, several makers of the same drug which has been on the market for some time already may make an agreement whereby the parties commit:

1. not to start research and development on certain types of genes or proteins that could lead to the development of new genomic drugs that compete with the existing ones, or

2. to discontinue or otherwise delay any ongoing proprietary research and development on the same subjects if some parties have already started to do so,

in order to sustain sales of the existing drugs.

An agreement not to pursue certain research and development will be deemed as unreasonable restraint of trade (AMA Sec. 19) if, as a result of such an agreement, competition otherwise likely in a market for technology on genes or proteins which could lead to the development of new genomic drugs or market for the new genomic drugs is substantially restricted.

4.2.2 Unreasonable license agreements

As patent rights are strengthened and the scope of patent rights protection is expanded, there are some patents that are newly awarded to inventors. The holders of such new patents, taking advantage of the expanded scope of patent protection, may try to exploit the right too aggressively or force licensees through a license agreement with excessively restrictive terms and conditions on their otherwise free business activities, hence distorting competition in a market.

Reach-through licenses

A certain patent holder, when granting a license to use a research tool, may make an agreement in which the products obtained by using the tool are treated as if they were subject to the said research tool patent, whereby the licensee must pay license fees in proportion to the sales of the products, or commit to grant an exclusive or non-exclusive license to the patent holder for any future invention generated from the products. Such an agreement is called “a reach-through license agreement.” It contradicts the general principle that a licensed patent right does not extend coverage to such products.

It could be a case of unfair trade practices (AMA Sec. 19; dealing on restrictive terms) if the holder of a research tool patent forces a license agreement that obliges licensees to commit to grant-back the exclusive license under any invention developed from the licensed research tool that should not be subject to the right of the research tool patent, which would effectively discourage them from conducting research and development, thereby depriving them of an opportunity to develop new technology and distorting competition in a market.

In addition, a case whereby the research tool patent holder obliges licensees to pay a license fee in proportion to the sales of products resulting from using the research tool, against the general principle that such products should not, by definition, be subject to the right of the research tool patent, is also likely to fall under the definition of unfair trade practices (AMA Sec. 19; dealing on restrictive terms).

Other forms of unreasonable license agreements

Other cases of licensing practices under patent rights in biotechnology and related fields likely to interfere with the provisions of the AMA include:

1. a case where a licensor, who has obtained a patent right by concealing the test results, etc., that would otherwise have aroused doubts about the lack of novelty, obliges the licensee not to challenge the validity of the patent, and

2. a case where the licensor makes it a condition that several genetic patents, etc., should be licensed as a package, etc.

These cases may well fall under the category of unfair trade practices (AMA Sec. 19) in view of the concept of the Guidelines as dealing on restrictive terms or tie-in sales.

4.2.3. Refusal of granting of a license by a patent holder, in particular, to a prospective licensee who utilises the former party's patent

Under the Patent Law, if a patented technology for developing new genomic drugs positioned downstream in the flow of the drug production process utilises a genetic patent, etc., positioned upstream in the flow, the downstream drug maker must obtain a license from the upstream patent holder.

In the development of new genomic drugs, it is very unlikely that the downstream drug makers can find an alternative to the upstream genomic patent, which makes it very difficult to do without existing technologies. Therefore, refusal to grant a license under the existing patented technology could have a crucial influence on the downstream drug makers.

Because the patent system grants the inventor an exclusive license to practice the invention, the decision itself by the holder of a prior patent not to grant a license to a party whose patent is related to the inventor's patent is an exercise of the primary right under the patent law. Therefore, such a decision does not infringe the AMA in general.

However, if the patent holder refuses to grant a license in the following cases, it could lead to violation of the AMA:

1. a case where the licensor had been aware and actually confirmed that his patent right would likely be utilised by the prospective licensee through earlier negotiations;

2. a case where the patent holder seems to have approved of utilisation of his/her patent, having made no objection, while surely and fully aware of the use of his/her patent by the prospective licensee;

3. a case where the patent holder once granted a license but terminates it just as the drug resulting from the patent is being launched on the market.

In such cases, the downstream drug makers, etc., have already invested a substantial amount of capital or acquired patents on drugs, medicines, etc., in anticipation of the availability of a license concerning an upstream genetic patent, etc., that the drug makers' patented invention utilises. The licensor's decision not to grant a license at this time will cause inextricable problems for the prospective licensee. This is a typical case where the "right of free trade" of a prior patent holder to withhold granting of a license needs to be restricted.

Accordingly, such a refusal to grant a license or to demand fees so expensive as to be deemed a flat refusal to grant a license is likely to fall under private monopolisation (AMA Sec. 3) or unfair trade practices (AMA Sec. 19; other refusal to deal). Further, demanding excessively expensive license fees, even if they are not so expensive as to be deemed a flat refusal, could be considered an unfair trade practice (AMA Sec. 19; abuse of dominant bargaining position).

4.2.4 Other issues related to refusal of granting a license

In addition to refusal to grant a license to a holder of a downstream drug market, an act which hinders entry of new competitors in the form of accumulating related patents and refusal to grant a license, or the merger and acquisition of businesses which would result in monopolistic accumulation of related patents, etc., may also lead to violation of the AMA if such acts substantially restrict competition in a market.

4.2.5 Action expected under the AMA in the exercise of a patent right which has grounds for invalidation

Concerning a patent right which has grounds for invalidation, making an agreement between the holder of the patent and the licensee with reciprocal obligations not to challenge the validity of the patent, and to restrict the quantity and prices of the products manufactured under the license, or to interfere with entities planning to enter the market, may lead to violation of the AMA (unreasonable restraint of trade (AMA Sec. 3), private monopolisation (AMA Sec. 3), or concerted refusal to deal (AMA Sec. 19)).

In addition, a license agreement made in return for withdrawing patent litigation or with other terms and conditions meant to restrict competition, may also lead to violation of the AMA.

4.2.6 Patent Pools

In biotechnology-related fields, it is sometimes proposed to create a patent pool for the efficient utilisation of a patented invention that is a valuable and scarce resource. Patent pools enable mutual or multi-lateral utilisation of pooled patented inventions among members and enable license arrangements to third parties on a reasonable fee basis. Therefore, patent pools may promote competition in a market; however, if they cause the restriction of free competition, the JFTC may take some measures based on the principles of the Guidelines.

Note: The Guidelines' comments on patent pools are as follows:

Where, for example, the licensing agreement for the patents, etc., are pooled in a corporate entity or organisation with the understanding of the members that they have accepted common restrictions, and the agreement imposes mutual restrictions on the members regarding the sales price, manufacturing volume, sales volume, sales outlets, sales territories, etc. of the patented products, etc., and substantially restricts competition in a market for particular products, then it will be illegal under the AMA as an unreasonable restraint of trade (AMA Sec. 3). Moreover, in the event that mutual restrictions are imposed on the members of the patent pool regarding the fields of research and development, and regarding the parties to whom the license may be granted or the technology that may be used, etc., thus substantially restricting competition in a market for particular products or particular technologies, then it will also be equally illegal under the AMA as an unreasonable restraint of trade (violation of AMA Sec. 3).

For instance, there may be situations in which it becomes difficult to conduct business activities in a particular field of trade without first obtaining licenses for the patents, etc. of particular products because right holders competing in a market for the said products form a patent pool relevant to that particular field of trade, and consequently, agree to pool all existing and future improved technologies in the said patent pool. In this situation, if the right holders refuse to grant licenses to new entrants or to particular existing entrepreneurs without justifiable reasons, or take other measures that have the effect of impeding the entry of other firms or of making it difficult for existing firms to conduct business, it will be illegal under the Antimonopoly Act as private monopolisation if these acts substantially restrict competition in a market for particular products or particular technologies (violation of AMA Sec. 3).

5. Conclusion

While stronger patent rights raise the incentive for researchers to develop technologies, it is possible that patent rights with a broadened scope of protection could hinder the development of subsequent competing technologies if the patent holder exploits the rights excessively, thus distorting competition in a market.

Especially, as mentioned above, in the case of biotechnology-related patents, genetic patents upstream in the flow, often having functions as substance patents, also have other uses, or by definition, have no readily-available alternative material.

Furthermore, because research tool patents with general and universal functions are often indispensable, their users may be forced to accept proposed conditions for licensing or other arrangements even if unreasonable, which may discourage researchers of downstream technologies from new research and development.

To ensure competition in a market, incentives to pursue research and development should be secured at all levels of the production flow in the industries. The patent system must therefore be applied carefully and appropriately; furthermore, we believe it is necessary to apply the AMA rigorously to anticompetitive acts.

KOREA

In Korea, the laws related to the intersection of intellectual property rights and competition policy include patent law, which is enforced under the intellectual property rights system, the Monopoly Regulation and Fair Trade Act, the Guidelines of Reviewing Undue Exercise of Intellectual Property Rights, the Notification on the Types of Unfair Trade Conducts Regarding Parallel Import and the Notification on the Types of and Criteria for Determining Unfair Business Practices in Intellectual Contracts. In order to prepare for the situation that conflicts between intellectual property rights and competition policy emerge as major challenge, the Korea Fair Trade Commission has enacted and enforced relevant notifications and guidelines. However, due to the short history of enforcing the competition law on intellectual property rights (hereinafter IPR), there have been few cases regarding the abuse of IPR so far. Given the growing importance of IPR these days, more cases regarding IPR are expected to take place ahead. Therefore, the KFTC is making endeavours to make more specific guidelines and adopt advanced system cases from the U.S. and Europe.

Considering the overall situation, the report touches upon the situation of Korea's bio-industry, relationship between patent and competition in bio-industry, competition policy enforcement on IPR system and related cases in the past in Korea.

1. Introduction – Current Situation and Prospect of Korea's Biotechnology Industry

From the point of completing the 'Human Genome Project', revolutionary changes in bio-industry have been made throughout a wide range of industries, from medical equipment industry to agricultural sector. In other words, bio-industry is predicted to become a key industry determining the national competitiveness in the 21st century.

In 2002, the total amount of bio-industry products in Korea reached 1.893 trillion won from 819.8 billion won in 1998 up by 130.9%. In addition, the total amount of investment in bio-industry in 2002 was 409.5 billion won from 187.6 billion won in 1998 up by 118.3%.

Under such circumstances, patent has become more important as groundwork for further advancement of bio-industry. In this regard, patent on biotechnology has been sharply on the rise in Korea. The number of total application for patent in Korea increased from 104,084 cases in 1998 to 150,032 cases in 2003 up by 44%. Among these, the number of patent application in biotechnology rose from 1630 cases in 1998 to 2817 cases in 2003 up by 73%. In particular, patent application on gene marked up from 401 cases in 1999 to 1301 cases in 2003 increased by 224%.

2. 'Patent' as Development Foundation of Bio-industry and Other Key Issues

As mentioned above, further specification and highly sophisticated expertise are strongly required with rising number of patent on biotechnology. Unfortunately, however, supply falls short of demand. In Korea, there are only 12 experts who can examine biotechnology sector. In addition, due to difficulties in handling the task, such as vague definition of the scope of patent, overlapping and conflict between patents take place. In a nutshell, problems have arisen, as quantitative growth could not meet qualitative improvement.

For example, extracting haemoglobin from maize involves 13 patents including gene, technology and method of converting characteristics. As such, tens of patents could be related in producing one completed bio product. Therefore, biotechnology has a value as a production technology as well as a tool to broaden the study to other fields. Moreover, the burden on investment in technology for domestic companies is increasing.

Even though the number of member companies registered in the Korea Bio Venture Association reached 600, only few takes a form of advanced high-tech bio venture. Due to R&D costs and rising burden on marketing capacity, more and more bio venture companies are transferring their patent rights to large companies, making strategic alliance each other or carrying out M&A. Therefore, exclusive monopoly of patent rights has become more concentrated on large companies while these companies acquire market dominant position, abusing their rights.

The issues related to the quality of patent application, transaction form such as patent pool and licensing, which imposes restraint, need to be reviewed from the perspective of competition across overall economy, even though they have been effective in promoting efficiency in individual companies.

3. Korea's Competition Policy on Intellectual Property Rights in the Biotechnology Industry

3.1 Importance of Competition Policy

10. Competition policy on IPR is related to all stakeholders involved, including IPR holders, licensors and licensees. In addition, 'consumers', who are the final beneficiaries from competition promotion, economic development and social welfare, are also included as direct but ultimately important customers. In particular, considering the fact that the bio-industry can have a wide range of influence on people's life through its various application to other industries, the scope of target customers can be expanded to people around the globe.

3.2 Competition Policy Enforcement in Intellectual Property Rights in Korea

3.2.1 Relationship between Intellectual Property Rights and Competition Policy

11. In following paragraphs, Korea's system on interface between competition policy and IPR will be introduced. Although the measures are different, both competition policy and intellectual property rights have the same ultimate goal to contribute to consumer welfare and economic development through technological innovation.

- Article 1 (Purpose) under Patent Act: The Purpose of this Act is to encourage, protect and utilise inventions, thereby improving and developing technology, and to contribute to the development of technology.

- Article 1 (Purpose) under Monopoly Regulation and Fair Trade Act (MRFTA): The purpose of this Act is to promote fair and free competition, to thereby encourage creative enterprising activities, to protect consumers, and to strive for balanced development of the national economy by preventing the abuse of market-dominating positions by enterprisers and the excessive concentration of economic power, and by regulating undue collaborative acts and unfair trade practices.

The Article 59 under the MRFTA allows the basic rights of patent rights imposed by the Patent Act. However, if IPR is abused or exercised beyond the scope, MRFTA is applied to such case. Therefore,

MRFTA focuses on whether any case concerned violates fair competition in the market by exercising its rights against the case which abuses or goes beyond the scope of IPR.

- Article 59 (Exercise of Right to Intangible Property) under the MRFTA: The provisions of this Act shall not apply to any act which is deemed to be an exercise of rights under the Copyright Act, the Patent Act, the Utility Models Act, the Design Act, or the Trademark Act.

The KFTC respects the position of the Korea Intellectual Property Office, such as requirements for patent registration, scope of patent application, duration of patent rights, scope of protecting patent invention and ex post review procedure on patent application, such as examination on the opposition to the grant of a patent, trial against ruling of refusal or revocation, invalidation trial of patent and trial to confirm the scope of a patent right. In this regard, the competition authority is overseeing the process of exercising patent rights. The competition agency can make a policy recommendation to the extent of giving an advice and exchange the views with patent authority.

3.2.2 Korea' Competition Policy on Intellectual Property Rights

Competition system on intellectual property rights managed by the KFTC is to be mentioned. In order to enhance consistency and predictability of legal application by compensating the MRFTA, the KFTC enacted 'the Guidelines of Reviewing Undue Exercise of Intellectual Property Rights' in August 30th, 2000. 17 different types of violent behaviours are mentioned. By providing 'white list' about the case, which is hardly considered as violation, it enables for parties concerned to check whether their behaviour is violating the competition law or not. For example, when a licensor requires a licensee to purchase parts, etc. for a licensed product from the licensor or a party designated by the licensor to ensure that the licensed product meets a certain standard of quality or performance, etc., such behaviour shall be considered a fair trade practice.

- Article 1 (Purpose) of the Guideline:… However, on the external or the formal front, even though the activities seem to exercise the intellectual property rights, if they are deemed to be unjustifiable act, going far beyond the purpose of the intellectual property rights, which aims to encourage invention and creation, or if they restrain competition in technology markets or goods markets, the Acts shall be applied. (the remaining part is omitted)

The guideline is applied to the transactions related to intellectual property rights, such as industrial property rights, know-how, copyrights, cross-licensing, pooling-arrangement and IPR transfer. As principles to judge over violation on transaction, specific activities, its effects on competition, contract duration and situation on relevant market are comprehensively considered. Moreover, application of the MRFTA, regulating abuse of market dominant position, business combination, undue concerted behaviour or cartel, unfair trade practices, restraint on resale price maintenance, is not excluded even though it is not specifically stipulated in the guideline.

- Article 3 (Unfair Business Practice in the Industrial Property Rights Contracts, etc.) of the Guideline: Unfair business practices, etc. with respect to industrial property contracts are defined as below. In addition to the criteria for these categories of practices, the effect on competition, the duration of the contract, relevant market conditions, and like factors shall be comprehensively taken into account in determining whether or not a particular act is unfair.

Moreover, in judging whether intellectual property system forms market dominance, and conditions and restraint on licensing are legitimate or not, the KFTC explores the way to fairly address the case through economic analysis based on 'rule of reason' rather than 'per se illegal'. In case of transfer of improved technology, when a licensee grants joint ownership of or the exclusive (non-exclusive) right to

use the technology improved by the licensee to the licensor upon receiving compensation, including the expenses required for such development and the anticipated profits there from; when either contract party reports or gives notice to the other party of an improvement in the licensed technology (product), or gives the exclusive (non-exclusive) right to use such improved technology on equal conditions; and when a licensor requires a licensee to report or give notice to the licensor prior to using the improved technology in order to ensure quality control or guarantee the performance of the licensed technology (product), they shall be considered fair trade practices. In addition, when the licensor declined the licensing approval over a particular industrial property for not accepting the above list falling under the unfair business practices; or when the licensor blocks the market entry of other business by declining the licensing approval though the person who wants to get the licensing approval about the industry property, which is necessary for providing particular goods and services, makes substantial efforts to get approval by suggesting reasonable conditions for a while, such behaviours shall be considered illegal.

Besides, through the Notification on the Types of Unfair Trade Conducts Regarding Parallel Import and the Notification on the Types of and Criteria for Determining Unfair Business Practices in International Contracts, the KFTC is exploring the interface between intellectual property rights and competition policy.

3.3 The KFTC's Cases regarding Intellectual Property Rights

Followings are about the cases in the past related to the abusive exercise of IPR. However, there is no case related to bio-industry or that based on the IPR guideline enacted in 2000. Therefore, following cases are about P&G in 1998 and Raychem Corporation in 1995.

3.3.1 P&G Case (1998)

This is the case restricting the M&A between the companies which develop similar technology brining less competition in the market. P&G Korea made notification to the KFTC in 1998 that it acquired shares to take over Ssanyong Paper. The KFTC defined the relevant market as the female sanitary pad market. According to the survey, the sanitary pad market is mainly allocated by P&G (63.8%) and Yuhan-Kimberly (21.8%). In terms of initial investment and technology, the market concerned has high entry barrier. The KFTC paid special attention to the size and speed of innovation in the market. It thought that new entrants might face difficulties in catching up with existing players due to short product life cycle and limits in technology. In addition, the competition authority focused on the fact that P&G has more than 300 patents and Yuhan-Kimberly more than 400 patents.

As it is hard to expect market entry and better market competition structure through this merger, the KFTC found out that it would hamper competition through high market concentration. As a result, on May 25th 1998, the KFTC allowed the merger under the condition that Ssanyong Paper should transfer all of its mechanical facilities related to sanitary pad and its industrial property rights (24 trademarks, 7 patent rights, 9 utility rights and 2 design rights) to the third party within a year after the merger.

3.3.2 Raychem Case (1995)

This case is significant in that the activity unduly limiting the transaction condition under the name of protecting intangible assets, such as technology, know-how and patent is not considered the exercise of patent rights, which excludes the application of MRFTA.

Raychem is a domestic subsidiary established in Korea by Raychem Corporation, telecommunication equipment manufacturer headquartered in the U.S. When Raychem signed additional agreement contract on sales of heat shrinkable closures with Young Jin Industry on January 17th 1991, it set the transaction conditions as follows:

" Young Jing Industry agrees not to manufacture nor supply the certified heat shrinkable closure to KT. (omitted) This additional agreement is effective for the period when Young Jin Industry deals the Raychem products and 3 years after the relationship abovementioned is completed."

Young Jin Industry reported Raychem's undue behaviour to set the transaction condition, which gives disadvantage to Young Jin to the KFTC on November 11th 1994. Considering the fact that contract between Raychem and Young Jin Industry is the contract which has noting to do with patent, on July 5th 1995, the KFTC judged that such behaviour was the violation of the MRFTA as Raychem gave harmful effect on Young Jin Industry by abusing its dominant position. In response to this, Raychem maintained that it was the exercise of patent rights excluded from the application of the MRFTA. However, the restrictive behaviour done in this case could not be seen reasonable.

4. Closing

So far, Korea's position on IPR and competition policy in bio-industry was explained. As there is the guideline on IPR cases in Korea, there is not that much problem in terms of system. However, Korea does not have enough experience in handling the licensing case. The KFTC will make steady efforts to meet the competition enforcement level to the international standards and face the challenges in competition law arising from globalisation. In addition, the KFTC is always open to any advice and suggestion from various competition authorities related to the interface between IPR and competition policy.

MEXICO

1. Intellectual Property in Mexico

Mexico is a net importer of intellectual property. Its dependency and dissemination rates rank low relative to other countries. Even though in 2001 it ranked twelfth in number of patents in the USA, out of a selection of twenty countries (see Table 1), its 87 patents were significantly less than the average number of patents for the top ten countries (7,082).[1]

Since 1993, out of the total number of patent applications received by the Mexican patent office, those submitted by individual or legal persons of Mexican nationality comprise less than 8% of total applications. Over time, this share has been falling, reaching 3.8% by 2003 (see Table 2). In terms of patents granted, the share for Mexican nationals is even smaller and has also been shrinking from 5.6% in 1993 to 2% in 2003 (see Table 3).

Mexico's patent office also classifies patent applications and patents granted by type of inventor. According to the Mexican Institute for Industrial Property (IMPI or Institute), most applications by Mexican nationals are submitted by independent inventors (almost two thirds), but the largest share of patents granted goes to "large" domestic firms. For non-Mexicans, the share of patent applications and grants is consistent throughout, the lion's share is for large transnational firms (see Table 4).

Tables 5 and 6 include information on the top 10 patent applicants by nationality, Mexican and non-Mexican. These show that while all ten foreign patent applicants are large firms, the majority of Mexican applicants tend to be research institutes (six out of the ten applicants). All of these universities and research institutes are public so that their ability to innovate largely depends on the availability and long term commitment of public funds. Another interesting difference is the relative size of the "large" domestic and foreign firms that apply for patents. Using the value of sales as an indicator of potential resources available for large firms, Mexican firms are far behind their international counterparts in their ability to use these resources for research and development. The ability of domestic firms to patent largely depends on their ability to attract capital and technology that can encourage domestic innovation and product development, and yet informal financing mechanisms, such as venture capital firms, are unavailable or incipient.

2. Institutional and legal framework

2.1 International

Among other agreements, Mexico has been a signatory of the Paris Convention (1883) since 1903,[2] which defines internationally agreed basic standards of intellectual property protection; in 1995 it adopted the Patent Cooperation Treaty (PCT, 1970),[3] which ensures that one international registration or filing will have effect in any of the relevant signatory States; it has also signed the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS, 1995),[4] which obliges members of the World Trade Organisation (WTO) to provide the prescribed mechanisms for enforcement of intellectual property rights. In addition, the North American Free Trade Agreement (NAFTA) included a chapter on intellectual property, whereby Mexico and the other two parties to the agreement acquired obligations to protect and enforce intellectual property rights.[5]

2.2 Domestic

Although judicial ordinances relating to industrial property existed since the end of the colonial period, the definition of the types of inventions that could be patented did not come about until 1890, with the Law of Inventions and Improvements. In 1928 a new law established patent types (inventions, models, industrial designs, etc.). The 1942 Law of Industrial Property made it obligatory for a patent to pass a novelty exam and established for the first time compulsory licensing for anyone who requested it. However, according to the authority in charge of overseeing industrial property policy, the IMPI, to date it has not received any such request.[6]

An amendment to the 1976 Law of Inventions and Trademarks was introduced in 1987. It allowed immediate patentability in some sectors and postponed patentability in others for a period of 10 years, thus allowing domestic industry to adjust. Biotechnology process for the production of pharmaceuticals, genetic processes, chemical products, and chemical-pharmaceutical products were among the inventions excluded from immediate patentability. However, by 1991 the Law to Promote and Protect Industrial Property (LPPIP) allowed early patentability in all of these processes. This policy change was largely driven by Mexico's ongoing negotiations during NAFTA and was influenced by its negotiations of the TRIP's. The influence of the TRIP's Agreement is reflected in the objectives of the LPPIP:

- to promote and encourage inventive activity that has industrial applications and represents a technical improvement, and to disseminate technological knowledge in production sectors;

- to promote and stimulate the improvement of the quality of goods and services in industry and trade in a manner consistent with the interests of consumers;

- to protect industrial property by regulating and granting patents, registrations of utility models, industrial designs, trademarks and advertising slogans, publishing trade names, declaring the protection of appellations of origin and regulating trade secrets;

- to prevent acts that infringe upon industrial property or constitute unfair competition in relation to industrial property, and to introduce sanctions and penalties for such acts.

In 1993 the IMPI was created and the patent system ceased to depend on the Ministry of the Economy. The Institute was given administrative authority in all industrial property matters, as well as full operative and budgetary authority.

The law, amended in 1994, states that inventions done by any individual shall be subject to a patent, and accordingly defines inventions as any human creation that allows matter or energy existing in nature to be transformed and used by man to satisfy his specific needs, and exempts from this definition

- Essentially biological processes for obtaining, reproducing and propagating plants and animals;

- Biological and genetic material as found in nature;

- Animal breeds;

- The human body and the living matter constituting it; and

- Plant varieties.

Furthermore, the law does not regard as inventions the following:

1. Theoretical or scientific principles;

2. Discoveries that consist in revealing something that already existed in nature, even though it was previously unknown to man;

3. Schemes, plans, rules and methods for carrying out mental processes, playing games or doing business, and mathematical methods;

4. Computer programs;

5. Methods of presenting information;

6. Aesthetic creations and artistic or literary works;

7. Methods of surgical, therapeutic or diagnostic treatment applicable to the human body and to animals; and

8. Juxtaposition of known inventions or mixtures of known products, or alteration of the use, form, dimensions or materials thereof, except where in reality they are so combined or merged that they cannot function separately, or where their characteristic qualities or functions have been so modified as to produce an industrial result or use not obvious to a person skilled in the art.

The patent granting process entails several steps. A patent application containing a detailed description of the invention "which shall be sufficiently clear and complete to be fully understood and, where appropriate, to serve as a guide for a person with average skill in the art to make it". Once the application has been filed, the Institute examines the form of the documents, and may require that further details or clarifications be provided.[7] The pending patent application is published as soon as possible following the expiration of a period of 18 months from the filing date of the application, or where applicable from the date of recognised priority. Once the patent application has been published and the appropriate fee has been paid, the Institute conducts a substantive examination of the invention, where it may request the technical support of specialised national agencies and institutions. Finally, once the substance examination has been carried out, the Institute can deny or grant the patent.

The Institute can declare a patent invalid, implying that the effects of the patent or registration concerned are cancelled retroactively from the filing date of the application. Invalidation may be declared only with respect to the claim or claims affected, or the affected part of a claim. To do so, any of the following conditions must be met:

- the patent is granted in violation of the provisions on the requirements and conditions for the grant of patents;

- the grant takes place in violation of the provisions of the law in force at the time of grant of the patent or registration;

- the application is abandoned during the course of processing;

- the grant has been flawed by serious error or negligence, or has been made to a person not entitled to it.

When an economic agent considers that a patent has been applied only to harm competition and take advantage of competitors, he may initiate an administrative declaration procedure. In this case, the

Institute could itself initiate an *ex officio* administrative declaration procedure or at the request of the person who has a legal interest and provides grounds for his claim.

Among industry participants, the general impression about the intellectual property framework in Mexico is that it is efficient, their main concern is the cost, both monetary and in terms of time and bureaucratic red tape, that patenting entails. A final concern is the relative ease or difficulty of challenging and enforcing these rights through litigation, which in Mexico is especially lengthy and particularly costly for an industry that faces rapid technological change such as biotechnology.

3. The biotechnology industry in Mexico[8]

The Mexican biotechnology industry is characterised by its relative novelty, fast pace of innovation, multidisciplinary quality, and multisectoral impact. These elements make it particularly hard to have accurate information on its size, structure, and potential performance. Biotechnology companies rely heavily on patent protection in order to innovate so that issues relating to the speediness with which patents are reviewed and granted, the enforcement of these patent rights, as well as licensing practices that may facilitate or inhibit follow-on innovation become particularly important.[9] In Mexico, however, there is still a gap between industry participants that undertake biotechnology research and innovation, and those that commercialise biotechnology research or who can potentially market and sell the final products. This means that, except for a few companies at the forefront, the Mexican biotechnology industry is only just facing some of the issues mentioned in the recommended readings for this roundtable, and instead is confronting a separate set of problems described below.

Although there are no official records that characterise or follow the biotech industry in Mexico, independent studies and articles estimate that by 1999 Mexico had granted about 800 patents for biotechnology research, most of them to U.S. nationals (50%) and only about 5% to Mexicans. The large majority of patents correspond to two sectors: the health/chemical pharmaceutical sector (42%) and the food/raw materials sector (41%).[10] A different classification separates patents into the following five categories: process and methodologies (47%); products (29%); diagnosis and treatment of human and animal diseases (15%); laboratory and industrial material and equipment (6%); and applications and uses of processes, methodologies and products (3%).[11]

The greater part of biotechnology research is undertaken by academics in universities and research centres. Industry participants regard these institutes as being of high quality but small in size relative to international players. An estimated 100 such institutions exist in the country, but only 15 of them have more than 10 researchers who are members of the National System of Researchers (SNI), and these 15 institutions concentrate about half of all biotechnology researchers who are members of the SNI.

Patenting is not a common practice among researchers. First, a culture of protection of intellectual property is scant. Second, only some institutes have offices that lend support to researchers in the form of undertaking the paperwork and paying for the expensive and sometimes lengthy patent process.[12] Finally, many researchers prefer to renounce their rights to, and potential benefits of, a patent to avoid bureaucratic red tape in their institutions.

Interaction between the academic, mostly research-based sector and the private actors that can potentially transform their innovations into a marketable product is still limited. Furthermore, only a handful of research institutions have entertained the possibility of vertically integrating into the production, marketing, and sale of their inventions by considering incubating companies.[13]

Industrial application of biotechnology research is still in its infancy, as a number of large companies in the manufacturing sector have still not exploited this research. Instead most of them use traditional

production processes that could potentially be optimised using biotechnological processes. These companies are mainly in the food/raw materials sector and include the alcoholic beverage industry (beer, rum, wine), companies producing vegetable dyes, probiotic and enzyme manufacturers, among others.

The SEP-Conacyt document identified about 100 biotechnology companies in 2000. Most of these are small or medium-sized companies, with the smaller ones concentrating in projects that do not require large investments. Among the medium-sized companies, only three develop pharmaceutical products domestically, and collaborate with academic institutions to develop research projects. The companies are: Probiomed, Laboratorios Silanes and Instituto Bioclón (a subsidiary of Grupo Silanes, specialising in fabotherapy). Another biotechnology firm worth mentioning among the medium-sized companies that have contact with academic institutions is Atlatec, part of Grupo Cydsa, which has successfully developed water treatment projects using biological processes and has collaborated with universities to develop research for these projects.[14] There are other companies that participate in this sector, but are partly or wholly held by foreigners. In other biotechnology sectors, such as the food technology sector, only a few companies have established successful collaborations with research institutes.

According to industry participants, the Mexican biotechnology industry can be divided according to their product applications into the following categories:

3.1 Agriculture

a. *Traditional*: there are 70 to 75 Mexican firms that produce plants using micro propagation methods and cell culture through cloning. They specialise in the production of elite plants. All of these firms are domestic, mostly small and medium in size.

b. *Agro biological*: examples of their products include bio fertilizers and bio pesticides. There are some Mexican firms in the market, all of them are small or medium in size. Other participants include transnational firms specialising in chemical products (e.g. Abbott, BASF, Dow Chemicals, etc.)

c. *Genetically modified plants*: mainly the seed producing industry. Intellectual property issues are very important for these industries, particularly in the case of hybrid plants, as second generation seeds generally lose vigour (potency) and cannot be reused by farmers. Hence, the rights to the first generation parent plants are very valuable for the seed producing company. Economic agents participating in these markets in Mexico are mostly transnational firms. The only large domestic player in the country is Grupo Savia, who not only reproduces but also performs innovative research. However, its substantive research is undertaken in the U.S.

2. *Biotechnology applied to health*: this industry is much more dominated by international firms. The reasons are twofold: the cost of research and development, which, as is the case in the rest of the world, lies between $250 and $500 million dollars; and the technological complexity for production is high, irrespective of whether these products are developed and commercialised within the company or licensed for reproduction. The few Mexican firms that participate are imitators or followers, purchasing patents or waiting for their expiration to begin production. Nevertheless, important Mexican players, such as Probiomed or Silanes, do possess this technological complexity, and are highly regarded in the industry. They are expected to eventually undertake innovative research themselves. A key concern for these domestic players is the recent discussion about the potential extension of a patent's life as a result of the lengthiness of the sanitary risk assessment process.

Biotechnology companies in Mexico face intellectual property issues that are in some ways distinct from those outlined for discussion in this roundtable. Those that carry out the research, universities and

research institutes, are generally not vertically integrated in the marketing and distribution process, and have scarce contact with private industry. Consequently, in many cases they have little time or interest in exploiting potential commercial applications of their biotechnology research or of licensing their invention for others to undertake follow-on research or product marketing. In addition, traditional industries that could begin to employ biotechnology research in their production processes still rely on traditional production methods and are reluctant to innovate. Small and medium domestic companies are beginning to collaborate with the academic sector and are still searching for new investment projects. Given the stage of development of Mexico's biotechnology industry, issues relating to the potential anticompetitive effects that commercial licensing agreements can have on innovation in this market have yet to arise.

4. The competition authority's role in patent policy

Article 28 of the Mexican Constitution, opens with a broad prohibition of "monopolies, monopolistic practices, [and] State monopolies." It then provides, however, that the functions exercised exclusively by the State in specified "strategic areas" will not constitute monopolies. The sectors presently listed as strategic areas are: postal services, telegraph and radiotelegraphy, petroleum and other hydrocarbons, basic petrochemicals, radioactive minerals, nuclear energy, electric power, and the functions of the central bank in producing coins and paper currency. Other provisions in this article stipulate that exclusionary privileges accorded to copyright and patent holders also do not constitute monopolies:

> "…privileges which for a specified time are granted to authors and artists for the reproduction of their works, and to those which, for the exclusive use of their inventions, may be granted to inventors and those who perfect some improvement..."

The Federal Law of Economic Competition (FLEC) follows from this constitutional article, and reiterates that privileges granted to inventors are not regarded as monopolies, and therefore not subject to the law.

Article 5 of the FLEC establishes that:

> *…Temporary privileges granted to authors and artist for the production of their work and those granted to inventors and individuals perfecting improvements for the exclusive use of their inventions, do not constitute monopolies…*

Nevertheless, Article 1 of this same law states that

> *The present law … is of general observance in the [Mexican] Republic and applicable to all areas of economic activity.*

Therefore, the exercise of patent rights are excluded from prosecution by the FLEC. However, using this market power to undertake anticompetitive practices in a different market is considered unlawful. Situations associated with refusals to license are addressed by the IP authority who could compel the patent holder to license its invention by invoking Articles 70 and 72 of its law:

> *"In the case of inventions, after three years from the date of grant of the patent, or four years from the filing of the application, whichever period elapses later, any person may apply to the Institute for the grant of a compulsory license to use the said invention where it has not been used unless there are duly justified reasons for such non-use…"*
>
> *"Prior to granting the first compulsory license, the Institute shall give the patent owner the opportunity of working the patent within a period of one year from the date of the personal notification addressed to him…"*

As explained in the following section, antitrust cases brought to the attention of the competition authority have been uncommon, either because the market is still relatively small and lacks development, and/or because there is insufficient information among industry participants about the scope of competition policy as it relates to the temporary privileges conferred onto them by the State. In either case, there will be a clear role for competition advocacy as the market develops.

5. Competition cases involving patents and the biotechnology industry

5.1 Patents

On October 1997 three purified water firms (plaintiffs) filed a complaint before the Federal Competition Commission (FCC, or the Commission) against another purified water firm (defendant). The plaintiffs explained that the defendant had been granted an exclusivity contract by the inventor to market the "Punzo-Flex" system in two towns in the state of Oaxaca. The system consists of an outlet with a plastic membrane and valve at the bottom of a 19 litre water container, that facilitated the drawing of water. The patent to this system was granted to an individual on June, 1997.

The plaintiffs claimed that consumers preferred this new container so much that they were not willing to buy water recipients without this valve. This situation endangered their business prospects to such an extent that they would face bankruptcy soon. They also claimed that the exclusivity right granted to the defendant was displacing them from the market.

The FCC considered that according to Article 9 of the LPPIP, an inventor has the exclusive right to exploit his invention. Furthermore, Article 25 of the same Law establishes that this right grants its holder the power to prevent other persons from producing, using, offering for sale or importing the patented product without its permission. On the other hand, Article 5 of the FLEC does not regard as monopolies privileges granted to inventors for the exclusive use of their inventions. The FCC also considered that the introduction of the "Punzo-Flex" system in water containers introduces a product innovation that promotes competition and welfare of consumers.

Consequently, the FCC concluded that the decision of the inventor to grant a limited number of licenses was not a practice that violated the FLEC. On this basis, in December 1998, the FCC dismissed the complaint. The plaintiffs, however, filed a reconsideration appeal, which was finally dismissed by the Commission.[15]

In 2002, the FCC authorised a merger consisting of the sale of a part of Refremex and the acquisition by CBI of brands related to the products of Squirt, as well as rights and property over the required formulae to prepare these products. The relevant market was that of carbonated beverages and was national in its geographic scope.[16]

5.2 Biotechnology industry

A number of international mergers between firms originally involved in the chemical industry but now considered to be biotechnological have taken place over the last decade. The few cases in the biotechnology industry that the Commission has analysed relate to some of these mergers.

In 1997, it authorised a merger where Monsanto acquired stocks in Asgrow. The merger allowed Asgrow to have access to R&D, development, production and distribution of hybrid seeds in the Mexican market. The relevant market analysed was the production and marketing of hybrid seeds, particularly maize and sorghum, and the geographic scope for this operation was deemed to be national.[17]

In 1999, the FCC analysed a merger between Monsanto and Cargill. In Mexico Monsanto acquired Cargill assets in its hybrid seeds' business, including: monetary assets and liabilities, inventories, fixed assets, germoplasm, as well as intellectual property and intangibles in the maize and sorghum hybrids business. The FCC rejected the merger, considering that the operation would confer substantial market power to the interested parties.[18]

Also in 1999, the Commission authorised a concentration notification related to the operation previously described. It had as precedent the merger between Monsanto and Deklab Genetics Corporation and consisted of the acquisition by Monsanto of stock in two societies where it held a minority position. The operation would give it full control of both. The relevant market analysed was research, production and marketing of hybrid seeds for maize and sorghum.[19]

In 2002, the FCC analysed a merger notification between SC Jonson & Son (SCJ) and Bayer. The operation included the acquisition by SCJ of intellectual property assets and patents related to household pesticides and personal mosquito repellents, as well as household cleaning products and air fresheners (excluding patents for the active ingredients). The FCC did not authorise the operation as the position of the acquiring agent, together with the existence of barriers to entry, would confer it substantial market power that would facilitate anticompetitive practices.[20]

6. Concluding remarks

The FCC and IMPI have had little interaction, partly because the market has not attained a level of development where competition issues become common. For example, although industry insiders note that the ease of patenting can lead to a proliferation of patents that act as barriers to entry for many players, the patenting authority noted that there are remedies for these kinds of situations, licensing and even compulsory licensing. To date, the IMPI has not received a request for compulsory licensing.

In the case of the FCC, although the exercise of patent rights are excluded from prosecution by the law, wielding this market power in a separate market or using this market power to erect barriers in a different market would be situations that would warrant the attention of the competition authority. To date only one of the cases that the Commission has reviewed and closed, mentioned here, involve these kinds of allegations.

Nevertheless, there is a clear role for competition and intellectual property advocacy in this and other industries where intellectual property plays an important role in spurring investment and innovation. The benefits of patenting biotechnology (and other) research, need to be imparted to universities and companies alike; a role for the industrial protection agency. The possibility and advantages of transferring this technology through licensing agreements should also be known to industry participants as these promote the entrance of other competitors to the market, who, by performing follow-on research become drivers of innovation in the industry; a role that both the competition and patent authorities could share. Finally, the competition authority could promote competition policy and legislation among industry participants. Clarifying that although a patent does not constitute a monopoly in terms of the FLEC, anticompetitive practices arising from the misuse of this privilege are clearly in violation of the competition legislation, and ensuring that these situations come to the attention of the FCC will contribute to promote competition and free access to these fast-changing, research-intensive markets.

Tables

Table 1: Patenting Activity Indicators, 1999

Country	Dependency rate	Innovation coefficient	Dissemination rate	Patents in USA, 2001
Argentina	6.2	0.3	1.1	58
Australia	6.8	4.2	14.0	1,031
Brazil	25.7	0.1	3.5	125
Canada	15.9	1.3	32.8	4,063
Chile	5.9	0.1	n.a.	12
Czech Republic	75.0	0.6	6.3	16
Finland	59.1	5.1	47.9	769
France	8.6	2.3	23.2	4,456
Germany	3.0	6.0	15.0	11,894
Greece	1,662.5	0.1	40.9	26
Hungary	60.6	0.7	11.9	61
Iceland	1,186.7	1.3	0.0	19
Japan	0.2	28.2	1.6	34,890
Mexico	***25.6***	***0.1***	***7.2***	***87***
Portugal	1,969.5	0.1	19.4	12
Spain	65.5	0.6	14.9	340
Sweden	37.6	4.7	56.9	1,935
Turkey	160.0	0.0	19.7	11
United Kingdom	7.6	3.6	20.3	4,356
USA	0.9	5.4	17.0	98,663

Sources: *WIPO, Industrial Property Statistics 2000.*
Science & Technology Ibero-American Indicators Network (RICYT in Spanish), Main Indexes of Science and Technology, 2000.
US Patent & Trademark Office, 2001.

Table 2: Patent applications filed by Mexican nationals in Mexico

Year	Mexican nationals	Total	Share
1993	553	8,212	6.73%
1994	498	9,944	5.01%
1995	432	5,393	8.01%
1996	386	6,751	5.72%
1997	420	10,531	3.99%
1998	453	10,893	4.16%
1999	455	12,110	3.76%
2000	431	13,061	3.30%
2001	534	13,566	3.94%
2002	526	13,062	4.03%
2003	468	12,207	3.83%

Source: IMPI, 2003

Table 3: Patents granted to Mexican nationals in Mexico

	Mexican nationals		
Year		**Total**	**Share (%)**
1993	343	6,183	5.55%
1994	288	4,367	6.59
1995	148	3,538	4.18
1996	116	3,186	3.64
1997	112	3,944	2.84
1998	141	3,219	4.38
1999	120	3,899	3.08
2000	118	5,519	2.14
2001	118	5,479	2.15
2002	139	6,611	2.10
2003	121	6,008	2.01

Note: The difference between patent applications and patents granted is not the result of refusal to grant the patent but mostly due to the high number of applications that are abandoned and the large number of pending applications.

Sources: IMPI, 2003 and Informe General del Estado de la Ciencia y la Tecnología, CONACYT, 2003.

Table 4: Patent applications and grants in Mexico, by nationality of inventor – shares, 2002

Inventor Type	Mexican Nationals		Non-Mexicans	
	Applications	Granted	Applications	Granted
Independent	63.9%	32.4%	3.8%	3.0%
Large firm	30.0	38.8	95.4	96.4
Research Institute	5.7	26.6	0.6	0.3
Small firm	0.4	2.2	0.2	0.4
TOTAL	100.0	100.0	100.0	100.0

Source: IMPI, 2002

Table 5: Top ten Mexican patent applicants, 1996-2002

Firm or institution	1996	1997	1998	1999	2000	2001	2002	Total	Sales millions USD
Instituto Mexicano del Petróleo	16	15	14	25	8	18	24	120	-
Servicios Condumex, SA de CV (Grupo Carso)	10	13	6	8	4	5		46	4,679[1]
Universidad Nacional Autónoma de México	5	7	15	3			12	42	-
Centro de Investigación en Química Aplicada	5	7	6	8	4	4		34	-
Central Impulsora, SA de CV (Grupo Bimbo)			21			9		30	4,048[1]
Grupo P.I. MABE			4	9	6	4	6	29	249.5[2]
Cinvestav	4	3		4			5	16	-
Instituto de Investigaciones Eléctricas	4	8		3				15	-
Consorcio Grupo Dina S.A. De C.V.		4	6					10	886.6[3]
Universidad Autónoma Metropolitana	4	3	3					10	-

Notes: [1] 2003 sales. The figure corresponds to the holding group.
[2] 2002 sales.
[3] The firm closed in 2001. The sales figure corresponds to 1997.

Sources: *IMPI, 2002.*
Sales figures from: http://www.gcarso.com.mx/Carso/Archivos/EdosFin4T03.pdf;
Grupo Bimbo's 2003 Annual Report in:
http://www.grupobimbo.com.mx/relacioninv/uploads/reports/IA2003GB.pdf;
The Wall Street Journal, http://interactivo.wsj.com/documents/ae500-a.htm; and
http://www.expansion.com.mx/data/img/2003/EXP874/pdf028-3.pdf.

Table 6: Top ten non-Mexican patent applicants, 1996-2002

Firm or institution	Country	1996	1997	1998	1999	2000	2001	2002	Total	Sales millions USD
The Procter & Gamble Company	USA	182	423	533	641	420	416	396	3,011	43,377
BASF Aktiengesellschaft	Germany	70	152	160	182	112	146	221	1,043	42,575
Kimberly Clark Worldwide, Inc.	USA		149	168	174		95	296	882	14,348
Minnesota Mining and Manufacturing Company	USA	73	168	146	80				467	18,232
Bayer Aktiengesellschaft	Germany	73	99	81	143	165	136	246	943	35,548[1]
AT&T Corp.	USA	87	86	114	25				312	24,992
Pfizer Inc.	USA		95	67	134				296	45,188
Johnson & Johnson	USA	89	87	49	71			100	396	41,964
Hoechst Aktiengesellschaft	Germany	78	92	84					254	2,606[2]
Motorola Inc.	USA	63	67	43	37				210	27,058

Notes: [1] *Sales in 2002*
[2] *Sales in first half of 2003*

Sources: *IMPI, 2002.*
Sales figures for all companies except BASF and Bayer are 10K's for 2003 from www.sec.gov.
Sales figures for BASF from ; http://www.hoovers.com/basf-ag/--ID__41755--/free-co-factsheet.xhtml, for Bayer http://www.gfw-nrw.de/gfw/GfW.nsf/ContentByKey/A94AAB5CE2E2CC9CC1256D240046597E/$FILE/chemie-03.pdf, for Hoechst http://www.business.com/bdcframe.asp?ticker=G.HFA&src=http%3A//rd.business.com/index.asp%3Fbdcz%3Dc.l.cc.ml.e%26bdcr%3D0%26bdcu%3Dhttp%253A//www.hoechst.com/%26bdcs%3D52C38EFC-C161-4938-842E-62A7BD4B92C7%26bdcf%3D4ee82171-ba94-11d4-90ff-00805fa7885a%26bdcp%3D%26partner%3Dbdc%26title%3DHoechst%2520Aktiengesellschaft&back=http%3A//www.business.com/directory/pharmaceuticals_and_biotechnology/manufacturers/hoechst_aktiengesellschaft/&path=/directory/pharmaceuticals_and_biotechnology/manufacturers

NOTES

1. Excludes the U.S. since its number of patents would bias the average upwards.

2. http://www.wipo.int/clea/docs/en/wo/wo020en.htm and http://www.wipo.int/treaties/en/documents/word/d-paris.doc.

3. http://www.wipo.int/pct/en/index.html.

4. http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm. The relevant article is number 27, section 5, regarding Patentable Subject Matter.

5. Chapter 17: http://www.nafta-sec-alena.org/DefaultSite/legal/index_e.aspx?articleid=168#A1701.

6. Informe General de la Ciencia y la Tecnología, 2003, Conacyt.

7. If the applicant does not fulfill this requirement within a period of two months, the application is considered to be abandoned.

8. The information contained in this section is largely based on conversations with industry participants as well as from a document assessing Mexico's biotechnology industry, co-edited by the Ministry of Education (SEP) and the National Council of Science and Technology (Conacyt): *Biotecnología Moderna para el desarrollo de México en el siglo XXI: Retos y Oportunidades*, 2001, SEP and Conacyt.

9. Some of these issues are outlined in detail in the recommended readings for this roundtable, for example, the Federal Trade Commission's October 2003 report, "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy".

10. Figures come from *Biotecnología Moderna para el desarrollo de México en el siglo XXI: Retos y Oportunidades*, 2001, SEP and Conacyt (hereafter SEP-Conacyt document).

11. See Briseño Garzón, Adriana, "México, la biotecnología y la protección de la propiedad individual" in http://www.agrobiomexico.org.mx

12. According to the SEP-Conacyt document, in Mexico the patent granting process takes four years on average, p. 62.

13. The Autonomous National University of Mexico (UNAM) and the National Polytechnic Institute (IPN) are among the few institutions that have regulations and offices promoting incubation of biotechnology companies (p. 67 SEP-Conacyt document).

14. Namely, the Autonomous Metropolitan University at Iztapalapa (UAM-I), in Mexico City.

15. FCC case numbers DE-18-97 and RA-07-98

16. FCC case number CNT-238-2001.

17. FCC case number CNT-13-97.

18. FCC case number CNT-114-98.

19. FCC case number CNT-36-99.

20. FCC case number CNT-121-2002.

NEW ZEALAND

Introduction

This paper is New Zealand's response to the invitation to make a written contribution to the June roundtable on competition policy and intellectual property with a focus on the biotechnology industry.

1. The Proper Role of Competition Authorities in the Patent Process

- *Should competition agencies be involved in decisions concerning whether to award a patent, or concerning how to phrase the patent?*

There can be a tension between intellectual property and competition policy objectives. As such, we consider that competition policy principles should be considered in the design of patent legislation. For example, in specifying which inventions are patentable, the general scope and term of patents, and the level of fees for patent renewal. However, the vast majority of individual patent applications do not raise competition concerns due to the availability of substitutes. Therefore, the case for general involvement of a competition authority on an ex-ante basis in the patent application process is not strong.

In New Zealand, the statutory criteria for granting a patent under the Patents Act (novelty, non-obviousness and utility) are technical. No explicit consideration is given to competition issues and the Commerce Commission is not involved.

- *Should competition authorities be allowed to challenge the validity of questionable patents that have already been granted?*

Where national patent legislation allows any person to challenge the validity of a patent, we see no reason to exclude competition authorities from mounting such challenges. However, challenges by competition authorities should not displace challenges by private parties.

2. Patent Quality and Scope

- *Have agencies encountered any cases in which competition was affected by poor patent quality?*

The Commerce Commission has not encountered any such case. There are no recent reported cases in which this issue has been addressed by the courts.

- *Specifically, have agencies seen any indications that biotechnology patents are being awarded without meeting statutory requirements of patentability? Have agencies seen any evidence that biotechnology patents are defined too broadly or ambiguously?*

We are not aware of any indications that biotechnology patents are being granted in New Zealand without meeting the statutory requirements of patentability, or that New Zealand patents in this field are overly broad, or unclear in scope.

- *How do overly broad or ambiguous biotechnology patents affect competition?*

Overly broad patents (in any area of technology) can reduce competition by granting greater rights than the patent owner is entitled to. This may be because the patent covers areas not disclosed in the patent specification, or because the patent covers things that are already known. In both cases, the ability of competitors to develop their own competing technologies, or to make legitimate use of existing ones is reduced, leaving the patent owner with less competition in the market than might otherwise be the case.

3. The Anticommons Problem

- *Does a proliferation of patents – particularly with respect to patented biotechnological research tools that facilitate the discovery and production of downstream products – lead to a tragedy of the anticommons?*

We have not observed an "anticommons" problem in New Zealand (although this may be due to the fact that only a small fraction of the patents granted worldwide are actually applied for and granted in New Zealand). This could, however, be a problem for New Zealand companies intending to exploit their own products in other, larger countries.

4. Exemptions

From a competition policy standpoint, should there be exemptions to patent rights?

Exemptions to patent rights must be consistent with the relevant international Treaties, the most relevant provision being Article 30 of the TRIPS Agreement.

Experimental use exceptions are likely to be consistent with TRIPS. Lack of experimental use exceptions could stifle innovation if researchers are unable to afford or obtain licenses to conduct research on patented materials or products – this could delay or prevent the development of products or processes competing with already patented ones. This could be a particular problem with patented genes, as researchers working on these genes, perhaps to determine further uses or functions of the gene, or to develop alternative diagnostic tests using the gene, have no choice but to use the gene.

Since patents are national rights, there is no particular need to harmonise exemption standards across national borders (in any case, the Courts ultimately determine whether a particular activity falls within an exception). Countries that had more liberal exceptions, such as those for experimental use, may find that they were more attractive to researchers than those with tighter or non-existent exceptions.

5. Reach-through licensing agreements

- *What are the competition policy implications of licensing agreements that involve royalties based on the revenue generated by a downstream product that the licensed technology only helped to identify and develop, but not to produce or sell? Should it be a violation of competition law for a company to use its patent rights to extract profits from something other than what it has patented?*

Reach-through licensing agreements may be caught by the prohibitions against anti-competitive conduct in the Commerce Act. The Commerce Act does provide for the exclusion of intellectual property rights from the ambit of the Restrictive Trade Practices provisions in the Act, but only insofar as the intellectual property right is a "statutory right". A statutory intellectual property right is conferred by one of the listed pieces of legislation. If a company has not patented the product or otherwise acquired it under one of the listed instruments, then any agreement entered into pursuant to that right could be tested under the provisions of the Commerce Act. Under an earlier formulation of section 45 the exemption applied to

provisions relating to the use, licence or assignments of rights under or existing by virtue of any copyright, patent, protected plant variety, registered design, or trade mark. The current formulation is far narrower.

6. Patent Pools

- *Patent pools arise when patents held by two or more parties are licensed as a package. What are the positive and negative ramifications of patent pools for competition policy? Might they help to ameliorate an anticommons problem in the biotechnology industry? Which characteristics of patent pools are pro-competitive, and which are not?*

Depending on the terms of the licensing agreement and the nature of the parties involved in the patent pool, the pool may fall foul of prohibitions against practices substantially lessening competition and could encourage monopolistic behaviour. Such pools may require members to use technology forming part of the package. Even where members are not required to use such technology, the fact that they will have paid for it as part of a package could operate as a disincentive to use alternative technology of competitors who are not members of the pool. A patent pool may also prejudice licensees by forcing them to pay for licensees which they do not require and may never exploit. The competition effect of a patent pool may depend on the number of licenses to be granted by the patent holders and the number of members of the pool. If this number is limited, a situation could arise where license holders do not exploit all aspects of the package but effectively prevent their competitors from doing so.

7. Unilateral Refusals to License

- *How have the competition authorities analysed unilateral refusals to license, both in general and in the biotechnology sector?*

The Commerce Commission has not been faced with the issue of unilateral refusals to licence in recent times.

Section 46 of the Patents Act in New Zealand includes provisions for compulsory licences where "a market for the patented invention is not being supplied, or is not being supplied on reasonable terms, in New Zealand." This compulsory licence is sought by application to the High Court.

- *Does the biotech industry have any characteristics that distinguish it from other industries for purposes of this analysis? For example, does the fact that many biotechnology patents are granted for research tools rather than commercial products have any bearing on the analysis of unilateral refusals to license? What if the patent covers a tool that is relied upon by a range of competitive research instruments and products?*

In its current formulation there is nothing in section 46 of the Patents Act which provides for special treatment of biotech patents.

NORWAY

1. Introduction

The tension between intellectual property rights and competition policy has long been recognised. Because an intellectual property right confer exclusivity upon its owner, whereas competition law strives to keep markets open, there is seemingly a conflict between these two areas of law.

An important issue is whether too many patents are granted, or whether they are defined too broadly or worded so ambiguously that it is difficult to determine their scope. If this is the case, the problem may be addressed to the legislator, which may restrict the possibility to obtain patents and/or restrict the possibility of being granted too broadly defined patents. Alternatively, if possible based on the present legal framework, the public authority, which grants patents, may pursue a more restrictive interpretation and/or a more restrictive practice of granting patents.

In the handling of actual cases, the competition authorities may encounter a variety of potentially anticompetitive conduct related to patent rights, e.g. by unilateral refusals to licence. The competition authorities may encounter such questions to a larger or a lesser extent depending on inter alia the answer to the above mentioned issue of whether too may patents are granted or not.

Thus, connected to the above an important question is to which extent the competition authorities may impose the patentee to grant licence to others on a compulsory basis. To the extent that the competition authority has such an authority the competition authority may consider and balance the conflict between competition policy and the exclusivity of patents on a case-to-case basis.

In Norway, there has recently been made changes in the Norwegian Patent Act, which inter alia imply that the authority to grant compulsory licences in general is conferred to the Norwegian Competition Authority (hereinafter referred to as "NCA") besides the courts. In the following we will particularly give an outline of these rules. In addition and at first we will give an overview of the extent to which the NCA may grant compulsory licences based on the regular competition rules. Norway adopted a new Competition Act with effect from 1 May 2004, which harmonises inter alia the prohibition against abuse of dominance with EC competition rules. This amendment also implies some changes in the NCA's ability to impose compulsory licence.

The issues that will be dealt with below are relevant to patents related to the biotechnology industry as well as other industries.

2. Currently applicable law – EC law, the EEA-agreement and national law

A patent is not incontestable pursuant to the competition legislation.

A unilateral refusal of granting a person or an undertaking a licensing agreement can fall within the scope of EC art 82. An equivalent provision is applicable for undertakings in Norway pursuant to the EEA-agreement art. 54 in so far as it may affect trade between the Contracting Parties. Furthermore the Norwegian Competition Act section 11 contains a similar prohibition that is supposed to be interpreted in the same way as EC art 82.

An intellectual property right confers an exclusive right upon its owner. EC article 82 prohibits the abuse of a dominant position. The question is whether article 82 can be applied in such a way as to limit the exclusive rights given by intellectual property law. The ECJ has made it clear that mere ownership of intellectual property rights cannot be attacked under article 82, but article 82 may apply to an improper exercise of the right in question. The question has been to what extent the owner of an intellectual property right can be compelled to grant a compulsory license to a third party under article 82.

ECJ stated in the so called Magill case (cases C-241/91 and 242/91, [1995] ECR 1-743) that there was an abuse of a dominant position when three television companies relied on copyright to stop publication of a comprehensive weekly guide by Magill TV Guide Ltd. They each were deemed to have de facto monopoly in the market for weekly listings that was turned into a legal monopoly by copyright. The Commission required the necessary information to be supplied by licence to third parties subject to payment of reasonably royalty, and both the CFI and the ECJ upheld the decision.

The ECJ's decision in the Magill case has been criticised, and it is even argued that the ECJ should have rejected altogether the possibility of compulsory licences under article 82, because this may reduce the incentives for others to create new products, which is an important part of the competitive process.

However, based on later judgements by the Community Courts, it seems clear that the possibility of a compulsory license under article 82 can not be excluded, even though it is stated that the principles in the Magill case is only applicable in exceptional circumstances.

3. Directive 98/44/EC on the legal protection of biotechnological inventions

Directive 98/44/EC (hereinafter referred to as "the directive") on the legal protection of biotechnological inventions regulates the possibility to be granted a patent for an invention containing genetic material, either a product containing genetic material or the procedure for processing such a product. The aim of the directive is to make biological inventions equally patentable as other inventions. The Member States of the EEA shall protect biotechnological inventions under national patent law, and shall, if necessary, adjust their national patent law to take account of the provisions of the Directive.

The directive was implemented into Norwegian law by amendments in the Norwegian Patent Act (hereinafter referred to as "the Patent Act") and in the Norwegian Plant Breeder Act, with effect from 1 February 2004.

The directive does not necessitate an alteration of the regular criteria for patentability under Norwegian law. According to the Patent Act it is possible to be granted a patent, provided that the invention meets the regular criteria for patentability like novelty, inventive merit and capability of industrial application. However, the Norwegian legislator states in the preparatory work related to the said amendments that the regular criteria for patentability and the scope of the protection shall be practiced in a restrictive way in order to prevent that patents entail disproportionate restrictions in others possible exploitation of biological material.

According to the directive article 12 it was necessary under Norwegian law to adopt statutory rules regarding compulsory licence for plant variety rights that may infringe already existing patents and vice versa. However, the directive does not require implementation of rights to compulsory licence based on other possible grounds. It neither requires which public authority should be eligible to impose a patent holder to licence to a third party.

Notwithstanding the directive did not require implementation of further provisions related to compulsory licence, the Norwegian government chose to use the opportunity to make other material changes in the Patent Act with respect to compulsory licence.

4. The new rules regarding compulsory licence in the Norwegian Patent Act

The Patent Act has conferred authority to grant compulsory licence in general to the Norwegian Competition authority, provided application by a third party.

Until recently solely the courts exercised this authority. The reason for also conferring this authority to the NCA, is the NCA's experience in assessing competition issues, which is relevant in a lot of the cases regarding compulsory licence. In addition it was decided to give the NCA authority to grant compulsory licences in general due to the fact that there has been very few applications for compulsory licence pursuant to the Patent Act. The fear of a complicated, time-consuming and expensive court case has probably caused this.

However, the recently acquired new authority for the NCA is only an alternative to a decision made by the court. It's not necessary to have the question examined by the NCA before bringing it for the court. The applicant may in other words bring the question directly to the court. A decision by the NCA may on the other hand be brought in for the courts as a guarantee of due process of law.

There has also been given some new procedural rules in the Patent Act concerning the new tasks for the NCA related to compulsory licence. Among others the applicant is obliged to pay a fixed fee to the NCA for the handling of an application. It is proposed to fix the fee to NOK 10,000 in order to avoid unfounded applications. In addition the Patent Act provides the NCA the right to impose other public bodies to provide the NCA with any information requested in patent matters. The NCA may also impose any private subject to provide the NCA with necessary information related to the handling of cases, and the NCA may call the parties for an oral hearing.

As mentioned above the NCA is given authority to grant a compulsory license on a wider range of grounds than necessary to meet the requirements in directive 98/44/EC article 12. The NCA is supposed to handle patents within all different areas, and not only patents regarding biotechnology, even though the directive leading to the amendments of the law is all about patents and biotechnological inventions.

Even though many cases will involve technical matters beyond the NCA's core area, it was considered to be more efficient if the NCA could grant compulsory licenses pursuant to all the different provisions of the Patent Act. The system would be less effective than intended if the different provisions for granting compulsory license should be enforced by different public authorities possessing different kinds of expertise. However, as mentioned above, the NCA is provided with authority to gain necessary information and technical assessments from other public authorities, e.g. from authorities with expertise within the particular field. This will ensure that the NCA is adequately and sufficiently informed when examining the cases and granting compulsory licenses pursuant to all the different provisions in the Patent Act.

A compulsory license means that a third party is given permission to utilise a patent without the patentee's consent. In order to be granted a compulsory licence, the applicant has to fulfil certain criteria. A licence agreement is normally based on consent with the patentee. Before a compulsory licence can be given, the applicant therefore must have tried to reach an agreement with the patentee on competitive terms. The applicant also has to be capable of exploiting the invention in a sensible way and in accordance with the license.

Provided fulfilment of among others the conditions mentioned above, the NCA is entitled to grant compulsory license if the patent is being neglected for three years, cf. Patent Act section 45, if exercise of a patent is dependent of access to another patent, cf. Patent Act section 46, if a plant variety rights cannot be exercised without infringing an existing patent, cf. Patent Act section 46a, if the patent is exercised in a

way that significantly restricts competition, cf. section 47(2), if the invention has been used by somebody who was unaware that somebody else had applied for a patent, cf. section 48, or if the invention represents significant technical progress of crucial importance and a licence is essential with regard to important public interests, cf. section 47(1).

The evaluations that have to be made pursuant to the Patent Act sections 45 and 47(1) and (2) will often involve economic assessments and competitive conditions, which are usually undertaken by the NCA. On the other hand a compulsory license according to the Patent Act sections 46 and 46a will more often involve technical matters.

5. Compulsory license when the exercise of the patent restricts competition

Pursuant to the Patent Act section 47(1), a compulsory license will be granted if it is considered necessary with regard to the public interest. Preventing behaviour that restricts competition is an aspect falling within the scope of section 47(1). Section 47(1) is therefore to a certain extent overlapping the Norwegian Competition Act section 11.

The need to control possible abuses of patents is most important when access to inventions of crucial importance to society is refused because the patentee is unwilling to grant a licence agreement based on consent or the patentee is not exercising the patent. Under such circumstances, compulsory licence is an effective measure for the society to get access to the invention. This situation falls within the scope of the Patent Act section 47(1). Furthermore the Patent Act section 45 will be applicable if a patentee is neglecting the patent. The scope of the two sections will often overlap and it is conceivable that both sections 45 and 47 can be invoked as grounds for a compulsory licence in the same case.

In connection with the recent amendments in the Patent Act there was also made a change in section 47, which now explicitly states in second paragraph that compulsory licence may be granted if the patent is exercised in a way that may result in significantly impediment to competition. A compulsory license can therefore be granted pursuant to both section 47(1) and (2).

Section 47(2) is only supposed to be used when patents are being abused. Furthermore the misuse has to be deemed to affect public interests.

It is not crucial that the misuse has affected the undertaking or person demanding compulsory license. The criterion for granting a compulsory license is that competition is significantly impeded, and the NCA has to consider whether other measures would be as efficient as a compulsory license, but less infringing to the patent holder. A demand for a compulsory license will not prevent the NCA from imposing an amendment of the general conditions in the licensing agreement to the patentee.

6. Conclusion

For the time being the NCA has no practice in applying the rules regarding compulsory licence in the Patent Act. Another important aspect is that the legislator in the preparatory work provides that the new Patent Act section 47 (2) shall be interpreted in the light of the case law under EC art 82. However, the wordings in section 47 (2) seems to give the NCA more flexibility in assessing possible abuses related to patents, than follows from EC art. 82, EEA-agreement art. 54 and the Norwegian Competition Act section 11.

SWITZERLAND

À titre préliminaire, la délégation suisse tient à relever que dans notre pays les brevets constituent de fortes incitations aux investissements dans la recherche et le développement.

L'industrie biotechnologique suisse est l'une des plus dynamiques d'Europe (Ernst & Young 2003). C'est un secteur avec une forte activité de recherche et de développement, qui enregistre des taux de croissance élevés et présente un fort potentiel d'innovation. De plus, un nombre croissant de demandes de brevet émane de cette industrie.

La Suisse est l'un des rares pays européens à avoir été très marginalement touché par le récent ralentissement qui a frappé l'industrie biotechnologique. Elle est ainsi en Europe, après la Suède, le pays dans lequel la densité des sociétés biotechnologiques indépendantes par habitant est la plus élevée (Allansdottir et.al, table 4.1).

Les brevets et les licences sur les inventions biotechnologiques sont considérés comme un puissant moteur de la recherche, des flux de savoir et de la mise sur le marché de nouvelles techniques.

À titre d'exemple, la Suisse dépose davantage de demandes de brevet par habitant pour protéger des inventions en Europe (OEB), aux Etats-Unis et au Japon que n'importe quel autre pays au monde.

1. The Proper Role of Competition Agencies in the Patent Process

What role should competition authorities play in the development of patent policy or in the patent granting process, if any?

a) For example, should competition agencies be involved in decisions concerning whether to award a patent, or concerning how to phrase the patent?

b) Should competition authorities be allowed to challenge the validity of questionable patents that have already been granted?

c) How can competition agencies, whose primary expertise is not in IP, effectively determine the scope and assess the validity of complex patents?

d) Should competition agencies simply establish good communication with IP agencies and play only an indirect role in the formulation and implementation of patent policy?

Selon la loi, les autorités suisses de la concurrence ne peuvent ni participer aux décisions relatives à l'octroi des licences ni s'opposer aux licences octroyées.

Selon la Loi fédérale sur le statut et les tâches de l'Institut Fédéral de la Propriété Intellectuelle, ce dernier (ci-après: IPI) a la charge de toutes les questions concernant la propriété intellectuelle en Suisse. Il est le centre de compétences de la Confédération pour toutes les questions concernant les brevets, les marques, les designs et le droit d'auteur. Les décisions de l'IPI peuvent faire l'objet d'un recours devant la Commission de recours en matière de propriété intellectuelle. La décision de celle-ci pourra ensuite être attaqué en dernière instance devant le Tribunal fédéral.

En pratique, entre les autorités de la concurrence et l'IPI, une bonne communication est d'ores et déjà établie, même si la Commission de la concurrence (ci-après: Comco) ne peut jouer aucun rôle, même indirect, dans la formulation et dans la formation de la politique des droits de propriété intellectuelle.

La Comco ne peut intervenir que lorsqu'un contrat de licence peut être perçu comme une restriction actuelle ou potentielle de concurrence. En soi, l'octroi d'une licence est plutôt susceptible d'intensifier la concurrence, dans la mesure où il peut contribuer à augmenter le nombre d'acteurs en mesure d'exploiter le bien immatériel sous licence.

Cependant, bon nombre de contrats de licence sont susceptible de remplir les conditions de l'art. 4 al. 1 de la Loi sur les cartels (LCart), ce qui justifie qu'ils soient qualifiés d'accords en matière de concurrence et dès lors inclus dans le champ d'application de la LCart[1].

Il y a deux manières par lesquelles les contrats de licence peuvent entrer dans le champ d'application de la LCart:

- soit ils constituent des accords illicites en matière de concurrence (art. 5 LCart) ;
- soit ils mettent en présence une ou plusieurs entreprises puissantes sur le marché (art. 7 LCart).

Il faut alors, d'une part, que la restriction à la concurrence soit notable pour qu'elle puisse tomber sous le coup de la loi sur les cartels, c'est-à-dire que les effets des droits exclusifs doivent être d'une certaine intensité sur la concurrence. D'autre part, l'exclusivité ou le monopole de fait ou de droit attachés à un bien immatériel ou un droit de propriété intellectuelle, qui ne sont pas synonymes de position dominante, doivent contribuer à conférer une position dominante, dont le titulaire peu le cas échéant abuser. Seules les pratique abusives peuvent être considérées comme illicites.

Les comportements des entreprises ayant une position dominante sont abusifs s'ils limitent artificiellement l'accès au marché, sans que cela résulte de l'évolution normale de celui-ci. Peuvent notamment constituer des comportements susceptibles de constituer un abus de position dominante dans la mesure où ils ne sont pas justifiés par un intérêt commercial légitime:

le refus d'entretenir des relations commerciales (art. 7 al. 2 lit. a LCart). S'il n'y a pas une obligation générale de contracter à la charge de l'entreprise en position dominante, il peut y avoir, dans certaines circonstances, un abus à ne pas vouloir entretenir des relations d'affaires (cfr. point 7);

la discrimination de certains partenaires (art. 7 al. 2 lit. b LCart). Le traitement des partenaires ne doit pas être rigoureusement identique. Ce que la loi demande, c'est que les prestations en faveur de partenaires se trouvant dans des situations comparables face à l'entreprise dominante soient sensiblement équivalentes;

- l'octroi d'une exclusivité sur l'acquisition ou la vente de certains biens ou services;

- les limitations de production, de débouchés ou de développement technique (art. 7 lit. e LCart). L'entreprise titulaire d'un droit de propriété intellectuelle commet un abus, par exemple, lorsqu'en décidant de ne plus produire le produit sur lequel elle détient un droit exclusif tente de restreindre par-là la production de ses concurrents.

La Comco n'a guère d'expérience en ce domaine; elle n'a pas connu de cas qui ont permis d'appliquer ces règles par rapport aux droits de propriété intellectuelle. Cependant, dans deux cas de concentrations

d'entreprises, la Comco a autorisé les concentrations moyennant des conditions qui ont une relation avec les droits de propriété intellectuelle. Dans la fusion des entreprises pharmaceutiques Pfizer Inc./Pharmacia Corp (RPW 2003/2 366), la Commission de la Concurrence a imposé la vente de produits et de droits de propriété intellectuelle à des tiers et dans la fusion Glaxo WellcomePLC/SmithKline Beecham PLC (RPW 2001/2 338) elle a aussi imposé aux entreprises de donner les licences de certains produits à des tiers pour qu'il n'y ait pas d'addition de part de marché et pour donner ainsi la possibilité à des tiers d'entrer sur le marché.

2. Patent Quality and Scope

The biotechnology industry is relatively new, complex, and rapidly evolving. Concerns about patent quality and scope have been raised in such industries, meaning that patents may sometimes be granted for technologies that probably should not receive patents because they do not meet statutory criteria, while other inventions may be eligible but the patents themselves are worded too broadly or ambiguously. How does the level of patent quality affect competition in the biotechnology industry? The following are more specific questions that can be raised in connection with patent quality and patent scope:

a) Have agencies encountered any cases in which competition was affected by poor patent quality? Please describe.
b) Specifically, have agencies seen any indications that biotechnology patents are being awarded without meeting statutory requirements of patentability? Have agencies seen any evidence that biotechnology patents are defined too broadly or ambiguously?
c) How do overly broad or ambiguous biotechnology patents affect competition?
d) In what ways does patent ambiguity (*i.e.*, difficulty in determining what a patent does and does not protect) make competition law enforcement more difficult? For example, does it matter that patent ambiguity might make it harder to determine the nature of competitive relationships between biotechnology companies?

a) No.
b) Swiss national applications are not subject to a novelty search, most of the biotechnology patents in Switzerland derive from European Applications with a nomination of Switzerland. There are no Swiss national cases of too broad or ambiguous patents in the field of biotechnology.
c) This is a matter of the legal uncertainty created by ambiguous patents. Challenging those patents would raise transaction costs and legal costs, restrain research and consequently limit competition.
d) The patent is a legally established exemption to competition rules. Thus, not the patent as such can violate competition rules, but only its abusive use (cf. the Myriad case).

In general, poor patent quality can lead to a reduction in investment and commercialisation of an innovation. It can slow progress in cumulative technologies and increase the level of rights fragmentation. The correct application of patentability criteria would help to increase the quality of patents. Patents which do not comply correctly with the patentability criteria give more cause for competitors to complain. Therefore, poor quality patents are likely to encourage infringement and litigation.

3. The Anticommons Problem

Does a proliferation of patents -- particularly with respect to patented biotechnological research tools that facilitate the discovery and production of downstream products -- lead to a "tragedy of the anticommons"? In other words, is there already such a tangled web of IP rights in biotechnology that companies face an inordinate burden when trying to develop products that depend on numerous supporting patents held by a multitude of other parties? If so, this would mean that patents may actually be discouraging innovation rather than promoting it. Have competition agencies observed an anticommons problem in any of their cases?

Heller and Eisenberg (1998) describe the 'tragedy of the anti-commons' as a situation where the necessary knowledge to conduct further research is covered by a large number of patents held by many firms. Transaction costs become too high to collect all the relevant information for further research, which results in an under-use of patented biotechnological information (anti-common). The preconditions for the anti-commons are a growing number of patents, many biotechnology firms, increasing university patenting and the use of defensive patenting which decreases the freedom to operate. The anti-commons could theoretically be the reason why the patent system can impede the combination of new ideas and inventions by raising transaction costs for follow-on innovation and by providing an opportunity for rent seeking.

A recent survey with the Swiss biotechnology industry could not confirm the existence of the anticommons problem (Thumm 2003). The survey results could neither confirm the break-down nor a systematic abuse of the existing patent system for biotechnological inventions in the case of Switzerland. The survey findings, however, could confirm that patents are an important factor for innovation in their existing form and that they provide an essential incentive for biotechnological inventions.

The Swiss competition authorities have never observed any kind of anticommons problems.

4. Exemptions

From a competition policy standpoint, should there be exemptions to patent rights? For example, should universities have exemptions for the purpose of conducting research? What other exemptions should be permitted, and under what circumstances? Would it make sense to harmonize positions across national borders, assuming that some markets are worldwide? What effects would follow, if any, if exemption standards are divergent?

In Switzerland moderate problems involving DNA patents were identified as: (1) strong dependency on previous patents (crowded art); (2) patents that lock access to technologies; and (3) difficulties to enter a technological field because of too many patents and conflicts with overlapping patents (Thumm, 2003, Figure 34).

Participants in the mentioned survey consider a broad research exemption and a limitation of the scope of protection of DNA patents to the specific disclosed functions as solutions (Thumm 2003, Figure 35, 36 and 39).

Furthermore, a clinical use exemption could be taken into consideration. This, however, is more a public health issue than competition issue.

Harmonisation would be desired. Different regulations in different countries either attract (research depends on the use of foreign research) or move away (the protection of own research is more important than the use of foreign research) research from certain locations. In this way a research exemption regulation could constitute a strategic advantage/disadvantage for a location.

5. Reach-through Licensing Agreements

What are the competition policy implications of licensing agreements that involve royalties based on the revenue generated by a downstream product that the licensed technology only helped to identify and develop, but not to produce or sell? Should it be a violation of competition law for a company to use its patent rights to extract profits from something other than what it has patented?

En pratique, la Comco n'a jamais analysé un tel contrat de licence, mais il est admis que le breveté a un intérêt à la fixation du prix, puisque le montant de sa redevance en dépend. Le versement de la redevance (contrepartie) ne devrait donc pas dépendre de l'usage que le preneur de licence fait du brevet (développement ou production et vente). Néanmoins, il se peut que la recherche et le développement puissent être freinés si le montant des royalties est trop élevé par rapport à l'usage que le preneur de licence fait du brevet.

Il s'agit donc de déterminer le prix de départ du licencié, mais non les prix aux stades suivants du commerce, car ceux-là ne sont pas couverts par l'existence du droit de protection et cela constituerait une restriction de la concurrence. Donc la faculté de fixer des prix imposés fait partie de l'existence du brevet. L'imposition des prix reste admissible comme un moyen de protection du breveté contre une concurrence effrénée de son/ses licencié/s.

Du point de vue de la concurrence, les contrats de licence qui fixent, directement ou indirectement, le prix minimum ou final auquel le preneur de licence doit offrir la prestation sous licence à des acteurs situés au stade suivant de la distribution (prix imposés du deuxième échelon) peut constituer une restriction importante de concurrence.

En effet les acteurs, du côté de la demande, voient leur faculté d'influencer le prix par leur comportement d'acheteurs/consommateurs réduite, voire supprimé. Ensuite, lorsque les prix sont imposés à tous les licenciés, les acteurs de l'échelon suivant voient également leur liberté de choisir leur fournisseur en fonction du prix restreinte ou effacée.

A noter que, selon leur niveau, des prix de revente imposés à tous les licenciés peuvent même barrer l'accès d'un marché aux acteurs de l'échelon suivant ou les exclure d'un marché. Enfin, le partenaire auquel le prix est imposé n'a plus la faculté de déterminer librement l'un des paramètres essentiels de son activité économique.

Du point de vue de leur licéité, on notera que les clauses de prix sont présumées supprimer toute concurrence lorsqu'elles sont incluses dans des licences horizontales (art. 5 al. 3 lit. a LCart) ou verticales (art. 5 al. 4 LCart). Selon le système de l'art. 5 al. 3 LCart, une preuve contraire est néanmoins ouverte aux parties à l'accord litigieux. Si une telle preuve ne peut pas être apportée, la clause est alors illicite (art. 5 al. 1 LCart). Si cette preuve est apportée mais que l'accord de prix minimum représente néanmoins une restriction notable de la concurrence, les parties conservent la faculté de démontrer que cette restriction peut être justifiée par des motifs d'efficacité économique. A priori, à rigueur de texte, il paraît difficile de trouver à l'art. 5 al. 2 lit. a LCart une justification pour une clause fixant un prix minimum. Cela étant, le Conseil fédéral considère que les prix imposés du deuxième échelon peuvent être justifiés lorsque la clause qui les impose vise le maintien ou la garantie de la qualité des produits et du service à la clientèle (Vulliety, SJ 2000 II 545). Le Conseil fédéral vise à ce propos le premier motif d'efficacité économique évoqué à l'art. 5 al. 2 lit. a LCart (i.e. réduction des coûts de production ou de distribution).

6. Patent Pools

Patent pools arise when patents held by two or more parties are licensed as a package. What are the positive and negative ramifications of patent pools for competition policy? Might they help to ameliorate an anticommons problem in the biotechnology industry? Which characteristics of patent pools are pro-competitive, and which are not?

Under a patent pool, an entire group of patents is licensed in a package, either by one of the patent holders or by a new entity established for this purpose. Patent pools are a possible remedy against the abusive uses of strategic patenting, against patent thickets and royalty stacking. They help to integrate complementary technologies, reduce transaction costs, clear blocking positions, avoid costly infringement litigation and promote the dissemination of technology.

Unfortunately patent pools are still rarely used in biotechnology[2]. To establish and run patent pools efficiently, and to promote their general advantages, some conflict potentials and possible disadvantages, like their misuse as a price-fixing mechanism, have to be taken into account and a number of recommendations should be considered (cf. Blind et al. 2002). Patents should be pooled early in order to avoid constellations with two or more pools driven by different interests. It has proven useful to include public non-profit research institutes as a key gravitational force for creating patent pools, since they can more easily balance the often controversial interest of the companies. Blind et al. concluded that it also has been useful to involve companies in patent pools which are successful in distributing new products and technologies since this can guarantee the successful acceptance of a new standard in the market.

Swiss biotechnology companies have very few experiences with patent pools (Thumm, 2003, Annex 23). Furthermore, biotechnology entities in Switzerland are cautious about collaborating with competitors which might be one reason why companies do not use these remedies. However, the companies indicate that anti-trust concerns are not the reason for their disconcern (Thumm 2003, Figure 27).

7. Unilateral Refusals to License

How have the competition authorities analysed unilateral refusals to license, both in general and in the biotechnology sector? Does the biotech industry have any characteristics that distinguish it from other industries for purposes of this analysis? For example, does the fact that many biotechnology patents are granted for research tools rather than commercial products have any bearing on the analysis of unilateral refusals to license? What if the patent covers a tool that is relied upon by a range of competitive research instruments and products?

La Commission de la concurrence n'a pas de pratique établie à ce sujet. Néanmoins, l'art. 7 al. 2 lit. a LCart prévoit que le refus d'entretenir des relations commerciales, dans la mesure où il n'est pas justifié par un intérêt commercial légitime, peut constituer un comportement susceptible de constituer un abus de position dominante. Cela étant, on peut concevoir que des qualifications techniques ou une activité économique insuffisante de l'intéressé peuvent constituer des motifs objectifs (et valables) de refus.

De nombreuses entreprises sont attirées par la perspective de dominer le marché grâce à la seule qualité intrinsèque de leur droit de propriété intellectuelle et refusent d'accorder des licences à leurs concurrents réels ou potentiels. Si le refus d'accorder une licence d'utiliser des droits de propriété intellectuelle émane d'une entreprise qui est en position dominante grâce à ces droits, ce comportement peut être constitutif d'un abus.

Le refus de contracter du titulaire d'un droit de propriété intellectuelle n'est abusif que dans des cas doublement exceptionnels. D'une part, la simple détention d'un droit de propriété intellectuelle doit être caractérisée par le caractère exclusif du droit conféré à son titulaire et n'engendre en règle générale pas, en tant que telle, une présomption de position dominante. Ce n'est que dans des cas exceptionnels, où l'objet protégé par le droit de propriété intellectuelle constitue lui-même un marché parce qu'il n'existe pas de produit ou service substituable, que le titulaire du droit occupe une position dominante. Il faut aussi

considérer l'hypothèse où l'ensemble des fabricants de produits substituables détient une position dominante collective. D'autre part, un abus ne peut résulter de la seule détention d'un droit de propriété intellectuelle, mais seulement, et exceptionnellement, des conditions et modalités d'exercice de ce droit.

Exceptionnellement, il y a abus lorsque le refus de concéder une licence d'un droit de propriété intellectuelle, contre rémunération:

(i) porte sur un produits ou service qui est indispensable pour l'exercice de l'activité exercée ou envisagée par l'entreprise requérante,

(ii) en ce sens qu'il n'existe aucun substitut réel ou potentiel,

(iii) que le refus empêche la requérante d'entrer sur le marché ou d'y rester ou qu'il empêche la requérante de mettre au point un produit nouveau, malgré une demande potentielle spécifique constante et régulière des consommateurs, de sorte qu'il exclut toute concurrence sur le marché de la part de l'entreprise requérante, et

(iv) lorsque ce refus n'est pas justifié par des considérations objectives.

Dans de tels cas, le titulaire du droit de propriété intellectuelle peut être contraint d'accorder une licence, contre une rémunération équitable.

À titre d’exemple, le refus de donner en licence le droit d'utiliser une technologie nouvelle peut être le moyen pour ne pas s'imposer face à des concurrents qui accordent des licences à tout intéressé.

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NOTES

1. Aux termes de l'art. 3 II LCart, la LCart n'est pas applicable aux "*effets sur la concurrence qui découlent exclusivement de la législation sur la propriété intellectuelle*."

   La LCart ne s'applique donc pas pour les restrictions découlant *exclusivement* de l'exercice des droits conférées par la législation sur la propriété intellectuelle (soit les restrictions étroitement liées aux fonctions essentielles que la législation assigne à un bien immatériel). Le droit exclusif faisait l'objet d'une protection absolue. La LCart s'applique, par contre, pour les *autres restrictions* découlant (aussi) de l'exercice des droits conférés par la législation sur la propriété intellectuelle. L'exercice du droit exclusif doit céder le pas aux impératifs de la LCart s'il constitue un accord illicite (art. 5 LCart) ou un abus de position dominante (art. 7 LCart). En Suisse, l'épuisement national prévaut en droit des brevets selon la jurisprudence « Kodak » du Tribunal fédéral (ATF 126 III 129) et donc pour éviter que les droits de propriété intellectuelle, en particulier des brevets, soient utilisés pour entraver les importations parallèles, le Parlement a affaiblit la réserve de l'art. 3 al. 2 LCart au profit des droits de la propriété intellectuelle en ajoutant que les restrictions aux importations de produits protégés par un droit immatériel sont soumises à la loi sur les cartels. Le nouvel article 3 LCart, entrée en vigueur le 1er avril 2004, a donc été complété comme suit: "*En revanche, les restrictions aux importations fondées sur des droits de propriété intellectuelle sont soumises à la présente loi*" (art. 3 al. 2 2ème phrase LCart). Par "restrictions aux importations", il faut surtout entendre l'interdiction des importations parallèles: le titulaire du droit de propriété ne peut pas s'opposer aux importations parallèles, si l'exercice de son droit exclusif constitue une entrave illicite à la concurrence au sens de la LCart. Donc, l'art. 3 al. 2 LCart s'applique que pour les cas dans lesquels le titulaire d'un brevet bloque les importations parallèles sur la base d'une entente avec une autre entreprise (notamment par le biais d'accord verticaux), ou celui dans lequel il se trouve dans une position dominante dont il abuse.

2. Patent pools are more common in the field of information technology. An example for a successful patent pool is the MP3 format for music files developed under the framework of an EUREKA project as a cooperation between the German Fraunhofer Institute and companies like AEG, Bosch, Philips and Thompson. The success of the technology was due to an early stage planning of a patent pool.

TURKEY

1. Introduction

The Act on the Protection of Competition No:4054 (hereinafter, referred to as the Turkish Competition Act),which was passed by the Parliament on 13th December 1994, is equipped with all necessary tools to deal with all private anticompetitive practices like its modern counterparts. However, it does not contain any specific clauses on Intellectual Property Right (hereinafter, referred to as IPR) issues. Therefore, the Act is applicable with respect to IPRs cases through its existing tools. The Turkish Competition Act establishes a "system of protection for competition" based on both competition enforcement (prohibition of anticompetitive agreements, abuse of dominance and anticompetitive mergers, and an exemption system for anticompetitive agreements) and competition advocacy. The Turkish Competition Authority (TCA), being an independent body, has been implementing Turkish Competition Act since November 1997 with respect to all anticompetitive issues including those of IPR.

The TCA has a good deal of experience in the area of competition enforcement (in particular against hard-core cartels and abuse of dominance, regardless of public or private undertakings) and competition advocacy. But, our experience of application in the area of IPR cases is relatively limited. The TCA has dealt with a limited number of licensing and sub-contracting agreements on the basis of an exemption evaluation. This is true for the case of biotechnology industry. The TCA has dealt with a few cases regarding biotechnology and all of them are merger cases. However, with regard to IPR, the TCA has mainly attempted to follow the principles and case-law of the EC competition law as laid down in the Customs Union Decision of the Association Council between Turkey and the EU. Therefore, despite relatively limited number of IPR cases, it is still possible to share our views with regard to the interface of competition policy and IPR in a general perspective, and the biotechnology industry in particular.

2. IPR Protection and Its Economic Rationale

2.1 Characteristics of Knowledge and the Economic Rationale of IPR Protection

Being a central factor in the process of economic growth and development, the knowledge has very features that differentiate it from physical materials. Physical objects are typically rival goods. However, knowledge is not a rival good, as the use by someone does not limit or impede the use of the same knowledge by someone else. The other difference between them is the excludability which is basically associated with the property rights over a good. A good is excludable if the owner has the legal power to prevent others from using it. Generally physical goods are excludable and grant the owner an exclusive property right to benefit from them. However, it is generally not the case with the knowledge.

Goods with high levels of both excludability and rivalry are private goods. In this case, there are private incentives for production, since producers can fully appropriate the benefits arising from the use of these goods by others. However, goods with low level of both excludability and rivalry are generally regarded as public goods. Knowledge can be considered as being a public good with characteristics of low level of rivalry and excludability. The need to lead private persons or companies to innovate makes it inevitable to treat knowledge as a commodity. These characteristics of knowledge in economic terms are considered a significant source of market failure with regard to knowledge creation needed to increase the social welfare, and the protection provided by a strong system of IPR is an important candidate to cure this problem. In other words, IPRs are a method through which knowledge can be turned into a rival good. As production of an intellectual good requires a lot of resources and such resources have an opportunity cost

associated with them, the person producing an intellectual good would need compensation for his/her investment.

The choice of whether to have an IPR system or not is indeed a matter of policy. In other words, IPR system can be a substitute for the creation of knowledge by the public for the society. It is up to the government preference to make a choice between doing the job directly and making the job done by private bodies by providing further incentive via IPR protection. And generally, in economic system based on free market rules, the state is expected to withdraw from economic activities and only to create the necessary environment by certain regulations. It is the private sector which would invest in knowledge creation. IPR is one of strong instruments constituting this environment.

It is generally intended to prevent the commercial exploitation of intellectual goods without compensating their holders. Like other forms of property rights, IPR grant their holders a defensive right, which allows them to exclude others from using the protected intellectual good. IPR confer a monopoly right to their holders and thereby tempting the production of new knowledge. IPR helps solve a central tension in the development of knowledge—the process of developing knowledge is much more costly for the first person than it is for those that subsequently acquire the knowledge. In this sense, intellectual property rights provide an incentive for someone to want to be first[1].

2.2 IPR as an Agreement between the Right Holder and the Society

Contrary to conventional property rights, IPR are temporary rights. As an instrument of economic policy, IPR are used to direct Research and Development (Intellectual Property Rights (hereinafter, referred to as R&D) investments to knowledge-creating sectors. In this way, the right holder is obliged to publicly disclose his work in return for the temporary monopoly right. In doing so, new knowledge enters the public domain and allows subsequent innovators to use this knowledge for new inventions which in turn have to meet the criteria of protection. The dissemination of new knowledge at the marginal costs of transmitting this knowledge leads to a maximisation of welfare, because knowledge is non-rival in nature. Incentives for the creation of new knowledge have to be given by granting a temporary monopoly, because without the prospect of adequate returns, risky R&D investments that produce new knowledge will not be undertaken. It is suggested that IPR are a compromise between preserving the incentive to create knowledge and the desirability of disseminating knowledge at little or no cost. [2]

IPR represents a sort of agreement between the right holder (inventor) and the society (consumers). On the one side, *the need to protect the incentive to innovate*, and on the other side *the need to meet the societies' needs and requirement*. This agreement should be based on a balance. The main issue is not the existence of an agreement but who has more benefits from this balance. We must consider this balance as a starting point in any discussions regarding IPR and public interest. As a general proposition, the existence of IPR protection which makes the knowledge a commodity can be acceptable as long as it does not grant a high level of protection which could result in the final creation of a continuous monopoly.

It is argued that "stronger IPR provides stronger incentives for innovators, and increases the potential for local spill-overs from R&D. Costs are higher prices due to monopoly power thus created and an increase in the cost of follow-on innovation, which may reduce local R&D due to increasing transaction and other costs of acquiring prior technology. Choosing an optimal national policy depends on weighing these costs and benefits."[3]

Here we see that while the IPR protection eliminates the market failures with regard to knowledge creation and production, this tool is source of another market failure by definition: *It grants monopoly over the right in question*. The creation of a relatively right balance is also important to alleviate this resulting market failure. An important way to create this balance is related to how to design the relevant IPRS rules.

However, this way is significantly restricted by the existence of international agreements, which force the countries to have minimum standards of IPR protection. In this context, the balance could only be achieved as much as these standards allow. Accordingly, competition policy could be regarded as an instrument in the creation of a relatively right balance in this agreement. This role of competition policy is directly related to the interface of competition rules with the IPR rules, which will be dealt with below.

3. IPR and Biotechnology Industry

3.1 In General

The conclusion of the Uruguay Round negotiations culminated with the signing of the Marrakesh Agreement in April 1994. This Agreement established the World Trade Organisation (Intellectual Property Rights (hereinafter, referred to as WTO). One of the agreements, signed as part of the Marrakesh Agreement, was the Trade- Related Aspects of Intellectual Property Rights (hereinafter referred to as TRIPS). The TRIPS agreement is considered to be the most comprehensive and influential agreement on international intellectual property rights. Unlike most other international agreements on intellectual property rights, it establishes the minimum standards on IPR protection.

TRIPS envisages the principle of non-discrimination for any industry. In other words, The Agreement requires WTO Member States to grant patent protection to all inventions in any branch of technology. Article 27 which regulates the patent states that "….*Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.*[4] *(…) patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced…*". Apart from the exceptions stated in paragraph 2 and 3 of the article, all inventions, products and processes in all fields of technology can benefit from the patent protection, if they meet the necessary conditions of novelty, inventive step and industrial applicability. Interestingly the exceptions contained in this article are related basically to the biotechnology industry.

According to paragraph 2 of article 27 "…members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law..." and paragraph 3 states that"… Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) *plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement…*"

Article 27 (3) of TRIPS allows exclusion from patenting of plants and animals and essentially biological processes for their production, even if such inventions are otherwise eligible for patents. It does however require the patenting of eligible inventions covering "micro organisms" and "microbiological" or "non-biological" processes and products thereof. TRIPS also requires the institution of an effective sui generis law for the protection of plant varieties. Unlike the case of other IPR, TRIPS does not oblige compliance with the pre-existing international treaty on the protection of plant varieties, UPOV, nor does it lay down in any further detail the scope or duration of such protection.

As is seen from the above-mentioned clauses, while TRIPS allows the member states to be free about the patentability of most of biotechnological innovations, it at least requires the members to provide protection for plant varieties either by patent or a sui generis system such as plant breeders' rights.

3.2 Biotechnology Industry

Article 2 of The Convention on Biological Diversity (CBD)[5] defines the "*Biotechnology*" as including any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

Biotechnology has in recent years attracted a significant amount of attention, as it is considered to be a solution for many emerging problems in particular in terms of health and agricultural industries. The so-called green revolution can be regarded as a candidate to solve the problem of hunger in least developed countries particularly. The fashionable concept here is the transgenic organisms or Genetically Modified Organisms (known as GMO).

As is stated above, regarding the economic rationale of IPR, the main argument put forward is the need to give further incentive to innovate for those private companies which risk their money in R&D activities. The nature of the incentive is basically based on the grant of a temporary monopoly for the exploitation of invention. When closely examined, market failure problems associated with the creation and diffusion of the knowledge can be observed in the biotechnology industry.

Being a very disputed issue, biotechnology is one of the leading industries which may benefit from the globally enforceable IPR rules. Biotechnology is one of the high-technology fields that have undergone an exceptionally strong rise in new innovations and experienced rapid growth in recent years. Using new biological tools, researchers have developed a wide range of possibilities for using living organisms, or parts of living organisms, to produce new products or processes. Biotechnology has applications in many sectors, including healthcare, agriculture, environmental protection[6]. However, the granting of IPR protection for biotechnological invention has leaded a big disagreement in particular between the so-called north and the south. In this context, the application of the IPR rules in this area is controversial issue. The fact that biotechnology is directly related to the health of human beings in many ways, makes the issue more complicated.

According to Lehman, together with pharmaceutical and chemical industries, the biotechnology industry is a technology-based industry in which the patent virtually equals the product. This is a very important point while discussing any issue related to IPR within these three industries. These three industries are much different than other patenting industries such as computers and electronics. While responsible for many patent filings the computer and electronics industries are characterised by extensive use of other techniques for managing inventions, including the use of trade secrecy and the pooling of patents with those of competitors to accommodate government and industry technical standards.

Lehman makes a further comment for the pharmaceutical industry, which can also be regarded as valid for the biotechnology industry as follows:

> *"…Most importantly, unlike industries which produce products requiring expensive and complex manufacturing infrastructures, the main issue with regard to pharmaceutical industry is that the patented products of pharmaceutical companies can be easily and cheaply replicated by generic producers without facing any significant cost of investment. As the investment cost in the pharmaceutical industry disproportionately is directed to laboratory research and clinical trials rather than the manufacture of the final product, patent exclusivity is the only effective way to protect and receive a return on that investment[7]. Therefore, patent protection is generally considered*

to be the only effective way of preserving the incentives of innovating pharmaceutical companies to invest in new drug development and production."

Apart from the environmental and ethical concerns which are not the subject matter of this roundtable, an important aspect of this controversy is related to some anticompetitive concerns associated with this industry. These concerns are the main reason why we discuss the interface between competition policy and IPR in biotechnology industry. At first sight, there should not be any difference among industries with regard to this interface. In this context, it could be argued that Competition Authorities might employ the tools within its reach with regard to anticompetitive practices related to IPR regardless of the industry. This proposition is generally right, and existing rules and case-law must be applicable for all industries. However, that should not prevent Competition Authorities from taking into consideration some sui generis conditions of certain markets either in favour or against the companies under investigation. The biotechnology industry is a good example for the markets with such sui generis characteristics.

3.3 IPR and Biotechnology in Turkey

3.3.1 IPR in Turkey: Generally[8]

Turkey is one of the countries, which signed and ratified the Agreement Establishing the WTO. As it is clearly known that developed countries had a 1-year transition period for adoption of national legislation to make them compatible to TRIPS Agreement. Developing countries including Turkey had 4 more years for reflecting the provisions of TRIPS to their national legislation. This period would end in January 1, 2000.

Turkey has adopted its national industrial and intellectual property legislation for patents However, (***Decree Law*** for Protection of Patent Rights Numbered 551 Dated June 27, 1995), trademarks (***Decree Law*** for Protection of Trademarks Numbered 556 Dated June 27, 1995), industrial designs (***Decree Law*** for Protection of Industrial Designs Numbered 554 Dated June 27, 1995) and geographical signs (***Decree Law*** for Protection of Geographical Indications Numbered 555 Dated June 27, 1995) in June 1995. All elements of this legislation are not only compatible to with the TRIPS standards but also contain many better and more effective provisions. This progress shows that Turkey is the first developing country, which amended its national legislation according to the TRIPS Agreement. When the situation in all other developed countries has been analysed, it will easily be understood that Turkey has adopted new legislation compatible to the TRIPS Agreement earlier than most of the developed and all of developing countries. Additionally, when the content and age of the previous legislation are considered this progress can be named as "revolution in the industrial property protection".

In addition to TRIPS, the Customs Union with European Union where obligations have been stated in the Association Council Decision numbered 95/1 and dated 06.03.1995 includes some provisions for establishment equal, strong and efficient protection of industrial property rights in all member states. These are based on;

- Accession to International Agreements related to intellectual property protection,
- Updating the national legislation to make them compatible to Community Directives and International Agreements,
- Updating the legislation for efficient enforcement of the laws.

Turkey has completed all necessary legislative and administrative studies, and established a well-functioning infrastructure for efficient and strong protection of industrial property rights. All these studies have created a very good environment for investment and technology transfer.

3.3.2 The Legislative Framework of IPR for the Biotechnology Industry in Turkey

The relevant legal document with regard to the patentability of biotechnological inventions is the Patent Decree (Decree Law No.551, Pertaining to the Protection of Patent Rights). Article 6 provides the subject-matters which are not patentable. The second paragraph of this article is as follows:

" …Patent shall not be granted for inventions in respect of the following subject matter.

a) Inventions whose subject matter is contrary to the public order or to morality as is generally accepted.
b) Plant and animal varieties/species or processes for breeding/plant or animal varieties/species, based mainly on biological grounds…"

The above-mentioned clause in article 6 regarding the patentability of biotechnological innovations has been considered to present certain ambiguities. Hence in order to clarify the content of this clause, an additional legislative work has been needed. This clarification is also important with a view to harmonize the IPR legislation with the Acquis Communautaire of the EC. To this end, the Turkish Patent Institute has recently initiated a work on the preparation for a secondary legislation to make further clear the position of biotechnological innovations vis-à-vis the Patent Decree Law. Actually this work will result in the inclusion of a new chapter into existing Regulation on Patent. The new chapter to be added is argued to make the Regulation compatible with the EU Parliament and the EU Council Directive of 98/44EC which envisages the common rules regarding the patentability of biotechnological inventions. This amendment to the Patent Regulation makes rules, which govern the patentability of the biological inventions further clear. It classifies the biotechnological inventions as those patentable and non-patentable. The details of which what is patentable or not are directly the issue of this roundtable. However, the coverage of the patentability might be relevant when considering the policy design for an optimum patent protection system.

For designing a good IPR policy for biotechnology industry, It can be argued that apart from those subject-matters which are explicitly stated not eligible for patentability, those allowed as patentable should be examined carefully with regard to the three conditions which are novelty, inventive step (non-obviousness) and industrial applicability. Here in particular, the condition of inventive step is considered as important and therefore it should be analysed for the purposes of quest whether the claimed invention introduces certain useful knowledge, which has the potential to contribute to the knowledge base and the social welfare. In this context, the examination of this criterion requires a good technical expertise to verify the condition is met.

Another important legislative development on the IPR protection of biotechnological innovations is the entry into force of the Act No: 5042 on the Protection of Plant Breeders' Rights of New Plant Varieties. This Act envisages a protection system of Plant Breeders' Rights regarding the innovation of new plant varieties. The passage of this Act by the Parliament fulfilled the condition envisaged within article 27/3 of TRIPS on the introduction of a patent protection or a sui-generis protection regime for the protection of plant varieties. The Ministry of Agricultural took into consideration the UPOV Convention 1991 as a model. Also it is argued that this Act is in harmony with the Acquis Communautaire of the EC.

The Act No: 5042 envisages conditions of granting protection for plant breeders' right in line with those introduced within the UPOV Convention[9]. The protection duration is in between 25-30 years

according to the type of the plant. It includes an article which envisages exception for farmers[10], However this privilege is subject to certain limitations. Importantly it introduces the possibility of compulsory licensing[11] based on specific conditions. At the end of third year of registration of the breeders' right, the right can be subject to a compulsory licensing where it is deemed necessary for public interests. Here, for purposes of compulsory licensing, the national defence and the need for the protection of public health are considered as public interests. When the system of compulsory licensing is closely examined, it can be seen that the system is based on strict limitations with a view to encourage innovators.

Considering these legal documents, Turkey can be accepted as being, to a great extent, in harmony with the international standards of IPR protection regarding the Biotechnology industry.

3.3.3 Importance of Biotechnology and IPR in Turkey

Turkey is still a developing country which is a net technology importer. No need to say that the technology is the key driver of economic growth and development. The position of Turkey as technology importer has important implications for the country. In this regard, the technology transfer is an important means of establishing a technology base in Turkey. In scientific terms, this is a significant way of creating for a knowledge base in Turkey.

Biotechnology is among the most important technologies for the Turkish economy. In particular, it promises to introduce certain challenges as well as opportunities for the agriculture industry which is still an important aspect of the Turkish economy. Up until now, traditional agricultural methods have dominated the Turkish agriculture industry. And as in the case of many developing countries relying on the agricultural industry for their economic growth, public research agencies have had a significant place in agricultural innovations. However, in parallel to the global trend, biotechnology has begun to dominate the Turkish agricultural industry in recent years. The above-mentioned Act No:5042 can be considered as directly related to this domination.

Together with revolutionary developments within the biotechnology industry, agriculture is not any longer a traditional industry. It has been transformed into a technology-based industry.

Turkey equipped with a richness of natural plant varieties is intended to benefit from the biotechnological innovations to boost its economy. The combination of its rich natural resources with biotechnological technologies can present Turkey important opportunities.

However, in grasping these opportunities to be provided by biotechnology, Being ready against the challenges of this transformation is crucially important for a sustainable agricultural industry.

An important aspect of these challenges is a global issue which might also impact Turkey. That is the issue of domination of the biotechnology industry by a few firms. In particular, the seed industry is argued to be subject to that domination. In particular certain seeds which have significant economic value are possessed by a limited number of firms.

At first sight, it can be argued that this is a global issue which should be treated globally. Correspondingly, there is a huge literature on biotechnological innovations in the agricultural industry with a view to evaluate the impact on developing countries. And an important aspect of the discussion is the protection of these innovations by IPR tools.

Generally it is argued that the global system of IRP protection as established by TRIPS works against the interests of developing countries, and it makes these countries dependent on technologies of the developed world. This argument can be supported or criticised depending on what is understood from IPR protection. However, it is a matter of policy choice. In other words, whether we accept or not, the

introduction of TRIPS standards has become a preliminary condition to become a part of the global economy.

Being a developing country which is also a candidate country for the EU membership, Turkey has chosen to introduce an IPR protection without any discrimination of industry as laid down by TRIPS. In other words, Turkey is in favour of introducing IPR protection for all industries. The IPR legislation of Turkey is mainly in line with major international agreements. What is important is that the Turkish legislation is strictly disciplined not only by TRIPS standards but also by the liabilities arising from harmonisation with the legislation of the EU as laid down in Customs Union Decision 1/95.

In this regard, the existence of IPR protection in Turkey is a given information for us for the purposes of these roundtables. In this context, to deal with the issues of market power or domination in the biotechnology industry, Turkey has two ways to follow. The first is the application of flexibilities allowed by TRIPS, and the other is the application of competition rules in curing the problems associated with anticompetitive practices.

4. The Interface of Competition Policy with the IPR Rules

4.1 General Considerations

It is a general and fashionable proposition that competition rules are in direct contradiction with the IPR rules. The main idea behind this approach is related to the argument that while the competition rules encourage competition and outlaw monopoly, the IPR rules by definition grant monopoly over the right in question. On the basis of this general proposition, at first sight, there seems to be a contradiction. However, a closer examination of the main philosophies behind these two legal systems demonstrates that rather than a contradiction, there is parallelism in terms of their objectives. The main purpose of competition policy is the protection of competition process, which betters off the social welfare. In this equation, the preservation of competition process is a tool in order to achieve the final objective of increasing the well-being of the society. In this juncture, the competition policy has the same objective with IPR rules. However, competition rules and IPR rules pursue their objectives in different ways.

Both seek to promote economic efficiency and growth and to enhance social welfare. IP rules do this by creating limited monopoly rights so that value of creating IP is increased as an incentive to invent and to the subsequent commercial development of an invention in the form of new products. Hence, IP rules are a part of a long-run strategy for dynamic efficiency. On the other hand, competition rules seek to promote economic efficiency, thereby raising output and benefiting from lower prices for existing products. Thus, two sets of rules (IPR and competition) have a common objective of greater economic welfare and social well-being. The tension comes from the fact that the IPR rules are part of a long run strategy to produce wealth and prosperity, whereas competition rules focus on short run objectives[12].

On the other hand, with regard to the interface of competition policy with IPR, competition policy has a relatively more functional role in particular with regard to the need for the above-mentioned balance. This role of competition policy should be realised by Competition Authorities very carefully. Here designing correct competition policy requires the Competition Authorities to perceive the rationale behind the IPR protection well and to intervene in cases related to a right protected by IP rules where actually necessary. The experience demonstrates that the over-jealous application of competition rules in particular in the area of IPRs may bring some sort of short-run benefits for the society, however it may significantly harm the long-run welfare of the society by chilling the incentive to innovate and invent.

This point is particularly important for industries where the innovation requires a great amount of investment cost for the basic research and product development with the possibility of failure to make the

innovation marketable. The biotechnology, pharmaceutical and chemical industries are such kind of industries, which are dependent on IPR protection. Explanation for why patents are more important to these industries in appropriating the benefits from innovation follows directly from the characteristics of R&D process. In essence, it takes several hundred million dollars to discover, develop, and obtain regulatory approval for a new medicine. Absent patent protection, or some equivalent barrier, imitators could free ride on the innovator's necessary regulatory approval and duplicate the compound for a small fraction of the originator's costs.[13]

In this context, with regard to the interface of the competition policy and IPR the distinction between the existence and exercise of the right should be significantly observed. The competition policy deals with the exercise and does not *per se* condemn the existence. Being aware of the "tension" between IPR and competition policy, the European Court of Justice (hereinafter referred to as ECJ) distinguished the existence (or specific subject-matter)[14] of such rights from the exercise of them, and treated the existence as falling outside competition rules, whereas the exercise, an issue which may be caught by competition rules.

This principle of distinction is transposed from the case-law of the ECJ into the Turkish application and carefully pursued by the Turkish Competition Authority. The main philosophy behind this distinction is directly related to arguments which support IPR protection. The existence of IPR is not on its own merit a competition infringement. However, the competition policy has a "right to say" with regard to the exercise of IPR. This fact shows that the right granted to the inventor is not absolute, and subject to certain limitations. The application of competition policy should pursue its pathway taking into consideration these limitations. Apart from the limitations inserted directly or indirectly into rules regulating the right in question, competition rules by definition may bring certain limitations over the exploitation.

Before applying competition policy to any IPR-related case, it is a logical proposition that there must be an existing IPR. Without any prior innovation, there is no ground for the application of competition rules. This understanding explains why Competition Authorities should be careful enough in the application of competition rules. IPR has an important role in the creation, marketing and dissemination of new knowledge. The competition policy has a role only after new knowledge is created and marketed. Competition authorities should be concerned with not only short run economic efficiency but also with long-run economic efficiency, which can be termed as dynamic efficiency. Short run efficiency is generally associated with the so-called static efficiency related to the level of prices. However, the so-called dynamic efficiency is about the introduction of new products and processes. Therefore, the competition authorities cannot ignore the need for dynamic efficiency. IPRs are generally related to this dynamic efficiency.

4.2 Competition Policy and IPR: Advocacy Role

Comments under the title "advocacy role" will have a general nature for the purpose of this roundtable and therefore can be considered to be applicable for the biotechnology industry as well. An interesting aspect of interface between competition policy and IPR is about what advocacy role a competition authority may have. As is known, advocacy is a very broad concept, and may cover many issues not directly related to the enforcement of competition rules. The possible role of competition authority (if any) in designing a proper IPR system in the country can be associated with its advocacy role. Advocacy may be based on either a direct clause or legal rules or else the sprit of competition law and policy.

The advocacy role of a competition authority in designing an optimum patent policy seems to be a very sensitive issue. There are some questions which might be relevant in understanding and (if necessary) limiting such role of competition authorities. Some of them are whether competition authorities be

involved in decisions concerning granting a patent, and whether the competition authorities be allowed to challenge the validity of a patent granted.

General conditions observed by the relevant authorities in granting a patent are novelty, inventive step and industrial applicability. And the inventors have to provide detailed information in order to meet these conditions. The process which governs the decision whether the invention is to be granted a protection or not requires a very technical analysis and examination in order to fully evaluate the information provided.

At first sight, the above-mentioned questions seem difficult to be answered. However, a closer examination of them demonstrates that the involvement of competition authorities in the patent granting process, and their possession of the right to challenge the validity of a patent (regardless of the industry) should not be allowed for some important reasons.

First of all, these roles bring additional and unnecessary burden on Competition Authorities. While Competition Authorities (even those in developed countries) do not have sufficient resources even to deal with the existing anticompetitive issues falling under the main prohibitions of competition law, they may not allocate sufficient resources to be involved in the patent process. In addition to this, any direct role in the patent granting process requires Competition Authorities to be actively involved in the process which is governed by qualitatively different rules and procedures than those of competition law. The existing resources of Competition Authorities will not suffice to play this role properly. As is known, it is a significant source of criticism that the patent granting process is very long and painstaking, and the inclusion of Competition Authorities in the patent process may further complicate the issue and threatens legal certainty needed by the innovators. Therefore, the Patent Offices must be the sole authority in granting patents. With regard to the right to challenge the validity of a patent, it could be argued that this is not the job of competition authorities. Such a role might lead the authority to be lost in complex and technical files, and importantly it prevents Competition Authority from fulfilling its main duties.

A Competition Authority has to respect the distinction between the existence and exercise of the patent right. The above-mentioned roles for a competition authority might further complicate the line in between. The primary expertise of competition authority is not related to the process of granting patents and there is no point in its allocating its limited resources in order to have an expertise with regard to the patent process. Therefore, the competition authority should avoid any direct role in the process of patent granting.

The above comment is basically based on the current philosophy underlying behind the existence of Competition Authorities. And under this approach, the inclusion of competition authorities in the patent process is not a logical option. However, it may be that Competition Authorities might be expected to fulfil new duties directly related to patent process. This new approach seems to introduce a revolutionary development in competition law enforcement area. And for the time being, it could be argued that Competition Authorities are not ready for such new duties.

With regard to its advocacy role, however, Competition Authority is required to have close relations with the patent offices for some important reasons. As is stated above, in particular considering their existing duties, instruments and resources the competition authorities should not be involved in the patenting process. However, that view should not be considered to be absolute. In other words, the competition authorities might still have a role of advocacy in this process.

As is known, Competition Authorities have a good deal of data regarding the markets. Data Competition Authorities have might be shared with Patent Offices in granting a patent related to the market in question. In this context, A Patent Office might take into consideration these data such as market share, concentration level, price level, the existence of anticompetitive practices etc. when exploiting its final

discretion whether to grant a patent protection or not. However, it should be admitted that the discretion of the patent offices is very limited and strictly regulated by the patenting criteria by Law. Despite this fact, the patent offices might still exploit the flexibility allowed by TRIPS, and probably available within their patent laws.

An important area of cooperation is related to the problem of anticommons. This problem cannot be solved by Competition Authorities alone. And also Patent Offices might fail to deal with this problem adequately via the resources within their reach. Therefore, it is important to deal with this problem by the cooperation of patent office with the competition authorities.

4.3 Competition Policy and IPR: Competition Enforcement Issues

4.3.1 General Overview

The Turkish Competition Act does not contain any clause directly dealing with IPR cases. And there is no clause which excludes IPR issues from the application of competition rules. Therefore, the existing competition rules are applicable to deal with the anticompetitive practices related to IPR.

Article 4 of the Turkish Competition Act, which aims at preventing the distortion of competition because of the agreements or concerted practices among undertakings or decisions of associations of undertakings preventing, restricting or distorting competition within the markets for goods and services, and article 6 of the same Act which aims at preventing the abuse of dominant position by undertakings holding dominant position in the relevant markets are parallel with the articles 81 and 82, respectively, of the Rome Treaty. And article 7 aims at controlling the concentrations which create or strengthen the dominant position of one or more undertakings as a result of which, competition is significantly impeded in the market for goods and services. The Competition Board adopted a Communique on the Mergers and Acquisitions (No: 1997/1) which regulates the notification and evaluation of the concentrations. The concentration control system based on article 7 and

The Communiqué no: 1997/1, is in line with the Council Regulation of 4064/89 of the EC on the control of concentrations.

In addition to these substantial rules, the Act envisages an exemption system (article 5) based on certain conditions. Article 5 of the Act allows the Board to exempt an agreement, concerted practice or decision restricting competition from the provisions of article 4 subject to the existence of certain conditions and upon the application of the parties concerned, and authorises the Board to issue group exemption communiques for the agreements of a particular category.

Any anticompetitive practice of IPR can be prohibited and may be sanctioned under the Turkish Competition Act.

Up until today, the number of IPR related cases dealt with by the TCA is relatively limited. The existing case-law are related to whether to exempt or nor certain licensing and sub-contracting agreements. However, Some problems mentioned in the document for the preparation of this roundtable have not been considered as an issue in Turkey. The issues such as “anticommon problem” and “reach-through agreements” have not been dealt in any case by the TCA. Therefore, it is not possible to make a specific comment based on an experience. However, it is understood that these issues cannot be dealt with only on the basis of individual cases and rather they require the formation of a comprehensive policy to be followed by the TCA. In particular, the issue of “anticommon” seems to be important for Turkey, which strives for the development of its technology base. In other words, this problem might be an impediment to the innovation policy of Turkey.

Granting patent protection for inventions, Turkey has expected to exploit all benefits of IPR system. An important aspect as mentioned above is the dissemination of knowledge and contribution to the knowledge base of the country. If the problem of "anticommon" has the potential of significantly impeding the achievement of this objective, then it might be necessary to find out reasonable solutions to cure this problem. The biotechnology industry is very important for Turkey. In particular, the biotechnological innovations in agricultural sector should be approach carefully, because agriculture has an important share in the Turkish economy. However, as is stated above, the TCA should be in cooperation with the Turkish Patent Institute to deal with this issue.

4.3.2 Exemption System

Exemption system is available within the Turkish Competition Act. At the moment, the TCA has not adopted a block exemption communique on certain licensing practices which might be anticompetitive. However, this should not be considered as a deficiency as there is the possibility of individual exemption.

The TCA has yet dealt with limited number of IPR related agreement for the purposes of exemption. These are licensing and sub-contracting agreements. When these decisions of the TCA are examined closely, it is seen that these cases are not sufficient to demonstrate the policy of the TCA regarding some vertical anticompetitive licensing practices, such as "grant back clauses", absolute territorial exclusivity, resale price maintenance and some horizontal licensing issues such as patent pools and cross licensing. However, here it is possible to refer to the principles of the EC Competition Law as an important source of guidance for the TCA[15].

Correspondingly, at the moment, there is no licensing agreement related to a biotechnological innovation, brought before the TCA for exemption purposes. Therefore, it is not possible to make a specific comment for this industry. On the other hand, the principles of the EC Competition Law in this specific area can be referred to. In addition to this, however, the general policy tendency of the TCA might shed some lights over the licensing practices regarding this industry.

As is known, Turkey is mainly a technology importing country. Therefore, when a licensing agreement is mentioned in any technology-intensive industry, it generally meant a technology transfer agreement with a foreign undertaking. The TCA, being aware of the role of the technology transfer for the Turkish economy, has followed an industry-friendly policy. By definition, the TCA has considered the transfer of technology itself an important development and benefit, which will be shared by consumers. In this context, the TCA does generally not obstruct the anticompetitive clauses within the agreements, which will introduce new technologies unless they have the potential of significantly restricting competition. Here, for the evaluation of these restrictive practices, the structure of the market in question is very important. If the market is concentrated, then the approach might be stricter. However, with regard to competitive markets, the approach might be flexible. In other words, the TCA has followed a case-by-case approach. Importantly as is stated before, in the evaluation of technology transfer agreements and sub-contracting agreements, which again bring technology, the EC competition law has provided the guiding principles for Turkish application. However, the TCA is well aware of the fact that the EC law is a supranational law with the purpose of strengthening the single market. Therefore, the TCA attach great importance on making a differentiation between the rules serving the EC's general purposes and the rules serving for the protection of competition process.

4.3.3 Research and Development Agreements Between the Competitors

As the biotechnology industry requires a great amount of capital which may not be afforded by a single firm, the firms might need a cooperation for the purposes of R&D studies. Being aware of the importance of such cooperation, the TCA adopted an important Communiqué on "Research and

Development Agreements" No:2003/2, which determines the conditions of exemption for R&D agreements between competitors. The Communiqué adopted by the TCA has an important role in creating legal certainty with regard to joint R&D activities between the competitors. Agreements whose subject are research and development (R&D) studies, and the joint use of R&D results by the participation of more than one undertaking often increase the speed of dissemination of technical information between parties, prevent the concurrence of R&D studies to the same end, and lead to new developments through the mutual exchange of complementary technical information. The contribution of such agreements to technological and economic development arises particularly when there exist the launching of new products in a market and the implementation of advanced production techniques. Owing to the spread and efficiency of R&D, it is expected that consumers would benefit from the market entry of new or developed products or services and/or price falls which occur as a result of new or developed production techniques. The acquisition of the expected benefit in terms of parties and consumers may sometimes be possible via certain limitations of competition. However, not limiting competition more than what is compulsory is an important condition for being able to obtain the targeted goals and sustain economic efficiency. Therefore, it is required to determine limitations in the said agreements, which may mean the infringement of competition rules.

The types of agreements to fall under block exemption are specified in article 2 of the Communiqué. Those agreements which do not encompass industrial practice, and which concern jointly conducting research studies or jointly developing research results are usually not caught by article 4 of the Act No: 4054. However, in some cases, for instance in the event that parties agree not to make R&D in the same area, the said agreements are included in the relevant articles of this Communiqué, since they may be caught by article 4 of the Act.

On the other hand, agreements which encompass the joint use of R&D results often involve competition-limiting provisions and are caught by article 4 of the Act as they provide parties with the opportunity of jointly determining how to produce developed products, or how to apply developed production processes, and how to use intellectual rights or know-how. Due to the fact that cooperation between parties is extended to the stage of industrial practice, block exemption granted to such agreements which also involve the joint use of results is limited to five years, commencing from the date of initial launching, in a market within the borders of the Turkish Republic, of products which are the subject of agreement, or products produced by employing production techniques which are the subject of agreement.

The joint use of results may be evaluated as a natural consequence of an R&D activity. In order to be able to obtain the goals and benefits expected from such agreements, and in order for undertakings to be able to benefit from the exemption regime, this joint use should be related to products and production processes which are the subject of R&D. Those developments achieved within the framework of agreements that have another fundamental goal such as licence of intellectual rights, joint production or specialisation and that only contain subsidiary provisions concerning R&D, rather than within the framework of an R&D program may not be accepted as the joint use of R&D results. Agreements involving the joint sale of products or production techniques which are the subject of agreement are also excluded from the block exemption granted by this Communiqué.

When the likelihood is taken into account that cooperation between parties may become not caught by an agreement aimed at R&D, there emerges the obligation to clearly define the goals of the said agreement, and the area where research and development studies would be performed. In case the scope, goals and study areas of an agreement are ambiguous, the said agreement shall become not caught by block exemption.

With this Communique, it is intended that besides an effective protection of competition, legal hesitations of undertakings which engage in R&D cooperation be relieved. It gains importance that in

practices and regulations aimed at the realisation of these goals, an administrative supervision as simple as possible and a legal framework as clear as possible be ensured. Therefore, in this Communique, instead of adopting the approach of also including seemingly reasonable limitations of competition (white list), the approach of only including necessary prerequisites for enabling undertakings to benefit from a block exemption, and limitations of competition which shall render an agreement not caught by a block exemption (blacklist) has been adopted. In this manner, it would be partially possible to preclude that certain undertakings engaged in cooperation in particular issues consider provisions as to limitations of competition under block exemption as the elements to be present in an agreement, thus precluding that sometimes parties involve in agreements obligations limiting competition more than what is needed. Determining those limitations which may not be deemed reasonable in terms of competition law, and granting freedom to undertakings in other arrangements aimed at cooperation are also compatible with the recent approach that priority and weight should be given to the assessment of economic effects that agreements between undertakings would create on the relevant market. Within this framework, listed in article 6 are the cases which render agreements of the types mentioned in the Communiqué not caught by block exemption.

4.3.4 Refusals to Deal and Compulsory Licensing

Article 31 of TRIPS

As is known, a compulsory license is an involuntary agreement between a willing investor and an unwilling innovator imposed and enforced by the state. Article 31 of the TRIPS Agreement has publicly recognised the option of compulsory licensing for the Member countries under some certain conditions and limitations. This represents maybe the most important flexibility introduced by the TRIPS Agreement as it significantly reduces the monopoly power of the right-holder over a certain patent. Under article 31, compulsory licenses are granted on the grounds of public interest, dependency, and insufficient exploitation of the patent or to remedy anticompetitive practices.

However, the application of compulsory licensing is one of the most controversial issues under competition law. It can be considered as a significant intervention into the patent protection. Being an industry sensitive to strong patent protection, the biotechnology might be significantly influenced by this tool.

Compulsory Licensing in Turkish Patent Decree Law

Turkish Patent Decree Law has a chapter on “compulsory licensing”. The chapter 7 section 1 envisages the conditions for compulsory licensing. Article 99 states that “ Compulsory license is (to be) granted where no offer for licensing offer has been made and where any one of the following situations/conditions materialises:

1. Failure to put to use/work the patented invention in accordance with article 96;

2. Dependency of subject matter of patents as mentioned in article 79.

3. On grounds of public interest as mentioned in article 103.

When examined closely, the system of compulsory licensing introduced in Turkish Patent Decree is in line with the European Patent Convention and the TRIPS. Therefore, it could be argued that the compulsory licensing as envisaged within the Patent Decree Law might be solution to curb the monopoly of patent holder over the innovation in question. However, it should be kept in mind that the application of this tool under Patent Law is subject to certain limitations.

However, the Patent Law Decree has a specific article (article 93) on abuse of competition. Article 93 is as follows: "Where a patentee commits an act in violation of the general provisions on unfair competition while putting his patent (application) to use, the court may condemn the patentee to offer his patent for licensing."

The meaning of "unfair competition" is generally interpreted as anticompetitive practices falling under competition laws. Article 93 enshrined within the Patent Decree Law can be regarded as an instrument which can be used against some unfair competition practices. However, It is important to stress on the fact that what is falling under competition law is mainly a business of competition authority. At the moment it is not clear how to apply the article 93. At least it could be argued that the existence of article 93 does not rule out the application of competition rules. Rather it is possible to regard the competition rules as giving more discretion in deciding whether it is suitable to apply as remedy a compulsory licensing.

Refusals to License and Compulsory Licensing under the Turkish Competition Law

Refusal to license is a very sensitive issue under competition law and therefore it might be useful to examine this issue in further detail in compare to other anticompetitive practices related to IPR. The main issue is that the acceptance of a refusal to deal as an abuse cause an encroachment with the specific subject matter protected under Patent Law. As is stated before, what is protected by the Patent Law is the existence of IPR, not the exercise of them. This distinction is very important in dealing with anticompetitive issues. And overzealous application of competition rules might distort this line.

Generally the refusals to license is an issue related to abuse of dominant position. Therefore- it is important not to forget that an undertaking which owns a patent or other intellectual property right is not necessarily in a dominant position and does not necessarily have market power, because the product or process to which the right applies may not constitute a market separate from other products. In other words, the patented product of an undertaking might be in fierce competition with the substitute patented products of competitors. Therefore the proposition of "patent grants monopoly over the right" should not be automatically associated with a situation of monopoly under competition law.

The Turkish Competition Act does not directly introduce an infringement such as refusal to license and accordingly, a remedy such as compulsory licensing. However, article 6 of the Turkish Competition Act prohibits abuse of dominant position and the list of abuse examples is not exhaustive. Therefore, even if the refusal to licence is not counted directly, it is still possible to consider it as an abuse and importantly the competition authority may decide on a compulsory licensing to cure the problem.

Compulsory Licensing under the EC Competition Law

Here it is important to summarise the EC case-law on compulsory licensing under article 82, as Turkey has followed the principles established within the EC competition law. The issue of compulsory licensing has been handled via the case-law on refusal to deal or supply (refusal to license) as an example of abuse of dominant position under the EC competition law.

The origin of compulsory licensing in the EC competition law can be founded in the case-law on refusal to supply. However, the "refusal to deal" as an example of abuse, is not mentioned in the list provided by article 82. And it has therefore developed as a product of case-law, based on the judgments of the ECJ and CFI. There are two important cases in the EC competition law, which have established the basic principles regarding the refusal to deal by dominant undertakings. The most prominent of these is *Commercial Solvents*[16], which was decided by the ECJ in 1974. *Commercial Solvents* involved a classic market-leveraging situation. In *United Brands*[17], the ECJ dealt with a refusal to deal in the vertical context. According to the principle accepted in the *Commercial Solvents*, it is an infringement of article 82 for an

undertaking in a dominant position to refuse to supply a competitor in a downstream market, where the effect of doing so would be to eliminate all competition in the downstream market. According to the principle accepted by the ECJ in the *United Brands*, it is recognised that dominant undertakings are under a positive duty to sell to a long-standing customer unless objective reasons justify the decision not to. In other words, a dominant undertaking is accepted to be under a general duty to deal with its long-standing customers and cannot stop to deal unless it has an objective justification.

These principles together constitute the basis of the case-law, which has been developed by later decisions of the ECJ and CFI. In particular the principle accepted in Commercial Solvent has become the basis for the emergence of an essential facilities doctrine in EC competition law[18]. The issue of compulsory licensing has been since Magill case considered associated with the doctrine of essential facilities[19].

According to the essential facilities doctrine; a company which controls facilities which are essential for another market, abuses its dominant position, where without objective justification, it refuses access to those facilities. This doctrine has been traced back to the formative years of the Sherman Act in the USA. It is considered by many commentators as being a significant restriction on the freedom of contract and private property of the undertakings. It is feared that it will chill the incentive to innovate and invest by the private undertakings. It therefore is argued that the doctrine should be disciplined by clear rules.

The doctrine holds that a company holding an important input for its competitor is under an obligation to deal with them. As an extension of this logic in the field of IPR, a company which own an IPR which is essential or indispensable for its other undertakings (probably its own competitors) to compete, can not without objective justification refuse to license and can be obliged under certain circumstances to license its competitors. In other words, there is a duty to compulsory licensing imposed on the undertaking in favour of its competitors. Here the abusive behaviour is the refusal to license by the undertaking (which is dominant) and the discovered remedy is compulsory licensing and forcing the undertaking to share its IPR with other undertakings.

The application of essential facilities doctrine in IPR cases, has been very controversial issue under EC competition law. The main problem is under what conditions a refusal to license can be considered as an abuse and in this context a final compulsory licensing be inferred as a remedy. In this context, it is important to see whether the rules governing the applications of article 82 with regard to refusal to license and compulsory licensing should be relax or strict to shift the balance between the IPR and competition law in favour of one against the other.

Regarding the issue, the basic principles in some landmark decisions of the European Courts can be examined to see the position of compulsory licensing under EC law. As is known, the ECJ established a basic rule that there must be a distinction between the existence and exercise of the IPR and competition rules can only intervene into the exercise of IPR. However, it is not an easy task to make this distinction in practice. With regard to this distinction the ECJ can be argued to be successful in delivering its judgment in Volvo v. Veng, by trying to make a clear distinction between the substance and exercise of IPR and as well as between the legitimate and abusive exercise of IPR. However, following the reasoning in *Volvo v. Veng*[20] the ECJ has established the so-called Magill doctrine, which states that only in exceptional circumstances, can the exercise of an IPR be a considered as abusive. The Magill doctrine requires the establishment of a three-part test to decide for a compulsory licensing (prevention of emergence of a new product, no justification for refusal and indispensability). The test in *Magill case*[21] has been strictly applied later in *Tierce Ladbroke*[22] and *Oscar Bronner*[23] cases by the European Courts.

In particular the constructive views of Advocate General in *Oscar Bronner* case are very important with regard to forcing a company to deal with its competitors. He focused on three points. First of all, the freedom of contract was not to be interfered with lightly[24]. Secondly, there should be a presumption in

favour of allowing undertakings to retain facilities, which they have developed. If access to a facility, was allowed too easily, there would be no incentive for a competitor to develop competing facilities and also the incentives for a dominant undertaking would be reduced[25]. Thirdly, the Advocate General stressed that the primary purpose of article 82 is to prevent distortion of competition and not to protect the position of particular competitors.[26]

Correspondingly, the ECJ probably influenced by the Advocate General's views has determined very strict rules to prevent discretionary interventions in particular where the asset in question is a result of high cost activities by private undertakings.

As seen by the case law concerning compulsory licensing, the ECJ seeks to achieve a balance between national laws that grant exclusive rights to protect creative effort and EC competition law that aims to prevent the abusive conduct via the use of such rights. It could be argued that while doing that, the Court do not attempt to establish a per se approach to stamp out abusive behaviour involving IPRs. As a result, the Court prefers to scrutinise the facts of each case and seek whether the circumstances of the case leads to prevention of competition. By stating that the circumstances should be exceptional, it assures the right owners that the competition authorities would not interfere with the use of IPRs unless a certain conduct contrary to article 82 occurred. However, it warns the dominant undertakings that use of IPRs in an abusive manner may lead even to require a compulsory license, which has always been considered as the basic means of exploitation.

However, it could be argued that all of the above-mentioned cases failed to bring exact rules to determine the possible justifications to be put forward by the proprietors of IPR. Despite some strict rules on what constitutes an abuse in the field of IPR, the lack of clear rules regarding the justifications seems to be a dark hole, which can shift the balance against the IPR. And considering the fact that each case has its own sui-generis conditions to be considered under article 82, it could be argued that the Commission and the undertakings who wants a free ride on their competitors assets can intentionally or negligently attempt to benefit this hole by interpreting it in their own favour.

The grant of intellectual property rights involves a balancing of the public interest in free competition with providing an incentive for research and development and for creativity. Any application of the compulsory licensing should not be inconsistent with the exclusivity, which is intended to preserve the incentive to create. If the article 82 could be used to impose a duty to license intellectual property rights to competitors on the market to which the rights primarily relate (if the firm is dominant, and the rights create a sufficiently important competitive advantage), it would have the most profound implications, both for competition law and for intellectual property.[27]

Compulsory Licensing under Turkish Competition Law

The status of compulsory licensing under the Turkish Competition Law is not clear enough. Up to now there is no direct decision by the Competition Board ordering a compulsory licensing. However, there are two cases in which the Competition Board ordered the undertaking with dominant position to deal with a view to remove entry barriers.

In the cases[28] on Newspapers distribution market, it ordered the incumbent distributors to allow their competitors to access to the final sale points, as it considered the access to this sale point as indispensable for competitors to survive. Here, the issue of access was evaluated on the basis of the criteria of essential facilities doctrine.

In Roaming Case, the Competition Board decided the refusal to deal by the two GSM operators with the newly entering IşTIM. The Turkish Competition Board has imposed administrative fines on Turkcell

and Telsim for abusing their dominant position in the telecommunications market via refusing to comply with their obligation to make roaming agreements with Aria, the third leading Turkish mobile operator. The main reason of the Competition Board was the barrier to entry created by the refusal to deal. And therefore, the Board ordered a compulsory dealing. Again in this case, the GSM infrastructure of the investigated undertakings was considered to be an essential facility by the competition board.

It is not possible to have a clear idea of how the TCA can treat the issue of the refusals to license. However, the existing decisions ordering to deal, can be argued to be parallel with the case-law in EC competition law (despite some consider the Roaming decision as a wrong application of the essential facilities doctrine). And therefore, it could be applied in a case of refusal to license. Whereas, in this application, it is important to bear in mind the need to establish a balance between the rationale of IPR protection and the objectives of competition law. This will probably be dependent on the main priorities of the competition policy to be determined by the TCA regarding the specific cases. It could be argued that the case-law of the EC which attempts to bring clear and strict rules (despite of the existence of some criticisms), can be a good example for the practice of the TCA.

Compulsory Licensing and Biotechnology

It is important for Competition Authorities to have a tool the compulsory licensing in order to apply where it is deemed necessary. However, an over jealous application of this tool might be in contradiction with the underlying objectives of competition policy in addition to those objectives of IPR. This is the case, in particular for industries, which require a significant level of investments. And generally in these industries the operating firm might face a significant risk of failing to make a marketable product following the investment. Therefore, patent protection in these industries is crucially important. Compulsory licensing as a tool to cure an anticompetitive practice might be considered as a significant intervention in the patent protection provided by the patent law. Therefore, it is important for Competition Authorities to be very careful in applying this tool. In this context, it can be argued that strict rules must govern the application of compulsory licensing as a remedy. Biotechnology like the pharmaceutical industry is one of these industries which are highly sensitive to patent protection.

Contrary to other industries, the biotechnology industry has some sui-generis characteristics, which should be examined very carefully by Competition Authorities before ordering compulsory licensing. First of all it should be accepted as a proposition that this industry is crucially important in meeting certain crucial needs of the society and will probably have an increasing importance as compared with many traditional industries. It has introduced revolutionary changes in many so-called traditional industries and turned them into technology-intensive industries. In particular, its increasing importance in pharmaceutical and agricultural industries makes the industry a priority area for investment purposes. This increasing importance of the industry should be accompanied with certain incentives for private undertakings in considering it as profitable area. And here again we see the situation of contract between the society and investors. Compulsory licensing might be a very harsh instrument in changing the balance in favour of the society. The short-run vision might hamper the long-run efficiency by both chilling the incentive to invest by the forced undertaking and by allowing a free ride for its competitors.

Actually the issue of chilling the incentive to innovate and allowing free ride is relevant for all industries. However, it should be regarded for industries such as biotechnology very carefully. Here it is important not to forget that the Patent Law envisages a compulsory licensing mechanism for certain situations. Therefore, the application of this tool under the competition policy should be considered in this perspective.

4.3.5 The Issue of Parallel Trade

The issue of parallel import is not directly mentioned in the document prepared for this roundtable. However, as with the case of pharmaceuticals, the biotechnology should be an industry of focus in evaluation the parallel trade issue as an important dimension of interface between competition policy and IPR.

As is known, exhaustion regime is a concept closely related to the issue of parallel trade. According to the exhaustion regime (national, regional or international) adopted by the country, the issue of parallel trade becomes further clear. Exhaustion is one of the basic principles of IPR throughout the world. It means that once goods produced under the IPR are put on the market by the owner or with his consent, the owner is no longer allowed further to control the distribution of those goods. He has "exhausted" his distribution right by the first sale of the goods.

Here it might be useful to define different exhaustion regimes shortly. *National Exhaustion* means that the right is exhausted only with respect to the countries on the market of which the goods were put. If the applicable law recognises only national exhaustion, a parallel importer (i.e. an importer of genuine goods) would infringe the relevant Law in the country of importation. *International Exhaustion* means that the trade mark right is exhausted by putting the goods on any market anywhere in the world. If a jurisdiction international exhaustion, the right owners in the jurisdiction cannot stop parallel imports into the jurisdiction by reliance on IP rights alone. *Regional Exhaustion* means that the exhaustion relates only to a market that is broader than the purely national market but is nevertheless limited to specific countries as in the case of the European Union[29].

The issue of parallel trade was discussed during the negotiations for TRIPS. However, it was impossible to find out a solution, and therefore the resulting consensus was article 6 of TRIPS. Article 6 is titled as “exhaustion” and is follows:

> “*For the purposes of dispute settlement under this Agreement, subject to the provisions of articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.*”

Article 6 does not envisage any uniform standard for the issue of parallel import and leaves the countries free in formulating their policy of exhaustion.

Generally views regarding whether to allow parallel trade or not are based on strong arguments. Those advocating parallel trade, have the following arguments[30]:

- Virtues of free trade and elimination of artificial segmentation of the markets
- Parallel trade can harden some anticompetitive practices
- Parallel trade is not an IP but a competition policy issue

Those advocating a ban on parallel trade has the following arguments[31]:

- International Price Discrimination by IPR Holder increases the global welfare.
- Negative effects regarding piracy and counterfeiting might be endorsed.

- Free Riding can chill the incentive for investment by licensee where the goods are imported.

- Issues related to safety and consumer confusion might occur

With regard to the exhaustion regime followed by Turkey, article 76 of the Patent Decree Law adopted a national exhaustion regime. According to this article " *Rights conferred by a patent shall not extend to acts committed with regard to a product under patent protection after said product has been put to sale in Turkey by the right holder of the patent or with his consent.*" On the other hand, article 13 of Decree Law on Trademark has envisaged the same regime with the Patent Decree Law.

The exhaustion regime adopted for the IPR policy in Turkey is based on national exhaustion. Despite the fact that the regime is based on national exhaustion, the Court of Appeal in the *Police case*[32] held that the exhaustion regime for Turkey is based on international exhaustion and therefore, the right-holder can not prevent parallel import of the goods in question from abroad, as its right is exhausted. Correspondingly, the TCA followed the line of reasoning formed by the Court of Appeal, and decided in two cases[33] that any restrictive clause within the licensing agreement which restricts parallel import of the same brand were against the Turkish Competition Act. It could be argued that the adoption of line of reasoning of the Court of Appeal by the TCA is in line with the main spirit of competition law and the idea of protection of competitive process.

Exhaustion is an issue of intra-brand competition rather than competition between different brands. Therefore, it may be considered as a secondary issue as compared with competition which should be existing between competitors producing different brands. However, with regard to industries in which inter-brand competition is almost in absence, the issue of exhaustion regime and parallel trade might be relevant to be considered by Competition Authorities.

Considering the fact that most of the markets in Turkey is generally associated with the structure of oligopoly and/or monopoly, the preservation of intra-brand competition is very important in Turkey. Therefore, the policy-option chosen by the TCA regarding the parallel trade should be considered reasonable.

Despite this general policy option based on specific exhaustion regime, an important proposition might be that instead of choosing a certain policy, the regime must be based on specific market conditions of the industry in question. In other words, the market structure and the market conditions should be considered as a benchmark in choosing the right policy of exhaustion. In this regard, the responsible authority in deciding the exhaustion regime must be competition authorities. But the competition authorities can cooperate with the patent office in finding the optimal solution. However, the application of that proposition requires a significant effort of applied research by Competition Authorities conducting based on practical market data.

In particular with regard to biotechnology, case-by-case approach in choosing the exhaustion regime might be very useful. In this regard, together with specific conditions of the market, sui generis characteristics of the biotechnology industry (or sub-relevant markets within this industry) might be taken into consideration.

5. Conclusion

In a report on Technology Transfer Regulation prepared by the EC Commission, there is an important evaluation regarding the application of competition rules against the anticompetitive practices of IPR:

> "In reviewing the current rules and devising a future regime, account has to be taken of the fact that innovation in new products and technologies are the ultimate source of substantial and major competition over time. Undue emphasis on short-term allocative efficiency may therefore create a socially unfavourable trade-off between static and dynamic efficiency"[34]

The above excerpt from the EC Commission might be considered sufficient as being final words in explaining how to treat the interface of competition policy with IPR. Importantly, it is highly relevant for the application of competition rules regarding the interface for biotechnology industry.

NOTES

1. *McCALMAN, P. (2002) "The Doha Agenda and Intellectual Property Rights"*

   www.adb.org/Economics/pdf/doha/McCalman.pdf p.1

2. ALKER D. and F. HEIDHUES, "Farmers' Rights and Intellectual Property Rights - Reconciling Conflicting Concepts". www.uni-hohenheim.de/i3v/00068900/23347041.htm

3. Hall B. H. "The Global Nature of Intellectual Property: Discussion" http://emlab.berkeley.edu/users/bhhall/papers/BHH%20toronto501%20disc.pdf

   Toronto IP Conference 2001, p.1

4. For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.

5. The "Convention on Biological Diversity (CBD)" was adopted at the 1992 Earth Summit in Rio de Janeiro, Brazil. This Convention sets out commitments for maintaining the world's ecological underpinnings as we go about the business of economic development. The Convention establishes three main goals: the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits from the use of genetic resources. http://www.biodiv.org/doc/publications/guide.asp

6. HIRSHHORN, R and J.LANGFORD, (2001) "Intellectual Property Rights in Biotechnology: The Economic Argument Prepared for The Canadian Biotechnology Advisory Committee Project Steering Committee on Intellectual Property and the Patenting of Higher Life Forms",

   http://cbac-cccb.ic.gc.ca/epic/internet/incbac-cccb.nsf/vwapj/EcoArgument_Hirshhorn_Langford_e.pdf/$FILE/EcoArgument_Hirshhorn_Langford_e.pdf p.14

7. LEHMAN, B. (2003) "The Pharmaceutical Industry and the Patent System"

   www.earthinstitute.columbia.edu/ cgsd/documents/lehman.pdf p.10

8. The information in section 4.1. regarding the IPR legislation in Turkey is compiled from the Web Page of the Turkish Patent Institute. www.turkpatent.gov.tr

9. Act of 1991 International Convention for the Protection of New Varieties of Plants.

10. Article 17 entitled "Farmer Privilege" of the Act. No:5042

11. Articles from 18 to 30 of the Act. No:5042

12. Charles River Associates (CRA) "The European Commission's draft Technology Transfer Block Exemption Regulation and Guidelines: A significant departure from accepted competition policy principles", CRA Competition Policy Discussion Papers No:8, March 2003, p.4-6

13. GRABOWSKI, H. (2002) "Patents, Innovation and Access to New Pharmaceuticals"

    www.dklevine.com/archive/grabow-patents_innov.pdf p.4-5

14. Centrafarm v. Sterling Drug, Case 15-74, [1974] ECR 1147.

15. Evaluating the licensing agreements, the TCA has taken into considerations the principles within the Regulation of 240/96 on "the Application of Article 85 (3) of the Treaty to Certain Categories of Technology Transfer Agreements". With regard to subcontracting agreements, which might have some anticompetitive licensing clauses, "the Commission Notice of Subcontracting Agreements in relation to Article 85(1)" has been regarded significantly.

16. Commercial Solvents v. Commission, Cases 6, 7/73 [1974] ECR 223.

17. United Brands v. Commission, Case 27/76 [1978] ECR 207.

18. The European Commission stated its understanding of the general essential facility principle as follows: "….An undertaking which occupies a dominant position in the provision of an essential facility and itself uses that facility (*i.e.* a facility or infrastructure, without access to which competitors cannot provide services to their customers), and which refuses other companies access to that facility without objective justification or grants access to competitors only on terms less favorable than those which it gives its own services, infringes Article 86 if the other conditions of that Article are met. An undertaking in a dominant position may not discriminate in favor of its own activities in a related market. The owner of an essential facility which uses its power in one market in order to protect or strengthen its position in another related market, in particular, by refusing to grant access to a competitor, or by granting access on less favorable terms than those of its own services, and thus imposing a competitive disadvantage on its competitor, infringes Article 86.." (Commission's decision in *Sea Containers-Stena Sealink*, O.J. No L 15/8, 18 January, 1994.

19. For further information on essential facilities doctrine see the following resources: (i) ANDERMAN, S. (1998) EC Competition Law and Intellectual Property Rights, , *Oxford: Clarendon Press.*, (ii) ANDERMASN, S. (2001) "Microsoft in Europe", www.ftc.gov/opp/intellect/020522anderman.pdf (iii) FINE, F. "NDC/IMS: A Logical Application Of Essential Facilities Doctrine", www.ftc.gov/os/comments/intelpropertycomments/ finefrank.pdf, (iv) FORRERSTER, I.S. (2002) "Compulsory Licensing in Europe: A rare cure to aberrant intellectual property rights ?", www.whitecase.com/ article_competition_ip_law_forrester.html (v) FREDRIKSSON, S. (2001) "When the refusal to deal becomes an abuse of a dominant position: A study of how article 82 EC Treaty limits the freedom of action for undertakings in a dominant position", Faculty of Law, Lund University.www.kkv.se/epdf/uppsats2002_fredriksson.pdf, (v) LANG, J.T. (2002) "Compulsory Licensing of Intellectual Property in European Community Antitrust Law", for the Department of Justice/Federal Trade Commission Hearings, Washington D.C. www.ftc.gov/opp/intellect/020522langdoc.pdf

20. Case 238/87: Volvo v. Veng, [1988] E.C.R. 6211

21. Joined Cases C 241& 242/91P, RTE and ITP v. E.C. Commission: [1995] E.C.R. I-743

22. Case T-504/93, Tierce Ladbroke v. E.C. Commission: [1997] E.C.R. II

23. Oscar Bronner v. Mediaprint, Case C-7/97, [1998] ECR I-7791

24. Oscar Bronner v. Mediaprint, Case C-7/97, [1998] E.C.R. I-s.779, par.56

25. Oscar Bronner v. Mediaprint, Case C-7/97, [1998] E.C.R. I-s.779, par.57 and par.62

26. Oscar Bronner v. Mediaprint, Case C-7/97, [1998] E.C.R. I-s.779.

27. LANG, J.T. (2002) "Compulsory Licensing of Intellectual Property in European Community Antitrust Law", for the Department of Justice/Federal Trade Commission Hearings, Washington D.C.

    www.ftc.gov/opp/intellect/020522langdoc.pdf p.22

28. Decision of the TCA, No: 00-26/292-162 and Date: 17.7.2000 (Biryay-I), and Decision of the TCA No: 00-49/529-291 and Date: 14.12.2001 (Biryay II)

29. HARWOOD, S. (1999) "Parallel imports and the exhaustion of rights: the world focus" Tibor Gold. www.shlegal.com/docs/parallelimports.pdf

30. For a detailed information regarding the views supporting parallel trade, see: FINK, C. (1999) "Entering the Jungle of Intellectual Property Rights: Exhaustion and Parallel Imports"

    www1.worldbank.org/wbiep/trade/ c_papers/fink-parallel.pdf

31. For a detailed study on the views supporting a ban on parallel trade see: OECD, (2002) "Synthesis Report on Parallel Import" Joint Group on Trade and Competition. COM/DAFFE/COMP/TD(2002)18/FINAL

32. Decision of Court of Appeal 11. Legal Department, No: 1998/7996 -Date: 12.3.1999 (Yargıtay 11. Hukuk Dairesi'nin 12.3.1999 tarih ve 1998/7996 Esas sayılı kararı).

33. Sesa Decision of the TCA, No: 00-44/47257 and Date: 11.06.2000, Armada Decision of the TCA, No: 01-25/238-61 and Date: 29.5.2001 (Rekabet Kurulu Sesa Kararı ve Armada Kararı)

34. EC Commission (2001) "Evaluation Report on the Transfer of Technology Block Exemption Regulation No: 240/96" http://www.europa.eu.int/comm/competition/antitrust/technology_transfer/en.pdf , para:190, p.43

UNITED KINGDOM

Introduction

In compiling its contribution for this roundtable, the United Kingdom (UK) has focused on cases that have been handled under its current competition regime (i.e. since the introduction of the Competition Act 1998, in March 2000). Prior to this date, the relationship between competition policy and intellectual property (IP) law in the UK was slightly different and the UK's competition rules were less in line with EU competition law. The introduction of the various provisions of the Enterprise Act 2002, in April and June 2003, has introduced further changes to the UK competition regime.

IP law plays a very important role in providing incentives for dynamic competition and innovation. The UK competition authorities recognise the importance of this role and would only expect to intervene in IP issues in exceptional circumstances. As observed by Pat Treacey, such circumstances are more likely to arise in markets characterised by rapid technical changes; high degrees of interoperability and intense patenting, often of incremental, but still patentable advances.[1] The biotechnology industry is one example.

Since March 2000, the UK has not produced much competition case-law relating specifically to the biotechnology sector. Nevertheless, we have had a few cases, mainly in other sectors, where the issue of intellectual property rights (IPRs) has entered into the analysis to a greater or lesser extent. The OFT has also published research papers on *Innovation and Competition Policy*[2] and *E-commerce and its Implications for Competition Policy*[3]. Both of these papers have looked in passing, at a more theoretical level, at the interaction between competition policy and IPRs. In addition, the Intellectual Property Institute (IPI) has recently conducted a study on behalf of the Department of Trade and Industry (DTI) looking at the competitiveness of current UK law and practices with regard to patents for genetic sequences.[4]

This paper addresses a number of the themes raised in the OECD letter of 24 March 2004 to all competition delegates and observers, providing brief descriptions of relevant recent UK cases where possible.[5]

First, we point to the recent change in the relationship between IP law and competition law in the UK and highlight some thoughts regarding the proper role of competition agencies in the patent/IPRs process. Then, insofar as can be inferred from the competition authorities' published case reports, we discuss the approach that has been taken regarding:

- IPR quality and scope;
- reach-through licensing agreements;
- patent (or IPR) pools; and
- unilateral refusal to license.

We do not have any decided cases that address the other issues raised by the OECD paper (the anti-commons problem and exemptions to patent rights).

1. The Proper Role of Competition Agencies in the Patent Process

What role should competition authorities play in the development of patent policy or in the patent granting process, if any?

- *For example, should competition agencies be involved in decisions concerning whether to award a patent, or concerning how to phrase the patent?*
- *Should competition authorities be allowed to challenge the validity of questionable patents that have already been granted?*
- *How can competition agencies, whose primary expertise is not in IP, effectively determine the scope and assess the validity of complex patents?*
- *Should competition agencies simply establish good communication with IP agencies and play only an indirect role in the formulation and implementation of patent policy?*

In looking at the relationship between competition agencies and IP law, we note that there have been moves in Australia and the United States (US) to increase the emphasis placed on competition in the process for granting patents. All other things equal, these moves appear to make it more difficult to obtain a patent in those jurisdictions.

Where IPRs are granted relatively easily, or are relatively broad, there is more likely to be a role for competition policy to limit their exploitation. This has been argued to be one explanation for a difference of approach in the US and Europe with regard to competition law and copyright. As Ian Forrester suggests, a case like *Magill*,[6] where the European Courts endorsed a Commission remedy under competition law that ordered broadcasters to negotiate a royalty-bearing licence for access to their programme schedules, probably would not have arisen in the US, because those schedules would never have been granted copyright in the first place.[7]

With patents, rather than copyright, however, the situation in the US may not be so different from Europe, with the broadening scope of patents being questioned. A recent article by Paul Klemperer highlights some difficulties in challenging overly broad patent protection in the US courts.[8] The fast-moving nature of the markets concerned and free-rider problems both make it hard for parties to bring successful cases against such patents, because they reduce the incentive for any one individual to take action.

In the UK, we have arguably moved in the opposite direction from the recent initiatives in the US and Australia. Before the Competition Act 1998 came into force, conduct by IPR owners that could potentially raise competition concerns was controlled more directly by IP legislation. Sections 44 and 45 of the Patents Act 1977, for example, provided for the nullity of certain restrictive conditions within contracts relating to patented products.[9] These two sections, however, have now been repealed by section 70 of the Competition Act 1998. At the time of the entry into force of that Act, the view was expressed that general competition legislation provided the appropriate mechanism to deal with any competition problems arising from this kind of provision in agreements relating to IPRs.[10]

The UK Patent Office has suggested that direct involvement of competition authorities in challenging the validity of patents that have already been granted is likely to raise various procedural complications. This suggests, therefore, that the best approach, regarding the formulation and implementation of patent policy, might be for competition agencies to play only an indirect role, but to establish and maintain good communication with IP agencies. Such communication should ensure that the competition authorities are at

least satisfied that the IP legislation has been appropriately drafted, reducing the need for them to question the validity of an IPR.

Accordingly, recent UK competition authorities' decisions have focused on whether the *exploitation* of a patent may be regarded as anti-competitive, rather than directly on questions of *patent validity*.[11] However, if the competition authorities were concerned that the rules for awarding patents, or other forms of IPRs, struck the wrong balance between the interests of the rights-holders and the broader interests of promoting competition and innovation, then there is scope for them to intervene – either through market studies, or in their role as ad hoc advisers to Government.

It should be noted that it is also possible for parties to challenge the use of IPRs under competition law through the UK courts, as well as via the competition authorities. In *HM Stationery Office v Automobile Association Ltd.*, the court found against the claim that the charging of a licence fee for use of mapping information amounted to the abuse of a dominant position.[12] The judge went on to point out that to disallow the fee would be tantamount to denying the validity of the IPR. In a way, this can be seen as confirming the focus of competition law on exploitation rather than validity of IPRs.

One issue that has not been addressed above is the interaction between competition law, IP law and other forms of regulation. This has been considered to some extent by the UK Competition Appeals Tribunal (CAT) in its judgments concerning both *Genzyme Limited (Genzyme)*[13] and *Napp Pharmaceutical Holdings Limited (Napp)*[14], in terms of the relationship between competition law and the Pharmaceutical Price Regulation Scheme (PPRS) in the area of pharmaceutical pricing. It was also addressed by the Competition Commission in its market investigation in the supply of prescription-only veterinary medicines, where the impact of marketing authorisations was examined alongside patent rights.[15]

In both *Genzyme* and *Napp*, the parties' defence suggested that the PPRS restricted their ability to exploit their IPRs anti-competitively. However, the CAT found that any restriction imposed by that regulation was insufficient to prevent a breach of competition law. Other forms of regulation may not necessarily remove the need for competition law to be applied in sectors where IPRs exist.

2. Patent Quality and Scope

The biotechnology industry is relatively new, complex, and rapidly evolving. Concerns about patent quality and scope have been raised in such industries, meaning that patents may sometimes be granted for technologies that probably should not receive patents because they do not meet statutory criteria, while other inventions may be eligible but the patents themselves are worded too broadly or ambiguously. How does the level of patent quality affect competition in the biotechnology industry? The following are more specific questions that can be raised in connection with patent quality and patent scope:

- *Have agencies encountered any cases in which competition was affected by poor patent quality? Please describe.*

- *Specifically, have agencies seen any indications that biotechnology patents are being awarded without meeting statutory requirements of patentability? Have agencies seen any evidence that biotechnology patents are defined too broadly or ambiguously?*

- *How do overly broad or ambiguous biotechnology patents affect competition?*

- *In what ways does patent ambiguity (i.e., difficulty in determining what a patent does and does not protect) make competition law enforcement more difficult? For example, does it matter that*

patent ambiguity might make it harder to determine the nature of competitive relationships between biotechnology companies?

We recognise that low quality or overly broad patents have the potential to damage competition.

The IPI study finds that while concerns relating to patent scope and quality were voiced in the UK in relation to patents for genetic sequences, those concerns do not appear to have been realised.

Moving away from the biotechnology sector, the OFT discussion paper on *E-commerce and its Implications for Competition Policy* suggests that the protection awarded by IPRs in e-commerce markets may be excessive in some cases. This paper points out that some innovations in these markets "*do not require significant upfront investments in R&D, they are often little more than ideas, and thus are unlikely to justify supra normal profits for the patent holder over a prolonged period. Moreover, many are key inputs into the development of e-commerce sites. The ability to restrict supply of such IPRs, or to charge excessive prices for them, may therefore have significant detrimental effects on competition in e-commerce markets*".

There are no recent UK cases where the quality or scope of an IPR was found to breach competition law. However, we have had cases both where the scope of an IPR had to be reviewed and where it could be argued that the behaviour of the parties was aimed at extending the scope of patents that they had received.

In a case involving *video rental distributors*, it was necessary to establish the scope of an IPR in order to assess whether a supply agreement had infringed the Chapter I prohibition of the Competition Act 1998.[16] The agreements between the distributors and retailers contained restrictions on the ability of retailers to sell ex-rental videos. In assessing the competition effects of these restrictions, the OFT considered whether the distributors were justified in including them in terms of IPR protection. Following EC precedent, the OFT stated in its case summary that:

"The OFT considers that the existence of an IPR, such as a copyright in a film, will not raise competition concerns. However, the way that IPR is exercised could infringe the CA98. The OFT's view is that a restriction in an agreement that does not go beyond what is necessary to protect the essential function or specific subject matter of an IPR cannot infringe the Chapter I prohibition."

It then proceeded in establishing whether each restriction identified was necessary to protect the essential function of the copyright concerned, as defined in section 18A(2)(a) of the Copyright Designs and Patents Act 1988. The case was closed because the OFT basically found that the restrictions **did not** go beyond what was necessary.

Also relating to the issue of the scope of IPRs, in *Genzyme*, the CAT discussed the possible extension of monopoly rights granted in one market to the appellant's position in another, related market. In short, Genzyme argued that the rights attributed to it should permit certain behaviour that exploited those rights to some extent. The OFT and CAT, on the other hand, both thought that the behaviour went beyond the legitimate exploitation of any rights that had been granted to Genzyme.

This case concerned the alleged exclusionary behaviour of Genzyme in relation to the supply of its drug Cerezyme, used in the treatment of Gaucher's disease, and associated homecare services. Cerezyme is an 'orphan drug', used for the treatment of a rare disease and subject to additional economic incentives for research and development being provided by the authorities. One way in which these incentives are provided is by granting orphan drugs a period of market exclusivity. However, in answering Genzyme's

argument that the OFT's decision was contrary to the EU's objectives in developing orphan drugs, the CAT stated:[17]

> "*We note in particular that orphan drugs legislation is rightly directed to encouraging investment in the research and development of orphan drugs, but we see no compelling reason why a manufacturer such as Genzyme, who already has a monopoly on the product, should, on the basis of the orphan drugs legislation, also have a monopoly on the methods of distribution of the product, or the supply of services necessary for the home treatment of the patients concerned. Indeed, to the extent that Genzyme's pricing policy may have some inhibiting effect on the entry into the United Kingdom market of new drugs for the treatment of Gaucher's disease, there may be some negative effect on the marketing in the United Kingdom of a second orphan drug for the treatment of that disease.*"

An earlier judgment of the CAT (then the Competition Commission Appeal Tribunal), again concerning the pharmaceutical industry, also addressed the issue of the scope of patent protection. In *Napp*, the appellant argued against the OFT's finding of excessive pricing of its sustained release morphine product, MST, in the community sector. Napp stated that an adequate return on investment should not be limited to the patent period and that many drugs which come off patent continue to command high prices and maintain substantial market shares because of legitimate "first mover" advantages. (In its decision, the OFT had basically argued that Napp's excessively low price for MST to the smaller hospital segment had enabled it to maintain its position and excessively high prices in the community.)

In addressing this point, the CAT agreed with the OFT's view that "a manufacturer with an innovative product cannot demand or expect prices to remain at excessively high levels indefinitely. Indeed, one of the principal purposes of the patent system is to confer a degree of exclusivity, thus enabling companies to recover substantial research and development costs and investment in new medicines… In the present case, it is now 20 years since the launch of MST, and Napp's formulation patent expired 10 years ago."[18]

The CAT went on to reject Napp's argument that its high prices can be defended by the need to earn an adequate return on its investment. It pointed out that "*in the case of many pharmaceutical products, the expiry of a patent leads to competitive (often generic) market entry, with the consequence that the incumbent supplier either lowers prices, or loses market share, or both, perhaps quite rapidly… In the present case, however, Napp has maintained* ***both*** *the price of MST* ***and*** *an exceptionally high market share for many years.*"[19]

It can be seen that in *Genzyme* and *Napp*, the CAT explicitly rejected the arguments of the parties that they should have been allowed to extend the scope of their patents into other markets (in the case of *Genzyme*) or over time (in *Napp*) through behaviour that was found to breach the competition rules.

3. The Anticommons Problem

Does a proliferation of patents -- particularly with respect to patented biotechnological research tools that facilitate the discovery and production of downstream products -- lead to a "tragedy of the anticommons"? In other words, is there already such a tangled web of IP rights in biotechnology that companies face an inordinate burden when trying to develop products that depend on numerous supporting patents held by a multitude of other parties? If so, this would mean that patents may actually be discouraging innovation rather than promoting it. Have competition agencies observed an anticommons problem in any of their cases?

We consider the anticommons problem to be a very interesting issue and a possible area for cases to arise in the future. We would be particularly concerned where such a proliferation of IPRs was

discouraging innovation, rather than promoting it. However, we have no competition case-law in the UK in this area to date.

4. Exemptions

From a competition policy standpoint, should there be exemptions to patent rights? For example, should universities have exemptions for the purpose of conducting research? What other exemptions should be permitted, and under what circumstances? Would it make sense to harmonize positions across national borders, assuming that some markets are worldwide? What effects would follow, if any, if exemption standards are divergent?

Ideally, case-law on applying on Chapter I of the Competition Act 1998/Article 81(1) EC, along with the criteria set out in section 9/Article 81(3) would enable genuinely beneficial cooperation in this field to take place. There is no established UK case-law in this specific area to which we can currently refer.

5. Reach-through Licensing Agreements

What are the competition policy implications of licensing agreements that involve royalties based on the revenue generated by a downstream product that the licensed technology only helped to identify and develop, but not to produce or sell? Should it be a violation of competition law for a company to use its patent rights to extract profits from something other than what it has patented?

The issue of reach-through licensing agreements seems closely related to that of patent/IPR scope, perhaps with more of a vertical than a horizontal focus. A reach-through licensing agreement in some ways extends the scope of an IPR so that an 'upstream' company/individual can earn a return on its investment in downstream markets where it is not operating directly.[20]

There have not been any recent UK competition cases where specific reach-through licensing agreements of a patent right were directly at issue. Considering IPRs in general, however, a related issue may be the licensing of a trademark developed in one product market to be used in other, related, product markets. A recent case were this issue raised competition concerns involved *Consignia plc and Postal Preferences Services (PPS) Ltd*. In this case, Consignia (a monopolist in the mail delivery market in the UK) granted PPS (a co-operative joint venture company in which Consignia had 44.6% shareholding) a licence to use Consignia's Royal Mail trademarks on its lifestyle data questionnaires.[21] The decision concerned the same issues as a UK court judgment, *Claritas*.[22]

In its decision, the OFT stated that the legitimate exercise of an IPR, such as a trade mark, by a dominant undertaking would not constitute an abuse. In assessing whether the exercise of such a right was legitimate in this case, the OFT considered Consignia's long term monopoly position and its potential effect on PPS's questionnaire response rates 'due to the unique status of the Royal Mail trade marks as a consequence of that position'. In view of these factors, the OFT thought it reasonable to suspect that the licensing of the trademarks was not legitimate and was therefore capable of amounting to an abuse under the Chapter II prohibition.

However, the investigation found that PPS had not achieved substantially higher response rates than its competitors; that the Royal Mail trade marks appeared not to have markedly boosted the response rate; and that potential customers of PPS data were likely to continue to purchase data from their current suppliers.

These factors led to the conclusion that PPS had been competing legitimately.

6. Patent Pools

Patent pools arise when patents held by two or more parties are licensed as a package. What are the positive and negative ramifications of patent pools for competition policy? Might they help to ameliorate an anticommons problem in the biotechnology industry? Which characteristics of patent pools are pro-competitive, and which are not?

Although the UK competition authorities have not dealt with any cases involving patent pools, the OFT has investigated a number of cases involving the collective selling of sports rights, such as media rights. We consider these cases to raise many similar issues to those raised by patent pools.

In the OFT discussion paper on *Innovation and Competition Policy* it is mentioned that the key question in assessing the impact on competition of IPR pools is whether the IPRs that are being pooled are substitutes or complements. When they are complements, the arrangement is likely to be pro-competitive. When they are substitutes the arrangement may well be anti-competitive. This has been roughly the approach taken by the OFT in assessing IPR pooling arrangements.

In the *Attheraces* case, for example, the OFT considered the lawfulness of the collective selling of certain media rights to Attheraces by 49 racecourses.[23] To fill its TV channel with sufficient content, Attheraces required a critical mass of content - picture rights. The racecourses argued that this meant that their rights were complements (in the economic sense of the word), and thus that joint selling was justified.

However, no individual racecourse (or group under common ownership) was crucial for the channel. For example, Attheraces required a critical mass of 70% of the rights and the largest racecourse group's share was less than 30%. Therefore, no individual racecourse could veto a deal by withholding its rights. As a consequence the OFT concluded that the racecourse rights were in fact substitutes and that the joint selling arrangement breached competition law.

7. Unilateral Refusals to License

How have the competition authorities analysed unilateral refusals to license, both in general and in the biotechnology sector? Does the biotech industry have any characteristics that distinguish it from other industries for purposes of this analysis? For example, does the fact that many biotechnology patents are granted for research tools rather than commercial products have any bearing on the analysis of unilateral refusals to license? What if the patent covers a tool that is relied upon by a range of competitive research instruments and products?

A number of recent UK competition cases where IPRs were at issue have involved some form of unilateral refusal to license, or to supply under reasonable terms, an IP-protected product. In these cases, the competition authorities have considered potential foreclosure and/or strengthening of market power effects arising from the way in which the IPRs were being exploited.

[Possible infringement of competition law was only found in cases were there was dominance (In *ICL/Synstar* there was no dominance and hence no infringement) – however, the OFT cases were closed without finding an infringement, as the dominant undertaking/IPR owner agreed on more favourable terms and conditions of supply – see *Capita/Bromcom* and *BSI*.]

In the *Capita Business Services and Bromcom Computer* case, Capita was the dominant supplier in the market for school information management systems and had refused to supply under reasonable terms the interface information required to access data in its system (SIMS).[24] Schools must license a number of 'modules' that require this interface information to enable them to extract and input data on SIMS. Capita

and Bromcom at least operated in the market for such modules. The OFT's initial conclusion was that, by restricting access to the adequate interface information – Capita was making the availability of necessary information conditional on the supply of an interface written and charged by itself – Capita could 'potentially limit innovation and choice by excluding competition between Bromcom's products and Capita's own modules'. The case was closed as voluntary assurances were accepted under which Capita agreed to supply the required interface information on request.

The *BSI* case, which involved the refusal to license an IPR, was closed without a decision being taken on whether BSI was dominant or had abused a dominant position.[25] BSI had refused to grant Barbour Index plc a licence to supply BSI standards online when BSI sold information on these standards direct to customers through its joint venture company British Standards Publishing. The case was closed as BSI agreed terms and conditions to supply an online licence to Barbour.

In *ICL/Synstar*, Synstar alleged that ICL, a supplier of computer equipment with mainframe functionality (the primary market), had refused to supply certain diagnostic 'proprietary' software to 'non-ICL hardware maintenance supported customers', thereby preventing third party maintainers from competing for hardware maintenance contracts for ICL mainframes, i.e. from competing in a secondary market.[26] However, the OFT did not find that ICL was dominant in the primary market and, because of whole-life costing by purchasers of hardware and other constraints on ICL, it was concluded that there was no relevant secondary market for hardware maintenance services in the UK for ICL mainframe computers. Thus, the OFT concluded that the refusal to supply an IPR in this case did not constitute a breach of competition law.

The UK Court of Appeal has also dealt with a case concerning unilateral refusal to license a patent on reasonable terms. This case involved Intel Corporation and VIA Technologies.[27] VIA based part of its defence against an action by Intel for patent infringement on competition law. It alleged that Intel had refused to license its patent on reasonable terms and, as such, had abused a dominant position.[28] According to VIA, this would affect its ability to compete with Intel as well as preventing certain products coming to market. VIA also questioned the validity of the patent in question.

Although VIA's defences were all struck out by the High Court in June 2002, they were upheld on appeal. The Court of Appeal did not investigate whether the allegations of dominance were correct, but proceeded on the basis that they were. It came to the view that the licence terms complained of by VIA were capable of infringing competition law. It based this decision partly on the ECJ decision in *Magill*, but stated that a patent holder may be under an obligation not to exercise his rights so as to exclude competitors from the market in circumstances that may differ from those identified in *Magill*.

8. Conclusions

The recent UK case-law cited above reflects the extensive EC case-law to which we are obliged to have regard according to section 60 of the Competition Act 1998. From the cases that we have observed, it is clear that the competition authorities have focused on the exploitation of IPRs and have not challenged their validity.

In addition to the cases highlighted above, the UK authorities have dealt with other competition cases that do not address any of the particular issues highlighted by the OECD, but where IPRs have played an important role in establishing dominance or abuse. An example of such a case is the OFT's decision relating to *BSkyB*, where both film and sports rights were central to the investigation.[29]

Primarily, cases have concentrated on preventing rights-holders from extending their market power beyond that necessarily granted by IPRs. Arguably, these cases have particularly focused on ensuring that

IPRs are not used to inhibit dynamic competition and innovation. In this sense, it may be more appropriate to view competition law as working alongside intellectual property law to encourage dynamic competition, rather than the two being in conflict.

NOTES

1. *Patent infringement meets competition law: "An indigestible dish"? – The Court of Appeal's Judgement in Intel v VIA*. Published on the Bristow's website in February 2003

   http://www.bristows.com/articles/detail.asp?frmAreaID=0&frmarticleid=456&frmpdtid=2 .

2. *Innovation and competition policy*, OFT Economic Discussion Paper 3, March 2002
   Part I: http://www.oft.gov.uk/nr/rdonlyres/f2f29154-6575-4980-b957-cd197c4b7606/0/oft377part1.pdf
   Part II: http://www.oft.gov.uk/nr/rdonlyres/429d9406-2740-43e9-995f-0b226724ba2c/0/oft377part2.pdf

3. E-*commerce and its Implications for Competition Policy*, Discussion Paper 1, August 2000
   http://www.oft.gov.uk/NR/rdonlyres/C58CF2CF-8E9D-496A-B989-8FF1BE9DE863/0/oft308.pdf

4. Patents for genetic sequences: the competitiveness of current UK law and practice (A study by the Intellectual Property Institute on behalf of the DTI).

5. Published reports by the UK competition authorities on these cases have not, typically, contained much discussion of the economic aspects of the interface between competition policy and IPRs.

6. *Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v Commission*, Joined cases C-241/91 P and C-242/91 P, [1995] ECR I-0743, on appeal from *RTE v Commission*, Case T-69/89, [1991] ECR II-0485 and *ITP v Commission*, Case T-76/89, [1991] ECR II-0575.

7. *Compulsory licensing in Europe: a rare cure to aberrant national intellectual property rights?*, Presentation by Ian Forrester, Q.C., Department of Justice/Federal Trade Commission Hearings, Department of Justice, Great Hall, Washington D.C., 22 May 2002.

8. *America's patent protection has gone too far*, Paul Klemperer, Financial Times, 2 March 2004, p.19

9. Section 44 rendered automatically void tie-in clauses in licences. Section 45 allowed either party to a licence concerning a patent or patents which had expired to terminate the licence to the extent that the contract related to the subject-matter of the expired patents in question. An infringement of Section 44 of the Patents Act meant that a patentee could not enforce his patent in the UK.

10. *Competition and IP – The Solutions*, Pat Treacey (May 2002). Bristows www.bristows.com .

11. We recognise that there might sometimes be quite a fine line between challenging the way an IPR is exercised/exploited and questioning the validity of that IPR. On the whole, however, even measures such as compulsory sublicensing still enable the rights-holder to earn a (monopoly) return on those rights and so do not really annul the validity of the IPR.

12. *HM Stationery Office v Automobile Association Ltd.*, 25 September 2000

13. *Genzyme Limited v The Office of Fair Trading* [2004] CAT 4

14. *Napp Pharmaceutical Holdings Limited and Subsidiaries v Director General of Fair Trading* [2002] Competition Commission Appeal Tribunal, Case No. 1001/1/1/01

15. *Veterinary Medicines; a report on the supply within the United Kingdom of prescription-only veterinary medicines*, Cm 5781, April 2003.

16. http://www.oft.gov.uk/nr/rdonlyres/bba4cd8d-6fd9-441a-9dc2-017522d18354/0/december2003.pdf

17. *Genzyme*, at paragraph 586.

18. *Napp*, at paragraph 416

19. *Napp*, at paragraph 417

20. The 'input' supplied by the 'upstream' company need not be physical – it may be an idea.

21. http://www.oft.gov.uk/nr/rdonlyres/522756ad-7a89-4fb6-b97c-864efc29873c/0/consigniadecision.pdf

22. *Claritas (UK) Limited v Post Office and Postal Preference Service Limited* [2001] U.K.C.L.R. 2.

23. http://www.oft.gov.uk/NR/rdonlyres/A98734AE-9CC1-4240-9E86-BD1DD47AFE6C/0/atr.pdf

24. http://www.oft.gov.uk/nr/rdonlyres/39da216d-b356-4893-802b-b00241a4bdf8/0/april2003.pdf

25. http://www.oft.gov.uk/news/press+releases/2003/pn+94-03.htm

26. http://www.oft.gov.uk/nr/rdonlyres/c0f9b63b-735f-4cd0-9db0-6645ad7357af/0/icl.pdf

27. *Intel Corporation v VIA Technologies* (20 December 2002) Neutral Citation [2002] EWCA Civ 1905.

28. Intel, for example, had offered VIA a licence under which VIA would be entitled to manufacture only chipsets when Intel required VIA to cross-license Intel under VIA's patents to manufacture any product. VIA alleged that this lack of reciprocity was anti-competitive and infringed both UK and EC competition law.

29. http://www.oft.gov.uk/nr/rdonlyres/111cb949-b636-444c-b557-5e73a0244a54/0/sky2.pdf

UNITED STATES

Executive Summary

Patents have played a central role in the growth of the biotechnology sector. Like other industries in which patents, research and development, and rapid advancements in science determine commercial success, the biotechnology sector poses formidable tasks for competition policy authorities. In addressing issues in this sector, competition agencies must:

- recognise and account for interdependencies between the competition policy system and regimes governing the definition and exploitation of intellectual property rights;

- devise analytical approaches that account for the competitive benefits and hazards of complex commercial phenomena within the context of an unusually dynamic technology environment;[1] and

- build institutional capacity that is well-suited to diagnose the relevant commercial arrangements accurately and, where intervention is warranted, to take timely measures to correct competitive problems.

From either an analytical or institutional perspective, these tasks are among the most challenging that competition policy systems are called upon to address today.

Policymakers in the competition and intellectual property fields should adopt a more interdisciplinary orientation that focuses not only on competition policy or intellectual property policy in isolation, but also accounts for interrelationships between the two fields.[2] Competition policy agencies are likely to find that the economically sensible application of doctrine in the biotechnology sector and in industries featuring similar levels of innovation requires greater understanding of the intellectual property system and demands careful attention to each high technology sector's distinctive characteristics. Successful policy making in biotechnology and related areas may require adjustments in the operation of competition authorities, particularly in the form of resource allocation choices that entail greater investments in expanding their base of knowledge. In all of these areas, the focus of policymaking should not be limited to doctrinal concepts but also should address the effectiveness and capabilities of the institutions responsible for devising competition policy and intellectual property policy.[3]

1. Introduction

By letter of 24 March 2004, the Chair of the OECD Competition Committee invited delegates to contribute papers in preparation for the Roundtable on Competition Policy and Intellectual Property with a Focus on the Biotechnology Industry. The Chair's invitation solicited views about the interaction of the competition policy and patent policy systems and about specific competition issues that arise in the biotechnology field.

To a large degree, this paper summarises recent work of the U.S. Department of Justice (DOJ) and the Federal Trade Commission (FTC) on the interrelationship between competition policy and intellectual property policy. This contribution draws heavily upon the results of joint hearings that the DOJ and the

FTC undertook in 2002 on the subject of Competition and Intellectual Property Law and Policy in the Knowledge Based Economy (Hearings).[4] Over the course of ten months, the DOJ and the FTC held 24 days of hearings and heard presentations from over 300 panellists, including representatives from academia, private industry, the private bar, and various government agencies. The FTC subsequently published a report, *To Promote Innovation*, that recommended adjustments in the patent system (FTC Innovation Report).[5] The DOJ and the FTC presently are completing a joint report addressing a range of issues concerning the design and application of antitrust doctrine to intellectual property.

The Hearings devoted special attention to the pharmaceutical, biotechnology, internet, and computer hardware and software industries. The proceedings indicated that both competition and patents play important roles in stimulating innovation in this field. The Hearings featured an active debate among participants, including disagreement about the degree to which the development of an "anticommons" was hindering innovation in biotechnology.[6] The results of the proceedings were generally consistent with the finding, reported below, that measures to ensure the robustness of the rights-granting process can make useful contributions toward discouraging the issuance of overbroad or weak biotechnology patents.

2. Recognising Interdependencies

The Hearings underscored the considerable degree of interdependency between the competition policy (CP) and intellectual property (IP) systems. Flaws in the regime through which a government grants IP rights can yield patents that are "questionable" or "weak" in the sense that a more robust process for vetting an application would have shown that the application failed to satisfy legal standards of patent-worthiness. When weak patents have true commercial significance,[7] such rights can curb competition and innovation unnecessarily. At the same time, faulty antitrust rules can diminish harmfully incentives to create and exploit IP rights.

A normative proposition that emerges from the recognition of CP-IP interdependency is the importance of efforts to address potential deficiencies within each regime. Inattentiveness to weaknesses in the rights-granting process may induce competition agencies or courts to apply antitrust doctrines expansively to mitigate the consequences of improvidently issued IP rights. In parallel fashion, the application of ill-conceived antitrust rules may lead courts to define IP rights broadly in an effort to eclipse the operation of the antitrust system. In either instance, the "first-best" solution is to correct flaws at their root rather than to rely on the "second-best" application of one body of legal doctrines to counteract the ill-effects of policies or rules generated in a separate area of law.

2.1 Patent Quality

Without reviewing all contributions from the Hearings or recounting the recommendations presented in the FTC Innovation Report concerning the U.S. patent system, it is possible to identify at least three basic measures that a regime for granting IP rights can take to achieve the innovation-related aims of patent policy without unnecessarily restricting competition.[8] Efforts to enhance the quality of the rights-granting process assume particular significance when the patent system in question creates strong presumptions of patent validity once a patent has issued.

Adequate Resources. One major determinant of patent quality is the level of resources provided to fund the operations of the rights-granting authority. The examination of patent applications involving biotechnology or other disciplines presenting similar technical complexity requires highly specialised skills. Not only must a patent office recruit and retain skilled specialists, but the office also must afford examiners sufficient time to undertake a proper inquiry, especially the review of prior art.

Robust Pre-Issuance Examination Procedures. Beyond providing appropriate resources, a rights-granting organisation can establish procedures that discourage the issuance of weak patents. Possible means to this end include disclosure requirements that compel applicants to provide, at the request of examiners, more information, and engaging a second examiner to perform a "second-pair-of-eyes" review for certain applications.

Develop Lower Cost Mechanisms for Post-Grant Review of and Opposition to Patents. An important ingredient of good patent system practice is the availability of a mechanism for post-grant review and opposition that permits meaningful challenges to patent validity. To date, global experimentation with various means of post-grant review has suggested interesting possibilities for using administrative processes, rather than the litigation of infringement claims in the courts, as relatively lower cost means to this end.

2.2 Competition Policy Doctrinal Quality

Competition policy institutions should strive to ensure that the design and application of competition doctrine does not unduly diminish incentives to create certain forms of intellectual property or impede the efficiency-enhancing arrangements for the exploitation of IP rights.[9] Ill-conceived antitrust rules not only impose social costs directly, but they also may induce courts to adopt doubtful interpretations of IP rights in an effort to blunt perceived overreaching by the antitrust system. Just as IP policymakers should be attentive to adverse spillovers associated with weaknesses in the rights-granting process, CP policymakers must consider the consequences of existing antitrust rules for the creation and exploitation of IP rights.

3. Institutional Implications for Competition Authorities

The issues and developments described above have a number of institutional implications for the operation of competition authorities. Presented below are approaches that competition agencies can take to improve the quality of policy involving areas, such as biotechnology, involving significant reliance on patents and substantial degrees of technological dynamism.

3.1 Increasing the Knowledge Base

One institutional implication of the foregoing discussion is the potential benefit to competition agencies from increasing their investments in activities that strengthen their base of knowledge. As noted below, such investments can take several forms.

Hearings and Workshops. The Hearings provided a valuable means for the U.S. competition agencies to compile a large body of information about the state of academic work at the CP/IP intersection and to collect the views of business officials about current industry developments. For CP/IP issues or for other subjects of competition policy, hearings and workshops can be useful instruments for informing competition agencies about noteworthy developments in theory and practice.[10]

Empirical studies. Empirical work about CP/IP issues can provide valuable insights for policymaking. Competition agencies can undertake such studies on their own[11] or regularly avail themselves of information gathering techniques, such as the hearings described above, to obtain the benefit of empirical work being done by other researchers.

Ex Post Assessments of Past Interventions. Substantial levels of uncertainty can accompany decisions about the application of competition policy principles in dynamic, innovation-driven industries. A valuable means for informing future decisions is to assess the affect of past policy choices. Routine, systematic efforts by the competition authority to perform its own studies or engage external consultants to conduct evaluations can provide valuable guidance about the choice of future enforcement approaches.[12]

Increasing the Number of Professional Staff with IP Expertise. One way to increase the competition agency's knowledge base is to hire additional attorneys or economists with expertise in intellectual property. For example, a competition agency might consider expanding its complement of patent lawyers.

3.2 Improving the Interdisciplinary Dialogue

The activities of many government institutions other than competition policy agencies affect competition. A major challenge for competition policy authorities today is to build relationships with other government bodies whose decisions directly or indirectly influence the competitive process significantly.[13] CP and IP authorities would likely benefit from sustained interdisciplinary cooperation, much in the way that CP agencies have developed stronger institutional relationships with other government bodies, such as sectoral regulators. Increased cooperation would serve to increase the awareness of policymaking interdependencies and to pursue policy improvements that raise the capacity of CP and IP to promote innovation.

4. Selected Intellectual Property Licensing Issues

The following discussion focuses on selected issues raised in the request for submissions.

4.1 Patent Infringement Research Exemption

The scope of the research exemption from patent infringement liability in the United States is quite narrow.[14] The exemption is a judge-made rule that the courts have applied infrequently, only in limited circumstances where a patented device is used "solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."[15] Research institutions are neither automatically granted nor denied an exemption under existing law. Whether such institutions are outside the class of potential infringers, will depend on both the "legitimate business" of the institution and the *de minimise* nature of the technical infringement.[16]

Whether, from a competition standpoint, universities should be immune from liability when their unauthorised conduct involves research and development is a matter of debate in the United States, as demonstrated by panellists' discussions during the Hearings.[17] Some Hearing participants believed that under current law the research exemption is unavailable to most institutions in the United States because their "legitimate business" is research.[18] Those in favour of a more robust exemption propose extending the exemption to activities beyond "idle curiosity," such as research efforts aimed at "design-around" activity or patent improvements, or the use of a patented research tool to create an unrelated product (in the biotech industry, for example, gene fragments might be used to produce an end product, such as therapeutic proteins or genetic diagnostic tests).[19] Many participants agreed that an exemption is appropriate when research asks how or if an invention works, but there was no consensus in favour of an exemption beyond this inquiry.[20]

The National Research Council of the National Academies issued a report entitled, "A Patent System for the 21st Century," in April 2004 that states some research uses of patented inventions should be provided limited protection from infringement liability.[21] The Council encourages Congress to consider appropriate targeted legislation and the federal government to assume liability for patent infringement arising from federally sponsored research in private universities.[22] The Council states that a recent Supreme Court ruling shields state universities from damage awards in patent infringement suits.[23]

4.2 Reach-through Licensing Agreements

Reach-through licensing agreements allow the owner of a patent on a research tool to collect royalties on subsequent downstream products. Such agreements provide a way to value the patented research tool

where valuation is uncertain.[24] The terms generally require royalties on the sales of downstream products that researchers identify or develop with a research tool and also can require an exclusive or nonexclusive license on future products or discoveries (*i.e.*, a grant back) or an option to acquire such a license.[25] In the biotech industry, for example, an owner of a patent on a receptor could enter into a reach-through licensing agreement with a pharmaceutical firm that would use the tool to learn more about the therapeutic effects of a potential product; however, the upstream patent owner would not earn royalties until the drug goes to market.[26]

Reach-through licensing agreements may create efficiencies if they allow risk–sharing between the parties.[27] These arrangements often provide for the waiver of any up-front fee to be collected by the upstream patent owner, and so can promote wider dissemination of the research tool to more biotech firms with limited investment capital.[28] Concerned that reach-through licensing agreements can also restrict access to upstream research tools when researchers must negotiate such licenses with multiple licensors in order to make new downstream products, the National Institutes of Health has adopted a policy restricting their use.[29]

DOJ and the FTC would apply "a rule of reason" analysis to evaluate these agreements, considering whether they would diminish competition in the properly defined market.[30] Factors bearing on this analysis include whether the agreement encourages unlawful coordination among competitors, inhibits market entry through exclusivity or exclusion, or reduces the incentive to innovate in the future.[31] Under a rule of reason analysis, the Agencies weigh these factors against the efficiencies of the particular arrangement.[32]

4.3 Patent Pools

Patent pools are often formed when multiple patent holders seek to simplify access to numerous patents that are necessary to make a product conforming to a standard or limited to a defined field of use. Patent pools are not subject to separate statutory or regulatory authority in the United States; instead, they are analysed under normal patent and competition laws. DOJ and the FTC discussed generally how they would analyse patent pools as part of their 1995 *Antitrust-IP Guidelines.*[33] Within the last few years the United States enforcement Agencies have analysed the competitive impact of several specific patent pools. DOJ has provided detailed specific guidance in its review of three proposed pools: the video compression technology proposal (MPEG-2); the three-company DVD proposal (3C DVD); and the six-company DVD proposal (6C DVD).[34] Although none of these matters involved biotechnology, the Agencies would expect to apply the same analysis in a biotech case. The FTC has provided guidance on patent pools through its 1998 challenge to a pool of patents related to lasers used in eye surgery to correct vision problems.[35] In addition, the United States Patent and Trademark Office has issued an official White Paper on patent pools, specifically in the area of biotechnology.[36] Each of these sources recognises that patent pools can have both procompetitive and anticompetitive effects.

4.3.1 Pro- and Anticompetitive Effects of Patent Pools

There are several procompetitive justifications for patent pools. Patent pools can eliminate the problem of multiple blocking positions, defined as a situation where two or more patent holders can each block a product in the absence of a license from both. Patent pools may reduce transaction costs, since a licensee will find it more efficient to negotiate (or litigate) with a single pool licensor than with the pool's multiple patent holders. Patent pools may also facilitate the integration of complementary technologies and help patent owners avoid costly infringement litigation.[37]

There also are several major risks of anticompetitive effects from patent pools. Patent pools can reduce competition if they include patents that otherwise would compete for licensees. The close

cooperation necessary for a patent pool can similarly reduce competition by providing a forum for price fixing, collusion, and classic cartel behaviour. Patent pools also can foreclose innovation and entrench a dominant technology by discouraging research and development of new products and cost-reducing process innovations.[38]

4.3.2 Factors for Analysis of Patent Pools

The United States applies a "rule of reason" analysis when examining the competitive impact of most licensing arrangements,[39] including patent pools.[40] Although no one factor is dispositive, competition authorities pay particular attention to the following issues when analysing the competitive effects of patent pools:

Limiting Pools to Complements; Avoiding Substitutes. Patent claims are "substitutes" if they involve products or processes that can compete with each other on a stand-alone basis. Patent claims are "complements" if they must be used concurrently, rather than alternatively, to achieve a particular product or process. Pooling of pure substitute technologies can decrease competition, whereas pooling of complementary patents can increase efficiency by removing the need to negotiate separate licenses for each product (among other factors).

Safeguards Against Downstream Coordination. Since a patent pool requires information sharing among its participants, the possibility exists that participants could coordinate to raise prices or fix other commercial terms. To lower this risk, patent pools should limit the collection of and access to competitively sensitive proprietary information of pool members and licensees.[41]

Nonexclusive, Non-discriminatory Licensing. To preserve a reward structure for the maximum number of potential innovations, patent pool licenses should be nonexclusive. This means not only that the pool license "out" to licensees should be nonexclusive, which permits the pool to work with as many end users as possible, but also that individual patent holders should license patents "into" the pool on a nonexclusive basis, thus preserving their ability to license individually outside the pool structure. Where pool participants retain the ability to license their patents outside the pool, a competitor can innovate around some patents in the pool and offer a different licensing package.[42]

Limiting the Scope of Grant backs. A "grant back" is a licensing term that requires the licensee to grant back to the licensor (and, in a pool, to the members of the pool) the right to use the licensee's existing and future patents.[43] Grant backs by patent pool licensees can ensure that no party can benefit from a pool while blocking others from using improvements to the standard specifications; however, if the terms of a grant back are too broad, they can deter follow-on innovation. To make grant backs more procompetitive, a pool might: (a) apply them only to innovations that rest upon existing pool patents; (b) limit them to complementary patents and not substitutes to the pool technology; and (c) make them nonexclusive, so licensees are free to license their own innovations to others.[44]

Clarifying Which Patents Are In the Pool. Where a patent pool clearly explains which patents are within the pool, potential innovators can more easily design around the pooled patents in order to develop competing technologies.[45]

Determining Whether the Antitrust "Safety Zone" Applies. If the licensor and the licensees that are parties to a pooling arrangement collectively account for no more than 20 percent of each relevant market significantly affected by the pool, and the restraints associated with the pool are not facially anticompetitive, the federal antitrust enforcement agencies are not likely to challenge the pooling arrangement on antitrust grounds.[46]

NOTES

1. Many competition systems have design features that deliberately facilitate the evolution of doctrine in light of experience and advances in economic and legal learning. *See, e.g.*, William E. Kovacic & Carl Shapiro, *Antitrust Policy: A Century of Economic and Legal Thinking*, 14 J. Econ. Perspectives 43 (Winter 2000) (describing the consciously evolutionary system embodied in the competition laws of the United States).

2. The distinction between intradisciplinary and interdisciplinary perspectives in treating competition policy and intellectual property policy is developed in William E. Kovacic & Andreas Reindl, *An Interdisciplinary Approach to Improving Competition Policy and Intellectual Property Policy* (Paper prepared for the Fordham Corporate Law Institute Program on Intellectual Property, New York, New York, Apr. 2004).

3. On the links between institutional arrangements and substantive competition policy outcomes, see Colin Scott, Institutional Competition and Coordination in the Process of Telecommunications Liberalisation, *in* International Regulatory Competition and Coordination 382 (Joseph McChahery *et al*. 1996) (analysing how different constitutional and institutional arrangements yielded contrasting telecommunications policy outcomes in the U.S. and EU, respectively); Gary Hewitt, "*Background Note*, 1 OECD J. Competition L. & Pol'y 177 (1999) (reviewing ties between institutional regulatory design and substance of competition policy); William E. Kovacic, *Competition Policy in the Post consolidation Defense Industry*, Antitrust Bull. 421 (Summer 1999) (analysing how interaction of competition policy and public procurement institutions affects competition in procurement markets).

4. A complete index to these proceedings, along with links to hearing transcripts and submitted papers, can be found at http://www.ftc.gov/opp/intellect/index.htm.

5. Federal Trade Commission, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy (2003) [hereinafter FTC Innovation Report], *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf.

6. The hearing proceedings involving the biotechnology sector are examined in Chapter 3, Section III, of the FTC's Innovation Report.

7. There is general understanding within the competition policy community that not all patents are commercially significant. For the most part, competition agencies and courts today generally foreswear the practice, reflected in earlier decisions and policy pronouncements, of calling patents "monopolies," as though the right to exclude inherent in the patent necessarily gave the holder of that right substantial market power. *See, e.g.*, U.S. Dep't of Justice & Federal Trade Comm'n, Antitrust Guidelines for the Licensing of Intellectual Property § 2.2 (Apr. 6, 1995), *available at* http://www.usdoj.gov/atr/public/guidelines/ipguide.htm [hereinafter *Antitrust-IP Guidelines*].

8. A central theme of the Hearings was the vital roles that both IP protection and competition can play in stimulating innovation.

9. *See, e.g.*, Makan Delrahim, *US and EU Approaches to the Antitrust Analysis of Intellectual Property Licensing: Observations from the Enforcement Perspective* (Remarks at the Spring Meeting of the American Bar Association Section of Antitrust Law, Washington, D.C., Apr 1, 2004), *available at* http://www.usdoj.gov/atr/public/speeches/203228.htm; R. Hewitt Pate, *Antitrust and Intellectual Property* (Address before the 2003 Mid-Winter Institute of the American Intellectual Property Law Association,

Marco Island, Florida, Jan. 24, 2003), *available at* http://www.usdoj.gov/atr/public/speeches/200701.htm; Timothy J. Muris, *Competition and Intellectual Property Policy: The Way Ahead* (Remarks before the Fall Forum of the American Bar Association Section of Antitrust Law, Washington, D.C., Nov. 15, 2001), *available at* http://www.ftc.gov/speeches/muris/intellectual.htm.

10. Other recent examples of joint DOJ and FTC work of this type include a joint workshop earlier this year on merger enforcement and an extensive set of hearings conducted in 2003 on competition policy and health care.

11. *See, e.g.*, Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration: An FTC Study (July 2002) (presenting results of empirical study on entry of generic pharmaceutical products), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

12. This topic has been a theme of previous OECD contributions from the United States. *See, e.g.*, United States, *The Role of Research in the Design and Implementation of Competition Policy* 12 (Feb. 2004) (CCNM/GF/COMP/WD(2004)30)). *See also* William E. Kovacic, *Evaluating Antitrust Experiments: Using Ex-Post Assessments of Government Enforcement Decisions to Inform Competition Policy*, 9 Geo. Mason L. Rev. 843 (2001) (examining importance to sound competition policy of ex post reviews of completed enforcement initiatives).

13. *See* William E. Kovacic, *Achieving Better Practices in the Design of Competition Policy Institutions* (Remarks before the Seoul Competition Forum 2004, Seoul, South Korea, Apr. 20, 2004) (discussing need for competition authorities to build networks to connect "archipelago" of government bodies that affect competition), *available at* http://www.ftc.gov/speeches/other/040420comppolicyinst.pdf.

14. *Madey v. Duke University*, 307 F.3d 1351, 1362 (Fed. Cir. 2002), *cert. denied*, 123 S.Ct. 2639 (2003) (describing the exception as "very narrow" and "strictly limited").

15. *Id.* at 1363.

16. *Id.* (remanding to the district court for consideration of these issues). Research institutions may also rely on another safe harbour for research activities that are undertaken solely for the purposes of developing and submitting required information to the Federal Food and Drug Administration. 35 U.S.C. § 271(e)(1) (2000), *Integra Lifesciences Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003), *reh'g en banc denied*, 2003 U.S. App. LEXIS 26547 (Fed. Cir. 2003) (limiting exception "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale, of drugs or veterinary biological products"). This safe harbour also applies to the development of medical devices toward that end, and includes experimental testing of generic copies of certain patented animal drugs and biological products. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669, 680 (1990); Judiciary Comm., Generic Animal Drug and Patent Term Restoration Act, H.R. Rep. No. 100-972(II) *at* 20 (Sept. 29, 1988), *reprinted in* 1988 U.S.C.C.A.N. 5659, 5673-74.

17. *See* FTC Innovation Report ch. 4, at 35-37 & n.228 (2003).

18. FTC Innovation Report ch. 4, at 35 & nn.222-223.

19. FTC Innovation Report ch. 4, at 34-37; *see also* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 Science 698, 699 (May 1, 1998) [hereinafter Heller & Eisenberg, *The Anticommons*].

20. FTC Innovation Report ch. 4, at 36-37.

21. National Research Counsel, A Patent System for the 21st Century (2004) (prepublication copy).

22. *Id*. at 93-95.

23. *Id*. at 65-66 (citing *Fla. Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank*, 527 U.S. 627 (1999).

24. *See* Janice Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 Wash. L. Rev. 1, 16 (2001) [hereinafter Mueller, *Rethinking the Experimental Use Exception*].

25. Heller & Eisenberg, *The Anticommons* at 699. A grantback is a provision in a licensing agreement that allows the licensor the "to use the licensee's improvements to the licensed technology." *Antitrust-IP Guidelines* § 5.6.

26. Heller & Eisenberg, *The Anticommons* at 699.

27. *See id*.

28. *See* November 6, 2002 Hr'g Tr., "Relationships Among Competitors and Incentives to Compete: Cross-licensing of Patent Portfolios, Grantbacks, Reach-Through Royalties, and Non-Assertion Clauses" at 172 (Charles F. Rule), *available at* http://www.ftc.gov/opp/intellect/021106ftctrans.pdf [hereinafter Nov. 6 Tr.]; *see also* Mueller, *Rethinking the Experimental Use Exception* at 16.

29. Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources, 64 Fed. Reg. 72090, 72091 (Dec. 23, 1999), *available at* http://ott.od.nih.gov/textonly/64FR72090.pdf; *see also* Nov. 6. Tr. at 152-53 (Barbara McGarey); Mueller, *Rethinking the Experimental Use Exception* at 8, 16 (discussing NIH's position).

30. *See Antitrust-IP Guidelines* § 3.1 (asking whether the a licensing restraint "harms competition among entities that would have been actual or potential competitors in a relevant market in the absence of the license.").

31. *See, e.g., Antitrust-IP Guidelines* §§ 3.1; *see also id.* § 3.2.3 (considering future innovation); *id.* § 4.1.2 (considering "licensing arrangements involving exclusivity"); *id.* § 5.5 (discussing portfolio cross licenses and patent pooling arrangements); *id.* § 5.6 (grantbacks).

32. *Cf. Antitrust-IP Guidelines* § 4.2 (considering "whether the restraint is reasonably necessary to achieve procompetitive efficiencies").

33. *Antitrust-IP Guidelines* § 5.5.

34. Letter from Joel I. Klein, Acting Assistant Attorney General, U.S. Dep't of Justice, to G[a]rrard R. Beeney, Esq. (June 26, 1997), *available at* http://www.usdoj.gov/atr/public/busreview/1170.pdf [hereinafter MPEG-2 Business Review Letter]; Letter from Joel I. Klein, Assistant Attorney General, U.S. Dep't of Justice, to Garrard R. Beeney, Esq. (Dec. 16, 1998), *available at* http://www.usdoj.gov/atr/public/busreview/2121.pdf [hereinafter 3C DVD Business Review Letter]; Letter from Joel I. Klein, Assistant Attorney General, U.S. Dep't of Justice, to Carey R. Ramos, Esq. (June 10, 1999), *available at* http://www.usdoj.gov/atr/public/busreview/2485.pdf [hereinafter 6C DVD Business Review Letter]. *See also* Letter from Charles A. James, Assistant Attorney General, U.S. Dep't of Justice, to Ky P. Ewing, Esq. (Nov. 12, 2002), *available at* http://www.usdoj.gov/atr/public/busreview/200455.pdf (review of licensing proposal for "third-generation" ("3G") wireless communication technologies). The Antitrust Division of the Department of Justice provides such guidance under the "Business Review Letter" process, codified at 28 C.F.R. § 50.6, which permits private parties to describe a business plan and receive a statement of the Antitrust Division's enforcement intentions.

35. *In re Summit Tech., Inc. and VISX, Inc.*, No. 9286 (FTC filed Mar. 24, 1998), *at* http://www.ftc.gov/os/1998/9803/summit.cmp.htm [hereinafter FTC *Summit-VISX* Complaint]; *In re*

Summit Tech., Inc. and VISX, Inc., No. 9286 (FTC Feb. 23, 1999), Decisions and Orders, *at* http://www.ftc.gov/os/1999/9903/d09286visx.do.htm (*VISX* Consent Decree), *at* http://www.ftc.gov/os/1999/9903/d09286summit.do.htm (*Summit* Consent Decree).

36. Jeanne Clark *et al.*, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents*? (Dec. 2000), at 4-11, *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf.

37. *Antitrust IP-Guidelines* § 5.5.

38. *See id.* For further discussion of the risk of anticompetitive effects, see the Department of Justice business review letters, *supra* note 34.

39. *Antitrust-IP Guidelines* § 4.

40. *See id.* §§ 4.1-4.3, 5.5.

41. 3C DVD Business Review Letter at 12; 6C DVD Business Review Letter at 12.

42. MPEG-2 Business Review Letter at 12-13; 6C DVD Business Review Letter at 12 n.66; *see* 3C DVD Business Review Letter at 12.

43. *Antitrust-IP Guidelines* § 5.6.

44. MPEG-2 Business Review Letter at 13-14; 3C DVD Business Review Letter at 12-13; 6C DVD Business Review Letter at 12-13.

45. *See, e.g.*, MPEG-2 Business Review Letter at 12.

46. *Antitrust-IP Guidelines* § 4.3. A pooling arrangement that falls within this "safety zone" generally should pass muster even if it involves features that otherwise typically might be problematic . Pooling arrangements cannot qualify, however, for safety zone treatment if they are used as vehicles to facilitate collusion.

BIAC

Preface

Innovation and creativity are essential for sustainable growth and economic development. Several core conditions enable innovation and encourage economic growth:

- *strong standards and effective enforcement of intellectual property protection,*
- *vigorous competition and contestable markets,*
- *open trade and investment in a stable economic environment,*
- *a strong and sustainable fundamental research and development infrastructure,*
- *sound policies and mechanisms to promote the science-innovation interface,*
- *efficient and transparent regulatory systems,*
- *ethics and the rule of law, and*
- *a strong emphasis on education at all levels.*

Intellectual property protection is one of the central public policy pillars on which the knowledge-based industries and global markets of the 21st Century rest. Rapid changes in key technological, policy, and social drivers all underscore their growing importance. Intellectual property rights (IPRs) provide an increasingly critical legal and policy toolkit for spurring innovation, for stimulating the investments needed to develop and market new innovations, and for diffusing technology and other knowledge in socially beneficial ways. Sound framework conditions for a well-constructed IPR regime, therefore, are indispensable.

Nonetheless, certain policymakers, non-governmental organisations, academics and others have questioned the role of IPRs in the emerging 21st Century economy. Some simply oppose the role of property rights and the primacy of market-oriented economies on ideological grounds. Others question the "social contract" associated with granting and promoting intellectual property rights when compared to public sponsorship, government subsidies or other government-directed tools. Still others oppose the underlying technological advances and global market competition that are taking place and, therefore, conclude correctly that IPRs play an important role in creating and sustaining these developments which they view negatively. Finally, some others recognise the importance of IPRs but argue that intellectual property rights increasingly retard, rather than promote, innovation and economic growth.

In this Discussion Paper, BIAC summarises an affirmative case for why a well-developed, carefully balanced system of intellectual property rights provides a fundamental foundation for promoting and achieving sustained creativity, innovation and economic performance in the 21st Century. The first section highlights the importance of IPRs in meeting today's and tomorrow's key economic and technological

challenges. It identifies some of the driving forces and challenges that demonstrate the importance of intellectual property rights and the need to get the legal and policy framework for IPRs "right". The second section draws upon this forward-looking, affirmative case for IPRs to suggest the pivotal role that the OECD should play and to recommend a proactive, multi-point OECD work program related to intellectual property rights over the next few years.

This paper has been prepared for the Ministerial Conference of the OECD's Committee for Scientific and Technological Policy (CSTP) in January 2004. It also, however, should be of equal interest to policymakers in national governments, other OECD Committees and the wider business community.

Executive Summary

Of course, the ultimate cause of all innovation is human creativity. But innovation does not occur in a vacuum; it requires a workable structure of incentives and institutions. Government policies that foster the right enabling conditions for innovation, and that allow entrepreneurship and markets to flourish, can provide a climate that encourages innovation and economic growth in the 21st Century. Increasingly, one of the core enabling conditions is intellectual property protection.

The American inventor and entrepreneur, Thomas Edison, once said, "the value of an idea lies in the using of it." IPRs have become a significant factor in both creating and using ideas that are translated into knowledge and inventions to promote innovation and economic growth. With the advent of an increasingly knowledge-based society, intellectual property protection ensures that innovators and creators have sufficient incentive to bring their works to market and to build on the innovations and creations of others for the benefit of society.

Intellectual property rights remain crucial policy tools for promoting innovation and economic growth in the 21st Century for many reasons, including:

1. IP protection stimulates innovation and spurs sustainable and widespread economic growth by providing incentives that ensure a sufficient supply of new inventions and creations

By providing certainty and incentives for invention and creation to overcome the problems of market failure with public goods, by enabling technology transfers, and by stimulating additional creative activity, IPRs stimulate innovation and create economic growth through increased productivity, increased trade and investment, and enhanced consumer welfare. As efficient market-oriented tools, IPRs are likely to enable firms to more fully appropriate the return from risky and uncertain investments. At the same time, however, it is important that critical attention be given to the quality of IPRs.

2. IPRs promote the disclosure of inventions and pioneering information, which stimulates innovation across and within industries

Intellectual property rights are a market-based mechanism for disseminating knowledge. Public disclosure is one the most important functions of most IPRs, and one of the most overlooked. IPRs spur subsequent creative efforts facilitating a vigorous cross-fertilisation of ideas.

3. IPRs promote risky, uncertain and costly investments

Forward-looking IPR protection provides the incentive for firms and individuals to invest in generating new technology and new products, including incremental improvements, especially where the returns from investment are longer term, where the investment involves significant costs or risks, and where the invention or creation may be easy to copy or imitate.

4. IPRs empower consumer protection in a global economy

The global economy increasingly depends on the international recognition and dissemination of IPRs related to branded products. Trademark protection is crucial to maintaining high-quality goods and services that earn consumer trust. The large and growing problem of counterfeiting, however, is a serious threat to legitimate commerce, as well as to public health and safety. The booming market in fake products too often puts the health, and even the lives, of consumers at risk. Counterfeiting also has a serious impact on reputation and consumer trust.

5. Effective competition policy depends on an appropriate IP regime

Intellectual property and competition policy are vital to maintaining competition and contestable markets because both encourage innovation and enhance consumer welfare. They, increasingly, should be viewed as complementary policy tools.

6. Securing the benefits of IP for the digital economy

Computers, telecommunications, semiconductors, entertainment and education content and other information-based sectors increasingly depend on IPRs as the legal and economic backbone of these industries. Digital piracy, however, threatens the continued growth of the digital economy. IPRs also play an integral role in broadband adoption and in creating new technology platforms and markets through de facto standards and network effects.

7. IP rights create new markets because IPRs are tradeable and transferable

IPRs facilitate the operation of markets and help create new ones because they are tradeable and transferable. The linkage between IPRs and contractual mechanisms such as voluntary licenses, distribution agreements, rights assignments, royalty agreements and other market-oriented transactions and relationships increasingly shapes the pace and direction of innovation processes in positive ways.

8. IP enables innovation in key economic growth sectors, such as healthcare

The large R&D, regulatory, clinical trial and other costs associated with healthcare innovation only can be sustained by innovator healthcare companies if the economic climate and policy framework encourages and supports the role of IPRs throughout the increasingly complex and risky process of innovation.

9. IPRs play a crucial role at the intersection between science and innovation

The quality of all our economies depends on their ability to acquire, protect, translate, combine and apply knowledge through new university-industry-government intersections and public-private partnerships. IPRs play an increasingly crucial role in facilitating these positive trends.

A Proposed, Proactive IPR Action Agenda for "Value-Added " OECD Work Concerning Intellectual Property Rights

- Integrate IPRs more fully, including the quality and the scope of IPRs, as a core enabling condition for innovation in all OECD activities
- Address the changing role of IPRs at the interface between science and innovation and in the interactions between different stakeholders
- Combat counterfeiting through new OECD work and the development of a new international anticounterfeiting convention that will provide for effective enforcement.
- Develop new economic methodologies and economic indicators for measuring IPRs and understanding the increasingly critical role they play in stimulating innovation and economic performance.
- Initiate a forward-looking project about the growing importance of IPRs in "converging technologies" by focusing on the changing role of IPRs in three key 21st Century drivers – biotechnology, information technology and nanotechnology.
- Provide comparative analyses and undertake "value-added" reviews concerning the intersection of IPRs and competition/antitrust policy.
- Focus on health-related innovation as a principal policy challenge for the early 21st Century, and develop new frameworks and policies for linking IPRs and health innovation.
- Analyse the role of markets for technology and the economic accounting of intellectual assets.

1. Introduction -- Intellectual Property Rights: An Increasingly Essential Foundation for Innovation and Economic Growth in the 21st Century

Intellectual property helped make possible the conditions for innovation, entrepreneurship and market-oriented economic growth that shaped the 20th Century. In the 21st Century, IPRs increasingly will define these conditions, and will dictate the pace and direction of innovation, investment and economic growth around the world.

Today, more than ever before, innovation, enterprise and intellectual assets drive economic growth and increase standards of living. Innovation is instrumental in creating new jobs, providing higher incomes, offering investment opportunities, solving social problems, curing disease, safeguarding the environment, and protecting our security. To help achieve these objectives, governments must create appropriate incentives for continued growth in innovation and technology development and embrace sound policies for assuring broad social diffusion and access to key scientific and technological advances that enable us, as Newton first observed, "to stand on the shoulders of geniuses". A critical enabling tool increasingly is intellectual property protection.

BIAC strongly believes that the role of government policy concerning intellectual property must be to create a legal and policy framework for IPRs in which minds can expand, in which innovation can drive economic growth, in which entrepreneurs can flourish, in which important societal needs can be met through market-oriented mechanisms and in which technologies can reach new frontiers.

To achieve these inter-related goals, BIAC focuses on the need to get the policy framework right in the light of a broad range of fundamental scientific, technological, economic and social drivers. These drivers are rapidly transforming the process of innovation. In the process, they provide both new opportunities and challenges for economic growth. BIAC does not advocate in this paper the need for ever stronger IPR regimes. For most companies that BIAC ultimately represents, the goal is to maximise the value of their intellectual property. Similarly, for those companies that BIAC does not yet represent because they do not exist today, the goal must be to enable them to form and grow to world class on the strength of the contributions they make to future societal objectives through the intellectual property they will possess.

BIAC supports the development of a sophisticated, forward-looking IPR policy framework for the 21st Century. This requires: (1) an increased appreciation for the vitality of the IPR "toolkit" and its central role in stimulating innovation and spurring economic growth; (2) renewed attention to specific intellectual property issues such as scope, quality, diffusion, access, strategic use and effectiveness of IPRs; and (3) a new "systemic understanding" about the intersection and interaction of IPRs with other enabling conditions for innovation such as competition policy, government regulatory regimes, the R&D infrastructure, capital formation, and open trade and investment.

If we are to realise the promise of a 21st Century in which innovators can generate new ideas, investors can be persuaded to take the risk to underwrite them, and entrepreneurs can turn these ideas into new products, then intellectual property rights must play an increasingly central role in policy formation. This section highlights the key reasons why intellectual property matters now more than ever. Each section also calls attention to new policy and empirical questions that must be answered objectively and sensibly if governments, business, universities and other stakeholders are to get it "right".

Intellectual property rights are essential for achieving many of today's challenges related to innovation and economic growth while providing the foundation on which tomorrow's societal needs can be met. Their vitality derives from the multiple roles they play. These include:

1.1 Stimulating Innovation and Spurring Widespread and Sustainable Economic Growth

Intellectual property rights are policy instruments that play an increasingly important and positive role in driving innovation and expanding information. By stimulating innovation, information and creativity, IPRs directly affect economic performance and create economic growth through increased productivity, increased trade and investment, and expanded economic activity that enhances consumer welfare.

- *IPRs Create Incentives for Invention and Creation*

Intellectual property rights provide an efficient mechanism to overcome traditional "market failure" problems associated with public goods, information asymmetry and innovation – especially, the imperfect appropriation of returns and uncertainty with regard to research and investment first identified by Nobel-laureate Kenneth Arrow. A principal source of market failure is the inability of individuals and firms to prevent others from making use of the new knowledge they generate. Without the incentives provided by the temporary exclusivity generated by IPR protection, there will not be sufficient incentives for business to invest in risky R&D and other value-enhancing activities because the benefits from those investments cannot be appropriated fully. In economic terms, innovation will be suboptimal.

The economic evidence is overwhelming that a significant gap exists between private and social returns to R&D and other risky and uncertain forms of investment. Most studies find social returns on R&D ranging from 20 to 150 percent although the magnitude of the positive social returns varies among sectors and among countries. With such large externalities, almost all economists agree that business will under invest in R&D and other socially desirable, knowledge-expanding investments without effective intellectual property protection. Innovators cannot earn a profit from their risky and uncertain investments because competitors are free to appropriate their inventions or creations without cost and gain the economic benefit of the invention or creation before the innovator can obtain a sufficient return.

Strong and effective IPR protection is a particularly powerful incentive that will permit firms to invest in generating new technology in sectors where the returns to technological or product investment are longer term and involve significant risks, and where the invention may be easy to copy or imitate. Such protection, in turn, is a highly effective way to promote the diffusion of knowledge in the long term.

Research is only one critical component of innovation. Studies confirm that research constitutes only about 25% of the cost of commercialising a new technology or technique and substantial up-front additional resources are needed to bring most products or processes to the market. The exclusive rights granted a patent holder for a limited time provide the incentive for encouraging all the up-front investments needed to develop an idea and to generate a marketable product or technology.

This compelling argument becomes even stronger in the emerging international economy. The incentives provided by IPRs improve the capacity of domestic firms to adopt new technology and ideas, to use their domestic markets as a springboard to compete more effectively in global markets, and to take advantage of the spillovers from foreign R&D and foreign IPRs. A strong and effective IPR framework also improves each country's ability to attract foreign investment and, especially, to attract certain research- or knowledge-intensive activities that likely will result in important social benefits through new knowledge and new skills. It is a market-driven mechanism that provides an essential building block for future innovation and economic development.

Government policies that appear to favour the spread and dissemination of a given stock of knowledge by relaxing or eroding IPR protection discipline form a strong disincentive to investment in and, hence creation of knowledge in the medium and longer term. By promoting secrecy and discouraging disclosure of inventions, they preclude many of the collaborative private-public partnerships and new types

of strategic relationships among firms that the OECD recognises as important innovation drivers. The erosion of IPRs often appears as a seductive option when viewed through the prism of short-term political considerations but it exacts a very high societal price over time by depressing the generation of knowledge and retarding the pace of innovation.

To be sure, other types of government support – such as subsidies, guaranteed procurement or prices – can substitute as drivers of innovation to varying degrees for intellectual property protection and are complementary to IPRs. In an era of sustained budgetary deficits and the need to allocate resources to meet other compelling social needs, however, the political realities in OECD nations strongly suggest that, realistically, public economic resources will be not available to substitute for IPRs as an effective spur to innovation and economic growth. As efficient market-oriented tools, IPRs are likely to enable firms to more fully appropriate the return from their risky and uncertain investments and this, in turn, will require significantly reduced levels of government support.

- *IPRs promote the disclosure of inventions and pioneering information, which stimulates innovation across industries*

Intellectual property rights are not a mechanism for hiding knowledge. They are a powerful market-based mechanism for disseminating knowledge. The diffusion of IPRs, and the bundle of rights that often go with them, can serve as a central policy tool in shaping the knowledge economy. The public disclosure of information is one of the most important functions of IPRs but, often, one of the most neglected by policymakers.

With the growth of complex, cumulative technologies and the blurring of economic activity across traditional sectoral boundaries, the diffusion of information and technology becomes ever more important for innovation. The social bargain explicit in the grant of a patent, for example, facilitates this objective. In return for the exclusive right to exclude others from manufacturing, selling or using the invention for 20 years from filing, the inventor must disclose the invention so that it can be put to practical application. The alternative is secrecy that may impose large societal costs and provide few of the positive economic externalities or social returns associated with IPRs.

Such disclosures facilitate a vigorous cross-fertilisation of ideas, thus spurring further creativity and innovation. This dynamic is particularly important in an era of increased multi-disciplinary activity and technological convergence. Inventions and creations in one sector often spark new ideas and innovation in others and, increasingly, help create entirely new areas of inquiry or new marketable products and services.

The disclosure requirements also serve an overlooked function in balancing the needs of current and future innovation. It creates a climate of competitiveness with multiple sources of innovation that provides the basis for future technological progress and economic growth.

- *IPRs promote risky, uncertain and costly investments*

Forward-looking intellectual property rights protection provides the incentives for firms and individuals to invest in generating new technology and new products, including incremental improvements. This is especially important where the returns from investment are longer-term, where the investment involves significant costs or risks, and where the invention or creation may be easy to copy or imitate.

- *IPRs enable technology transfer*

IPRs increasingly facilitate the operation of markets. Strong and effective intellectual property rights are an essential tool for technology transfer. They encourage private and public enterprises to transfer

technology not only through voluntary licensing and other contractual arrangements but also through the development of innovative approaches for promoting technological development, direct investment, technology sales and dissemination, and cooperative ventures. For example, the increasing use of public-private partnerships or the creation of business-government-NGO collaborations to meet emerging technological or societal challenges often would not be possible without IPRs. They provide the bridging mechanisms that make these promising collaborations work.

IPRs also play a growing role as part of the growing recognition about the importance of technology diffusion to the process of technological change. An OECD study, for example, found that smaller countries that are more dependent on technology and knowledge developed abroad require effective policies, such as IPRs, to facilitate the inflow of knowledge and capital-embodied new knowledge and to create a competitive business climate.

- *IPRs help stimulate and focus the process of knowledge creation and innovation through the necessity of finding legal means to "invent around" or "reverse engineer" patented inventions*

By providing exclusive rights to an invention, the patent system frequently spurs others to innovate by developing alternative solutions to technical problems or new and improved inventions. Innovators are stimulated to "invent around" or "design around" the original invention in order to avoid infringing the applicable patent(s). While this may, in some circumstances, lead to "me-too" innovation, it most often leads to the emergence of different technologies and competing pathways that promote competition and spur innovation. The circumvention of existing patents means that new technological solutions put market pressure on the exploitation of existing technologies.

History also provides a number of examples about inter-industry technology "leaps." Perfume sprayer mechanisms influenced the development of the carburettor, while various e-commerce innovations have come from the banking industry rather than the computer industry. Such technological convergence among industries is enabled by an intellectual property system that creates a public pool of knowledge, allowing companies to look beyond their own industry boundaries for R&D innovation.

1.2 Empowering consumer protection in the global economy

The increase in cross border trade has promoted a growth in trade of trademarked / branded products that also incorporate copyrighted content and patented innovations. As a result, recognition of famous brands exists around the world. Moreover, international efforts to harmonize patent and trademark acquisition procedures have made it possible for companies to seek IPRs in more countries, in turn promoting the introduction of new products into markets around the world.

The new global economy increasingly depends on the international recognition and dissemination of IPRs related to branded products. Trademarked brand names, copyrighted systems and patented inventions define the multinational marketplace as products and services are negotiated, shared and transferred with little regard to jurisdictional barriers or related to the country from where they originated. With increased trade and investment, and the concomitant growth of branded products, IPRs increasingly serve as trade facilitators.

Nevertheless, counterfeiting and digital piracy are booming. Innumerable fake products, ranging from pirated software and copied CDs to counterfeit medicines and aircraft parts, plague global trade and harm consumers. Counterfeiting increasingly poses a direct and serious threat to public health and safety. The market in fake pharmaceuticals and healthcare products is thriving in both developed and developing countries, too often putting the health and even the lives of consumers at risk.

Counterfeiting also threatens legitimate trade and economic growth. The best estimates suggest that companies are losing more than $ 200 billion annually to counterfeiting and piracy. In addition to lost sales, counterfeiting damages the reputations of legitimate manufacturers because the quality of fake products usually is inferior and can taint consumer perception of the genuine product. Moreover, counterfeiters pay no taxes or duties, thus costing governments as well. Counterfeiting causes global job losses of more than 200,000 jobs per year. In this way, counterfeiting, which counts for approximately 5 – 7 % of world trade, threatens economic growth as a whole.

1.3 Supporting and enhancing competition

Both intellectual property and competition policy are vital to maintaining competition in a market-driven society because each, in its own way, encourages innovation and enhances consumer welfare. In protecting the rights of inventors and allowing innovators and creators to profit from their ideas and inventions, IPRs also depend on a legal and policy framework that ensures competitive markets.

Intellectual property and competition policy often are viewed incorrectly as sitting in an adversarial relationship characterised by a "zero sum" game. In fact, they increasingly should be viewed as complementary policy tools and legal regimes aimed at promoting the same goals – innovation, economic growth and consumer welfare. Even the limited term of exclusivity accorded intellectual property rights holders is procompetitive. By protecting creative innovations and avoiding exploitation and free riding by imitators, this temporary exclusivity promotes new product innovation and creates new technology markets that stimulate competition and rivalry in the longer term. In addition, by ensuring competition and promoting innovation, competition policy ensures the fair and reasonable use of intellectual property rights in marketing, distribution and dissemination.

Intellectual property policy, properly designed and implemented, interacts with competition policy to promote allocative efficiency by encouraging the production of higher quality products at the lowest costs. Nevertheless, as Professor Robert Pitofsky, the former Chairman of the U.S. Federal Trade Commission, has observed, competition policy must consider a set of special characteristics in markets characterised by the strong presence of intellectual property: incentives to innovate are particularly important; competition at the research and development level is critical; markets are dynamic and market shares often unstable; predictions about the way markets will develop are uncertain; and the issues facing policymakers are unusually complicated and highly technical.

1.4 Securing the benefits of IP for the digital economy

Computers, telecommunications, semiconductors, entertainment and educational content, and other information-based sectors depend on IPRs as the legal and economic backbone of these industries. Intellectual property protection for these sectors -- especially digital-related copyrights, software patents and other computer-implemented inventions -- are the essential tools that create new businesses, new jobs and new markets that drive the digital economy.

The Internet and low-cost information processing, storage and communications have created numerous new markets and competitive opportunities that have reshaped the process of innovation. Most innovation processes today use the Internet as an integral component. And, as a communication device, it has permitted the diffusion of knowledge, facts and ideas literally at the speed of light. It also has introduced new competition into numerous markets and made them more efficient and productive. All of these broad, social benefits depend on effective intellectual property protection – copyrights, patents, trademarks and domain names, and semiconductor mask works.

With many higher value-added economic activities in the digital economy increasingly dependent on intellectual property rights, they encourage, reward and protect innovation and creativity in both incremental innovations and in breakthrough new platforms and technologies. IPRs have been a powerful instrument for economic development, export growth and the creation and diffusion of new information technologies with widespread social benefits. Sound legal and other framework conditions for a well-constructed IPR regime, therefore, are indispensable.

For example, copyright only confers exclusive rights on the person who originates a form of expression, and not on the idea, the thought or the information embodied in that expression. It, therefore, serves an important role in the diffusion of knowledge because the bundle of exclusive rights that make up copyright include a right to use the work, especially in research, scholarship and public access to knowledge and learning.

In short, IPRs are essential for the digital economy because creative products and services tend to have public good and information asymmetry characteristics. Consumption by one person does not preclude another from using the same product (non-rivalrous) and people cannot readily be stopped from using or consuming the product (non-excludable). This creates strong incentives for consumers to become free-riders by obtaining the good's value without incurring any of the costs associated with producing and distributing them. In such situations, economists recognise the need for a mechanism – copyright – to stop the free-riding and encourage the production of these types of products. If the producer or creator cannot recover the costs of investment in the product and achieve some reasonable profit, then there will be an undersupply relative to a socially optimal level. Innovation, creativity and economic growth all will suffer.

At stake is the continued growth of the digital economy. The new ability in the digital economy to duplicate and transmit at virtually zero marginal cost all types of digital information – data, images, voices, and other digital content – makes the framework for intellectual property and the available enforcement mechanisms even more important than in the past. The costs of reproducing digital information are now close to zero for both rights holders and infringers, and digital copies are perfect copies of the original. When combined with high-speed computers and communications, the balance of risks and rewards between innovators and imitators has shifted and threatens to result in suboptimal levels of creativity and innovation. Without new digital rights solutions that both protect intellectual property and work easily and flexibly for consumers, the dynamic economic and social benefits of new content creation and the advantages of the Internet as a powerful distribution channel are put at serious risk.

IPRs and digital content also are integral to broadband adoption and what some are calling "the great digital broadband migration". A tremendous amount of data and content increasingly is available in the digital broadband world, and it needs to be protected in an appropriate manner. The need to stimulate demand for broadband services (innovative content, software applications and other products and services) further underscores the need for adequate and effective intellectual property protection. Without it, copyright owners increasingly will go uncompensated and will reduce investments in creating diverse, new content; hardware companies will shy away from innovating for fear of facilitating piracy; and consumers will become confused and frustrated and be without new content and services.

Another important role of IPRs in the digital economy relates to its utility in helping multiple firms and individuals solve industry-wide problems and to create entirely new markets through the development and improvement of industry standards that have procompetitive networking effects. IPRs serve as a central facilitating mechanism in the standardisation of network apparatus and as a tool for achieving compatibility and interoperability of core network technology often is not appreciated.

1.5 Creating New Technology Markets because IPRs are Tradeable and Transferable

At the centre of the innovation process and technological change today is information and it's application, knowledge. Estimates suggest that more than one-half the store of human knowledge was produced in the second half of the 20th Century, more than one-half of all patents have been issued in the last 30 years, and the number of marketable new products, services and innovations has tripled in the last 20 years. An important component of this explosive growth is the role played by IPRs in creating new markets for technology and accelerating the pace of future innovation. The principal reasons for this are the market-oriented characteristics of IPRs; they are tradeable, transferable and transparent.

Many of the current attacks on IPRs completely ignore the fundamental point that an important precondition for market-based allocation is the definition of property rights. IPRs enable markets to work and benefit society in two principal ways: they perform an allocational function and they encourage production, i.e., they provide an efficient mechanism for deciding who gets to use what and a powerful incentive for creating things. This directly results in both static and dynamic economic benefits.

A growing body of economic literature and empirical evidence, including the recent OECD/BIAC patent survey and the OECD IPR Workshop, confirm the importance of the linkage between IPRs and contractual arrangements or other market-oriented mechanisms to propel innovation. For example, procompetitive licensing can avoid wasteful imitation and the misallocation of resources. In cumulative technologies, contracting combined with strong IPRs create additional incentives for IP rights holders to support other innovators making product improvements because the IP rights holder can profit from, rather than being threatened by, new improved products. The message is clear: strong IPR and private, market-oriented instruments can be complementary in reducing social costs and improving innovation.

By assigning exclusive rights to market for a limited time, IPRs improve the value of the property by permitting the owner to appropriate the value of his or her invention or creation through subsequent sale or licensing, and through further production and improvements. They also avoid the very high administrative and transaction costs of splitting ownership among numerous people or of holding IPRs in common ownership. The lower transaction costs that come from voluntarily assigning IPRs to owners and their ability to assign economic value to those rights helps facilitate opportunities for trade and market-oriented transactions without the need for direct governmental intervention.

1.6 Enabling innovation in key economic growth sectors, such as healthcare

Intellectual property rights enable innovation in a number of key economic growth sectors. Healthcare is one such sector. It is important that IPR supports innovation and, at the same time, promotes other public interests.

Biomedical progress and healthcare innovation are playing a major role in increasing life expectancy, improving the quality of life and eradicating diseases that previously were life threatening. These advances are made possible by an innovative, enabling set of technologies that are transforming what we know about human disease and are permitting researchers to target increasingly complex diseases. The realisation of this promise, however, depends critically on strong and effective IPRs to stimulate the very costly investments in resources needed to research and develop these innovations from the laboratory through clinical trials to the market, to disseminate the new technologies widely to spur incremental improvements and new breakthroughs, and to provide a market-oriented framework for the exchange of rights.

Increasingly, new insights and approaches to biomedical research and healthcare are made possible not only by revolutionary advances in biology and chemistry but also by information technology and by

the development of powerful tools, such as mass spectrometers and genomic arrays. All of these R&D-based, innovator sectors contribute to medical progress by translating fundamental research findings into innovative treatments and diagnostics for the benefit of patients. The discovery and development process, however, is a risky business with no guarantees of success. The large R&D and other costs associated with these developments only can be sustained by innovator healthcare companies if the economic climate and policy framework supports and rewards successful R&D and clinical trials through IPRs, understands the increasingly complex process of innovation that saves lives and improves the quality of life, and creates greater patient and consumer choice.

In human-related biotechnology, for example, countries only can nurture their own research-based biotechnology industries, attract foreign investments and transboundary collaborations in biotechnology, all the while providing state-of the-art healthcare to their citizens by enacting and enforcing an appropriate IPR framework. Moreover, as biotechnology becomes a principal foundation for economic growth and development, protecting these IP rights also can provide countries with an opportunity to create high-value jobs for the 21st Century and to develop new economic clusters appropriate to the needs of that country. Many biotechnology companies, for example, invest more than 45 percent of their annual income into research and development, meaning that nearly one half their value consists of intellectual capital. Life science companies in human health, both large and small, depend on IP rights to raise capital efficiently, to create the foundation for sustainable and innovative business models, and to invest in highly risky new areas over an extended period of time.

Healthcare innovation also highlights the intersection of IPRs with domestic regulatory regimes and the importance of other rights closely related to IPRs. For example, data exclusivity recognises the innovator's investment in conducting the rigorous pharmacological, toxicological and clinical trials necessary to establish the safety and efficacy of new drugs before they can be provided to patients. Such data are proprietary to the innovator, but must be submitted to the health authorities for their evaluation of the product's safety and efficacy. Data exclusivity, mandated by TRIPS Article 39(3), precludes governments for a reasonable period of time, typically five to ten years, from using or relying on the original registration or the data submitted by the innovator for the benefit of third parties seeking to market a copy of the product without providing its own data. After the period of data exclusivity ends, the originator's data can be relied on by the authorities to approve the marketing of copy products, thereby obviating the need for the second applicant to repeat trials already conducted by the originator. Data exclusivity, which must be afforded regardless of the existence of patent protection for the product, accordingly provides an incentive to conduct the extensive testing of new products. It recognises that use or reliance on such data for the benefit of others unfairly places the innovator at a disadvantage since others do not bear the significant costs of extensive and lengthy clinical trials required for market approval.

1.7 IPRs play a crucial role at the intersection between science and innovation

The quality of all our economies depends on their ability to acquire, protect, translate, combine and apply knowledge. This knowledge is needed to solve today's problems and to prepare the foundation for solving tomorrow's. Without new knowledge and new combinations of knowledge, there will be no innovation. IPRs can play a critical role.

Connectivity, excellence and focus have become essential to the success of any company, university or nation. With the changing nature of university-industry-government relations and the evolving role of universities as both platforms for creating knowledge and engines of economic growth, it is important to recognise the growing role of IPRs, especially for universities and for new types of university-industry-government intersections. (See also BIAC paper on "Promoting Public-Private Partnerships : Industry – University Relations").

2. A Proactive IPR Action Agenda for "Value-added" OECD Work Concerning the Importance of Intellectual Property Rights for the 21st Century

BIAC believes that the structure, capacity and economic focus of the OECD make it uniquely positioned to "add value" to national and international policymakers concerning intellectual property rights in several ways:

- in recognising the growing importance of intellectual property rights to innovation and economic growth;
- in undertaking empirical studies and economic analyses that help policymakers understand the important role IPRs play in the science-innovation interface and in stimulating innovation that produces economic growth; and
- in developing a forward-looking legal and policy framework for IPRs in the light of rapid and profound technological and economic change.

As a result, BIAC recommends that the OECD, generally, and DSTI and the Futures Programme, specifically, undertake an enhanced and comprehensive work program related to intellectual property over the next few years. We, therefore, set forth a proactive action plan of those OECD activities that BIAC believes are most important and where the OECD's work would add the greatest value.

2.1 Integrate IPRs more fully as a core enabling condition for innovation in all OECD countries

The OECD has undertaken valuable initial work to assess the evolution of IPR systems in OECD countries and to relate them to broader trends related to innovation processes and economic performance. Also, as the OECD recognises, IPRs do not operate in a vacuum. They influence and are influenced by a broad range of context conditions such as the nature of the technology or market, industry structure, other government policies, and the process and dynamics of innovation in each sector.

As a result of changes in the science and technology knowledge base, trade and investment in global markets, business models and practices related to IPRs, and the shifting boundaries of new knowledge and new markets, BIAC believes the OECD can add significant value by "broadening and deepening" its attention to IPRs across all its activities, especially in DSTI and in the Futures Programme.

In this process, BIAC expects and will support measures that improve the quality of IPRs. To achieve this goal, the OECD should continue its comparative analyses and benchmarking of patent regimes and patent offices to ensure the quality of patents.

Recommendations:

- Integrate considerations of IPRs in all existing OECD work programs to the extent they are not already included;
- Explore cross-cutting, new linkages between work on other issues affecting innovation and economic growth and the role of IPRs;
- Give critical attention throughout to the quality of granted IPRs;

- Undertake an initial economic assessment of the linkage between IPRs and investment and capital formation, and of the key emerging trends.

2.2 Address the changing role of IPRs at the interface between science and innovation and in the interactions between different stakeholders

The days when companies, universities and public entities performed different, clearly demarcated roles in innovation are past. Innovation is marked by greater interdependency and traditional boundaries have blurred. In an increasing number of fields, the linear model of research and development no longer provides an adequate description of events or a framework for public policy. Today's modes of knowledge production and knowledge application depend on networking, multidisciplinary approaches and the interaction of discovery-based science with practical problems.

Thus, knowledge has become more mobile and diffused, not just through information technology. The best creators of knowledge move where their efforts can be rewarded; innovation comes from combining more knowledge and from multiple sources; and, increasingly, new discoveries are transferred rapidly into new marketable products and services.

Particularly in this regime of greater interdependence, it is essential that any system for IPR gains critical stakeholder support. BIAC fully supports that the work of the OECD be geared towards improved economic growth and social well-being.

2.2.1 Recommendations

- Assess the changing role of IPRs in fundamental research and early stage applied research – especially with respect to complex, multidisciplinary research involving multiple players -- in response to profound changes in the science and technological base, in the process of innovation and in business models.

- Develop policy recommendations for promoting better public-private partnerships and industry-university relations, and for utilising IPRs more effectively and efficiently to achieve these objectives.

2.3 Update the OECD's work on counterfeiting and develop an appropriate OECD instrument for combating counterfeiting on an international basis

Positive action by governments towards eliminating counterfeit and imitation goods is of the utmost importance to international trade and consumer welfare. While substantive IPR laws have become more comprehensive and widespread in the last decade, enforcement remains the weak link in effective intellectual protection in many countries and prevents consumers and firms from realising the full benefits of open trade and investment.

The OECD's 1998 Report, under DSTI's direction, regarding the economic impact of counterfeiting shed valuable light on the scope and magnitude of the global counterfeiting problems plaguing not only consumer products companies that depend on consumer trust in their brands but also an expanding range of high-tech industries, ranging from aerospace to pharmaceuticals to telecommunications. The OECD is the appropriate global forum to pursue the issue of counterfeiting enforcement because it has both the economic analytical capabilities and the capacity and experience in developing model laws, instruments and ongoing policy analysis in this area.

2.3.1 Recommendations

- Expand the OECD's profile with respect to all aspects of counterfeiting across the full spectrum of OECD Committees and work programs;

- Update the OECD's 1998 Report and provide a new roadmap and recommendations for addressing this increasingly costly global issue;

- Develop an OECD Anticounterfeiting Convention, or other appropriate instrument or guidelines, along the lines of the OECD's highly influential Antibribery Convention;

- Engage both OECD Members and OECD Observer nations in the new work program related to counterfeiting.

2.4 Develop new, more robust methodologies and economic indicators for measuring intellectual property rights and the critical role they play in stimulating innovation and economic performance

Current IPR indicators provide a useful measure of innovation output, national innovation outcomes, R&D intensity, and other economic and technological benchmarks. As the OECD has recognised, however, the traditional IPR input-output indicators, such as patent indicators, are limited in their current utility and even may provide a misleading or incomplete picture to policymakers. For example, current IPR indicators: (a) tend to focus on quantity rather than the quality of the rights; (b) lack standardisation across national systems; (c) reflect an outdated view of the innovation process as a linear process rather than a complex, intersecting system with multiple feedback loops; (d) fail to take account of changes in the underlying IPR legal regimes, in the underlying science and technology base, and in the globalisation and geographical dispersion of IPRs; and (e) are constrained by the available methodologies used to construct IPR indicators.

Existing economic indicators and methodologies are woefully inadequate for providing a sophisticated understanding about systemic linkages, the science-innovation interface, or the changing nature of the innovation process. They also come up short in providing effective measurements about the increasing role of intellectual or knowledge-based assets in dynamic national and global economies.

Recommendations

- BIAC supports the OECD Patent Project to develop an international statistical infrastructure for patents, with a strong emphasis on the development of databases and methodologies.

- NESTI and DSTI should undertake a multi-year program, in conjunction with business, academic and government experts, to develop new methodologies, indicators and other analytical tools for measuring and assessing IPRs and the increasingly important linkages between IPRs and innovation and economic performance. This also should include tools to measure IPRs role as a source of information and an enabling mechanism for technology transfers and the development of technology markets. The OECD's focus on measuring inventive performance, international trade and investment flows, diffusion of knowledge, the effects of other national policies such as S&T investments and regulatory regimes on IPR, and the internationalisation of innovative activities will be significantly enhanced by this work.

- As recommended by the OECD Experts Workshop, the OECD also should undertake more empirical studies about IPRs, innovation and economic performance. Many of the current attacks

on IPRs stem from misunderstandings or misperceptions that have no basis in fact. Increased empirical work and factually-based evidence will provide policymakers with a more objective and comprehensive understanding about the role of IPRs.

2.5 Initiate a forward-looking, horizontal project about "converging technologies" by focusing on the changing role of IPRs in three key technological and economic drivers for the 21st Century – biotechnology, ICT and nanotechnology

The early decades of the 21st Century will be marked by the increased scientific and technological convergence of three fundamental drivers – biotechnology, advanced information technology and nanotechnology. Revolutionary advances at the interfaces between previously separate technological and economic spheres will transform traditional disciplines, business models and government policies. These converging technologies have the promise to achieve tremendous improvements in human capital, innovation, economic performance , and the quality of life. IPRs already are playing a critical role in converging technologies, multidisciplinary research and evolving business models. It is essential to get "ahead of the curve" and prepare policymakers for the changes made possible by converging technologies, including a significant emphasis on the role of IPRs.

2.5.1 Recommendations:

- The Futures Programme, with DSTI's assistance, should undertake a series of forward-looking projects to explore the potential of converging technologies and research to improve human and economic performance, as well as the overall potential for revolutionary changes in the economy and society, and the role of IPRs. Now is the time to anticipate the IPR policy issues and plan an integrated, forward-looking approach that will yield optimal results for society.

- For each key economic driver – biotechnology, advanced information technology, and nanotechnology – DSTI also should examine the appropriate IPR framework and policies needed within each area to meet the challenges and opportunities posed by technological convergence and by the unique factors associated with each of them.

2.6 Provide comparative analyses and undertake "value-added" reviews concerning the intersection of IPRs and competition/antitrust policy

BIAC agrees with the OECD's recent findings that the growth in IPRs during the last decade corresponds to new structural innovations, such as public-private partnerships and new business models that are based more on knowledge networks and markets. Innovation processes throughout the OECD have become more competitive, more cooperative, more globalised, and more reliant on new entrants with competitive ideas and products. It, therefore, becomes much more critical that IPRs and competition policy be viewed as complementary policy tools and not as a "zero sum" game.

The recent major report by the Federal Trade Commission in the United States, *"To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy"* aims to strike a balance between monopoly and disclosure. It expresses the realisation that patent offices have often assumed an incorrect attitude by considering applicants as their clients, rather than assume the role of guardian of the public interest. As a result, they have granted too many poor quality patents that stifle innovation.

2.6.1 Recommendations:

- Provide a comprehensive overview of the current research and policy reviews in member countries, including the European Union, about the intersection of IPRs and competition policy.

- Establish a joint working party between the Trade and Competition Committee and the Committee on Science and Technology Policy to develop suggested guidelines and policies for a sophisticated intellectual property-competition policy interface and to ensure the vigorous competition that enables IPRs to operate effectively and efficiently.

- Initiate a pilot project that analyses how both IPR and competition policies must work together to promote innovation and adjust to rapid changes in business models and innovation processes. BIAC suggests using the emergence of de facto standards with network effects in ICT as an initial subject for such an examination.

2.7 Focus on health-related innovation as a principal policy challenge for the early 21st Century, and develop new frameworks and policies for linking IPRs and health innovation

The dawn of the 21st Century provides an entirely new landscape for healthcare. It already is providing entirely new approaches to many diseases in both the developed and developing world. In order to realise the enormous promise of the ongoing revolution in the life sciences, policymakers increasingly must recognise the critical role of innovation as a key driver of improved healthcare and the role of IPRs as a core enabling condition.

2.7.1 Recommendations:

- Initiate a broad, new project to foster health-related innovation and to develop public policies that encourage and reward innovation in human health-related products, services and technology, that can deliver on societies' expectation for health while contributing to economic growth, and that increase patient and consumer choice in human health.

- Continue and expand the ongoing activities of the Working Party on Biotechnology related to IPR and innovation, both with respect to human health and with regard to sustainable industrial biotechnology.

2.8 Analyse the role of markets for technology and the economic accounting of intellectual assets

BIAC supports the OECD view that markets for technology are increasingly important for knowledge-based economies and that IPRs play a pivotal role in the development of technology transactions and new technology markets. Markets for technology can provide a means for technology diffusion, can increase the efficiency of R&D and innovation by stressing complementary strengths of firms and non-profit organisations, and can provide new sources of revenues that can create virtuous cycles of new investments in innovation.

2.8.1 Recommendation:

- Develop an analytical framework for analysis that will better inform governments and other stakeholders about the evolution of markets for technology, including their functioning and effect on innovation and economic performance.

SUMMARY OF THE DISCUSSION

The Chairman opened the discussion by observing that there is a diversity of opinion on the proper role of competition agencies in the formulation and implementation of intellectual property policy. In some countries, the competition authority may intervene in the formulation of IP policy while in others it may not. He proposed to begin by examining these different systems. Second, he suggested that the Committee focus on two of the issues at the intersection of competition law enforcement and IPRs – unilateral refusals to licence and exclusive dealing on the one hand, and patent pools on the other hand. The third issue he recommended for discussion was the IP / competition law interface specifically as it pertains to biotechnology. He noted that although a number of countries have little experience with biotechnology cases, several jurisdictions have commissioned expert reports to assess the effectiveness of their IP system in biotechnology and to determine whether it leads to a competitive industry.

1. The proper role of competition agencies in the formulation and implementation of IP policy

The Chairman drew attention to the United States' contribution, which discusses the results of joint hearings that the Department of Justice and the Federal Trade Commission held in 2002 regarding "Competition and Intellectual Property Law and Policy in the Knowledge Based Economy." It mentions the interdependence between competition policy and IP systems and the importance of efforts to address potential deficiencies within each regime. He invited the U.S. delegation to identify the most important messages to communicate to patent offices about this interdependence, and to explain what role if any it sees for competition authorities in the formulation and implementation of IP policy.

A delegate from the U.S. stated that the operation of the patent system affects the competitive process in important ways. To begin with, poor quality patents (meaning patents that are issued even though they do not meet the standards of patentability laid out in the patent scheme of the individual jurisdiction) can adversely affect competition in two ways. The first occurs if the patent right creates market power. The delegate took care to point out that patents do not, by themselves, immediately create market power. But where an improvidently granted patent does create monopoly power, then its use will restrain competition.

The second effect is less direct. Although it has not been proved rigorously, the U.S. experience suggests that when patent agencies issue weak patents, the competition policy and law system tends to compensate by using competition law principles to circumscribe the operation of improvidently granted patents. Unfortunately, the competition policy system under those circumstances is a fairly crude instrument for correcting deficiencies in the patent system. The report that the Federal Trade Commission issued after the joint hearings suggests several ways in which the Patent Office might be made more robust.

First, the U.S. delegate noted, the patent reviewing system needs to be adequately funded. Complex fields such as biotechnology require highly skilled specialists to examine and evaluate patents. Second, the patent system might profit by establishing more rigorous mechanisms in the period before a patent is granted to test and evaluate the application. Third, there needs to be a more effective procedure for post-grant review. One possibility would be for the U.S. to adopt approaches that the European Union has used, including an administrative process for evaluating the patent quality *ex post*.

The U.S. delegate emphasized that he was not suggesting that competition agencies be involved in the evaluation of patents themselves. Instead, he was suggesting measures that the patent office itself might take to make the evaluation of applications more effective. If patent offices follow these suggestions and thereby make their systems more robust, competition agencies and courts will be less tempted to use competition doctrines to correct perceived problems.

The one area in which a more vocal role for competition agencies would be desirable is having interdisciplinary dialogs with patent agencies to foster greater mutual understanding of each other's fields.

Canada's contribution explains that the Competition Bureau has several statutory means of intervening in IP policy. The Chairman asked the Canadian delegation to discuss those provisions, how frequently they have been used, and how effective they have been.

A delegate from Canada responded that the Competition Bureau has relied on its statutory right to appear before any Federal Board, Commission or other Tribunal Agency to give evidence or provide comments with respect to competition issues in an intellectual property matter on only two occasions. The first concerned a government appointed commission that was examining the impact of Canada's compulsory licensing regime on the manufacturing of drugs. The Bureau made submissions suggesting that it did not believe that there had been any demonstrable, adverse effect on the level of research and development that was occurring. The second intervention related to the possibility of establishing copyright collectives to administer rights in the field, for example with respect to photocopying. In both cases, the Bureau's recommendations were largely accepted.

The delegate from Canada also explained that section 32 of the Canadian Competition Act allows the Bureau to seek to have the Attorney General to apply for a special remedy from the Federal Court in circumstances where the exercise of an IP right would result in a lessening of competition. The remedies can be quite broad. For example, they allow the court to order that the patent be revoked, for example. Therefore, this is not a process that one would proceed with lightly. In fact, there is very little jurisprudence in this area. The last two cases took place in the mid-1960s and reached settlements. The Canadian Competition Bureau has issued IP enforcement guidelines that describe how it interprets section 32, making clear that the Bureau would use this provision only when a lessening of competition results from the exercise of an IP right.

The United Kingdom's contribution notes that "there have been moves in Australia and the United States to increase the emphasis placed on competition in the process for granting patents" but states that "in the U.K. we have arguably moved in the opposite direction from the recent initiatives in the U.S. and Australia." The Chairman asked the delegation from the U.K. to discuss why its statutory regime changed and whether the UK authorities see any advantages in either the old or the new system.

A delegate from the U.K. explained that the U.K. system changed in March 2000, when the Competition Act 1998 came into force, bringing U.K. competition law in line with EU competition law. Previously, the Patent Act dealt not only with IP issues but also allowed for certain interventions to be made if patents were being unreasonably exploited. The Competition Act now deals with exploitation that raises competition issues.

The contribution from New Zealand states that the statutory criteria for granting a patent under the Patent Act (novelty, non-obviousness and utility) are technical, that no explicit consideration is given to competition issues, and that the Commerce Commission is not involved. The Chairman asked whether this disregard for competition issues at the licensing level is justified.

A delegate from New Zealand responded that there is actually a very close relationship between competition and IP policy in New Zealand. Competition policy and IP policy are managed by the same branch of the Ministry of Economic Development. One IP-related competition issue that New Zealand takes very seriously is how successful some nations have been at equating stronger and stronger IP rights with free trade. As a technology importing country, New Zealand does not accept this trend. It believes that, from a competition viewpoint, there is an optimal level of strength which has probably been exceeded. Variances from the optimal level reduce efficiency. In addition, there is a concern that in certain areas the Patents Office has been granting patents that are too broad. The Ministry of Economic Development has talked to the Patents Office about how they are examining gene patents, for example. On the basis of those discussions, the Patents Office agreed to re-examine its procedures. Finally, the delegate made it clear that patent holders are not exempted from the restrictive business practices aspects of the competition law. However, there are no specific examples of New Zealand's Commerce Commission pursuing a patent holder yet.

Turkey's contribution states that the involvement of competition authorities in the patent granting process and their possession of the right to challenge the validity of patents should not be allowed. The Chairman invited the delegation from Turkey to explain its views on this matter.

A delegate from Turkey replied that the patent examination process requires very technical and detailed information and expertise. The Turkish competition authority therefore believes that if it were to become involved in the examination process, it might create a heavy and unnecessary burden for itself. This would not be prudent because the competition authority does not currently have sufficient resources to handle its existing responsibilities, let alone new ones. At the moment, it seems impossible to obtain additional funding.

The Chairman remarked that participants do not see much that competition authorities should do in terms of defining or challenging the scope of IP rights, with Canada being a slight exception. This does not mean, however, that competition authorities are not troubled by poor patents.

2. Competition law enforcement and intellectual property rights

The Chairman began this phase of the discussion by noting the challenges faced by countries that now find themselves in the position of needing to adopt domestic regulations that are compatible with the EU directives in this area. He then called on the European Commission to present its views on the problems of competition law enforcement and intellectual property rights.

A delegate from the European Commission began by noting that the Commission recently undertook a full review of its existing rules, reassessed the relationship between IPR and competition law, and on 27 April 2004 released a completely new set of rules on patents, know-how and software copyright licensing. They are essentially composed of a block exemption regulation and a set of new IPR guidelines. The approach taken is that licensing is in general pro-competitive, so there are clear safe harbours, and that is true with respect to exclusive licenses, as well. The new rules also distinguish, for the first time, horizontal and vertical relationships, so whether agreements are between competitors or between non-competitors is basic to the formulation of policy rules. The Commission endeavoured to arrive at a better balance between the protection of incentives to innovate and occasionally necessary intervention against licensing agreements that restrict competition.

The E.C. delegate also discussed two examples in which the incentive to obtain a license in the first place and the incentive for follow-on research have to be balanced. First, in the area of grant-back obligations, the Commission made a distinction between severable versus non-severable improvements. Severable improvements can be exploited by the licensee without infringing the originally licensed

technology, whereas non-severable improvements cannot be exploited without infringing the basic licensed technology. The new rules exempt grant-backs, including exclusive grant-backs, of non-severable innovations. On the contrary, grant-backs of severable improvements are exempted only if they are non-exclusive, because this framework maintains the incentive to do follow-on innovation, which would otherwise be hampered. This, the delegate observed, is an example of a new regulation that completely changes the previous rules, which were much stricter, in order to strike a different balance.

The second field discussed by the E.C. delegate involved patent pools. Recognising the pro and anti-competitive effects of pools, the E.C. has devised a set of rules which in the end are very convergent with the U.S. practice. In a nutshell, pools are regarded favourably if they involve only complementary and essential patents. If, on the other hand, a pool includes patents that are substitutes for each other, then it creates an immediate collusion risk of jointly selling competing technologies. The pool would thus ordinarily offend Article 81, though an individual assessment would still have to be made. The inclusion of non-essential patents is also a problem because they may foreclose third party technologies. In this area, however, the E.C. is probably less strict than the U.S. in that the E.C. makes a case by case analysis.

The E.C. delegate then turned to unilateral refusals to licence. In principle, he explained, there is no competition law liability for a refusal to license, even by a dominant firm. However, there can be exceptions under certain circumstances. The *IMS* decision sets out three necessary conditions. The first is that it must be a situation in which a competitor is trying to develop a new product for which there is a potential consumer demand. Second, it must be a situation where the refusal to license leads to an elimination of competition in a secondary market. Third, there must not be an objective justification for the refusal to licence. Here again, one can see the difficulty of balancing the protection of the original inventor with the incentives for follow-on innovation.

Like the E.C., the Korean Fair Trade Commission has also enacted guidelines for reviewing the exercise of IP rights. Those guidelines provide a "white list" of practices not considered to be violations of competition law. The Chairman asked the Korean delegation to discuss which practices are on the white list and which are on the black list.

A delegate from Korea replied that it is stipulated in Article 59 of the Monopoly Regulation and Fair Trade Act of Korea that the just exercise of IP rights is exempted from Korean competition law. However, if behaviour by patent holders goes beyond the IP rights' purpose of promoting inventions and creativity, then that behaviour will be subject to the competition law. The KFTC guidelines in principle prohibit 17 types of behaviour that can harm competition when the licensor of an IPR unduly restricts certain consumer transactions, quantities, geographic sales regions, or technological improvements. However, there is also a white list of exempted practices that may, after a comprehensive review, be shown to cause only an insignificant restriction of competition or, in some cases, even an increase of competition. For instance, the black list prohibits licensors from restricting the sources from which a party must purchase motor vehicle parts and equipment. However, the white list allows such restrictions if they are necessary to guarantee the quality and performance of the licensed goods. Finally, bundling is on the black list, but if bundled packages are necessary to maintain the quality of the licensed products, this behaviour will be also seen as a fair trade practice.

3. Unilateral Refusals to License / Exclusive Licensing

The Chairman then focused the discussion more on refusals to license and exclusive licensing. He noted that Norway's contribution discusses a recent amendment to the Norwegian Patent Act that gives the Norwegian Competition Authority the power to grant compulsory licenses when a patent has been "neglected" for three years. The Chairman then called on the Norwegian delegation to discuss why the

Norwegian Patent Law was amended, whether the NCA had any role in enacting the amendments, and what criteria are used to establish that a patent has been neglected.

A delegate from Norway began by noting that under the Norwegian Competition Act, Section 11, the NCA already has the ability to impose compulsory licenses in situations involving abuse of a dominant position. The new authority to grant a compulsory license pursuant to the Norwegian Patent Act stems from the implementation of directive 98/44 EC on the legal protection of biotechnological inventions. It was necessary to adopt statutory rules under Norwegian law regarding compulsory licensing for plant variety rights that may infringe already existing patents. Even though the directive did not require implementation of further provisions related to compulsory licensing, the Norwegian government chose to use the opportunity to make other changes to the Patent Act that give the NCA a more general ability to impose compulsory licensing under certain conditions. The Norwegian competition authority did not initiate the enactment of these amendments, but did support the changes in its comments on the proposed amendments.

The reason for giving this new authority to the NCA was its experience in assessing competition issues, which are relevant in many cases involving compulsory licences. However, the NCA's new authority is still only an alternative to a court decision. In order to be granted a compulsory license by the NCA, an applicant must meet certain criteria. The applicant must have tried to reach an agreement with the patent holder on competitive terms, must be capable of exploiting the invention in a sensible way, and the patent must have been neglected for three years. Thus, third parties have been given a tool to gain access to inventions of crucial importance to society. However, in each case the NCA must balance the need to stimulate original innovations with the interest of society in getting access to patents that are left unexploited for no particular reason on the other.

The Chairman then mentioned his impression that, unlike the situation in Norway, in the U.S. the unilateral non-use of a patent cannot be a basis for antitrust liability. He asked the U.S. delegation whether his impression was correct, and if so, whether they could provide the reasons for the difference in policy.

A delegate from the U.S. answered that he was indeed unable to find a good, relevant case involving the non-use of a patent over time. However, there was a very controversial case that the FTC brought and settled in the 1970s involving Xerox. Xerox had patented the basic technology for the plain paper photocopier. The FTC alleged that Xerox told its engineers to imagine every possible path that could be taken to accomplish the same result, and to patent those technologies, as well. There would thus be a technological fortress from which infringement suits could be brought against anyone who tried to compete with Xerox. The FTC alleged that Xerox never had an interest in exploiting its alternative technologies, but developed them just to create barriers to attacking the existing technology. The eventual settlement required Xerox to license any three patents in its portfolio with no royalty, which unmistakably inspired entry by many companies in the 1970s and 1980s into the dry paper copier market. The delegate emphasised again, though, that Xerox was an intensely controversial case that was not litigated before the courts. It provoked a massive debate in the literature. The literature basically poses the question: What is the appropriate rate of output from a patented technology, and what is the appropriate fee to be charged for it? The most severe attack in the U.S. literature is that until one has confident answers for those questions, one should not be able to force a firm to use or license that asset.

In contrast to the U.S., the Chairman observed, the U.K. has a number of recent competition cases that involved some form of unilateral refusal to license an IP–protected product. The Chairman asked the U.K. delegation to explain the analysis it applies to unilateral refusals to license and to describe the Synstar case.

A delegate from the U.K. began by noting that the initial consideration is whether the refusing company has the potential to foreclose a market or to engage in other anti-competitive acts. Therefore, the

analysis is essentially one of dominance and whether dominance is being used through an IPR to create unfair or unreasonable terms that might reduce competition. The Synstar case involved hardware maintenance contracts for computers. Synstar alleged that ICL, a supplier of computer equipment with mainframe functionality, had refused to supply certain diagnostic software to customers whose hardware was not supported by ICL maintenance contracts, thereby preventing third party maintainers from competing for hardware maintenance contracts for ICL mainframes. The primary market was computers with mainframe functionality, and the Office of Fair Trading found that ICL had no dominance at all in that market. OFT then concluded that maintenance services were not a separate market because mainframe customers tend to consider the cost of maintenance contracts as part of the overall cost of buying a computer. Given that there was no relevant secondary market, and that ICL was not dominant in the primary market, there was no merit to Synstar's complaint.

Mexico's contribution discusses a case in which the Federal Competition Commission concluded that an exclusive license did not violate the Federal Law on Economic Competition, and in fact that it even promoted competition. The Chairman invited the Mexican delegation to provide details about the Punto-Flex case.

A delegate from Mexico explained that under the Mexican Constitution, the IP are exempted from the general provision against monopolisation. That fact has led many scholars and lawyers to believe that IP protection is completely outside the reach of competition law. However, the FCC has a different interpretation, and this case is a good illustration. As in the U.K., the FCC must show that the IP owner has a dominant position and that it is abusing that dominant position, for example by foreclosing the market. In the Punto-Flex case, a company had invented a very imaginative way of dispensing water. The FCC found that the company did not have a dominant position. In fact, the FCC determined that the invention was actually creating more competition because it was giving new options to the market. Therefore, even though the patent was licensed exclusively, there was no harm to competition and the case was closed.

The Chairman next called upon the Canadian delegation to elaborate on the circumstances under which it would ask a court to impose mandatory licensing.

The Competition Bureau examines refusals to license under Section 32, and its approach under this provision is described in its IP enforcement guidelines. Essentially, the examination would involve a two-step-process. First, the Bureau establishes whether the refusal to licence has adversely affected competition to a substantial degree in a relevant market that is different or significantly larger than the subject matter of the IP. In making this determination, two factors have to be satisfied. The IP owner would have to be dominant in the relevant market, and the IP must be an essential resource for firms participating in the relevant market. In other words, the refusal must prevent other firms from competing effectively in the relevant market.

If step one is satisfied, then the Bureau would establish whether invoking a special remedy would adversely alter firms' incentives to invest in research and development. Accordingly, the Bureau would determine whether the IPR holder would still have made the innovation if it had known beforehand that a special remedy would be imposed. If the answer is yes, then this suggests that it is desirable to impose a remedy.

4. Patent pools

The Chairman next turned to patent pools and observed that the contribution that dealt most extensively with them came from the U.S. The contribution specifically mentions a 1998 case in which the

FTC provided guidance on patent pools. The Chairman invited the U.S. delegation to discuss its framework for analysing patent pools in the context of the 1998 case.

A delegate from the U.S. replied that patent pools have strong pro-competitive potential in the biotechnology industry. They facilitate the exploitation of technology by removing blocking impediments. They also promote the integration of complementary technologies and reduce the transaction costs of obtaining licenses. In addition, patent pools are seen as a far less expensive approach to reconciling difficulties than litigation.

The delegate from the U.S. explained that all of these efficiency rationales were absent in the VISX / Summit case. The technology in issue was designed to permit the use of laser surgery to correct nearsightedness. Only two firms had approvals from the food and drug safety regulator to provide the technology in question, so there were no alternative patents outside the pool. The two companies pooled their patents. The FTC alleged that the technologies were not blocking at all, but were in fact substitutes. The case was resolved by a settlement that dissolved the pooling arrangement and permitted those who had signed contracts using the pre-existing licenses to abandon them.

The Chairman commented that the Japanese guidelines for patent and know-how licensing agreements under the antimonopoly act deal, among other things, with patent pools and indicate which pooling practices might be considered illegal. He asked the Japanese delegation to clarify whether the guidelines distinguish between pools involving complementary technologies and pools involving substitutable technologies.

A delegate from Japan explained that the Guidelines are not based on the differences between complements and substitutes. Patent pools can have a pro-competitive effect in terms of increasing the utility of the pooled patents, and they can also promote the exchange of technologies among IP owners. However, if a pool imposes mutual restrictions on members regarding sales price, manufacturing volume, or sales volume, for example, and by doing so substantially restricts competition, they are problematic under the Japanese antimonopoly act. Therefore, under the Guidelines, the Japanese Fair Trade Commission examines whether each patent pool is anti-competitive on a case by case basis, rather than always considering the issue of substitutes and complements.

The Chairman then called upon the delegation from Chinese Taipei to comment on a case that the Taiwanese Fair Trade Commission has been working on for the past five years concerning the recordable compact disc technology market. According to Chinese Taipei's contribution, the case touches on many of the subjects under consideration in this roundtable, particularly patent pools.

A delegate from Chinese Taipei said that the CD case involves three licensors who are internationally known high-tech firms. Several Taiwanese licensees complained to the TFTC, alleging that two of the licensors had formed an anticompetitive patent pool. The TFTC examined the nature of the different patents involved to see whether they were all essential, finding that some of the patents were not really related to the technology at issue. Furthermore, the three big licensors had an exclusive arrangement that made it difficult for any rival firms to compete.

Another interesting factor, the delegate explained, is the royalty rate. In 1996, when the parties formed the patent pool, there was a formula based on either a percentage of the average sales price or 10 Japanese yen, whichever was greater. In 1996 the royalty rate seemed reasonable. But in the year 2000, when the market was so competitive, the average selling price of the product declined dramatically. As a result, the royalty rate based on selling price was no longer applicable and the minimum rate of 10 Japanese yen was applied. Consequently, the Taiwanese manufactures had to pay a relatively large royalty fee that constituted almost 18 percent of all costs. That raised an interesting and difficult issue as to

whether and how to evaluate this royalty as a price fixing agreement. Ultimately, the TFTC found that the pool violated the Fair Trade Act by jointly setting a royalty rate without prior approval from the TFTC, abusing a monopolistic position by maintaining a royalty rate that adversely affected downstream competition, and bundling valid, essential, and complementary patents with invalid, inessential, substitutable, and irrelevant patents, which constituted an unlawful tying arrangement.

The Chairman noted that several contributions mention the possibility that a patent holder might use its patent to achieve a dominant position in an unrelated market as a particular concern. He invited the French delegation to discuss this concern.

A delegate from France began by emphasizing that IP-related restrictions may be justified if they contribute to economic progress, notably in promoting new technologies or new products. As a result, IP rights need to be protected. Competition law cannot put into question the very existence of exclusive IP rights, but it can prohibit abuse. The delegate then gave an example, referring to the sanctions imposed on Sandoz-Novartis in 2003. Sandoz produced and sold two patented drugs derived from cyclosporine. The drugs were vital for patients who had organ or marrow transplants.

In 1994, Sandoz had initiated a marketing policy for hospital customers based on a fidelity and rebate scheme. Rebates on cyclosporine drugs were offered on the condition that hospitals also bought seven other Sandoz products, even if there were competing products on the market. The Conseil concluded that Sandoz, which enjoyed a dominant position in the cyclosporine market, had abused its position in markets for the sale of the seven other products.

5. The intellectual property / competition law interface in biotechnology

At this point, the Chairman remarked that one of the striking features of the contributions is the fact that competition authorities have examined so few cases in the biotechnology sector. Nevertheless, in a number of countries, there have been attempts to look at the interface between IP rights, competitiveness and competition in biotechnology. Several reports have been commissioned by competition authorities and patent offices. The Chairman then called on the Swiss delegation to discuss a study by the Swiss Federal Institute of Intellectual Property entitled "Research and Patenting in Biotechnology, A Survey in Switzerland."

A delegate from Switzerland commented that the report was commissioned because the Swiss patent law is currently undergoing partial reform. Certain concerns came up, particularly in the biotechnology field, which the report addresses. Its objectives were to improve understanding of the economic aspects of patenting, of any concrete, practical problems, and of shortcomings with the current Swiss legislation.

The study did not find any breakdown or systematic abuse of the existing patent system for biotechnological inventions in Switzerland. The anticommons problem was not deemed to exist at this point in time. Furthermore, the study found that patent pools and patent consortia are not currently used very much, though the delegate recommended them as a remedy to technology transfer and exploitation problems, especially for universities. The delegate thus viewed patent pooling as more of a solution than a problem.

Patent quality and scope, however, were found to be causing more problems. Therefore, one measure taken in the reforms is to require the concrete disclosure of the functions of DNA patents. Compulsory licensing is possible under some circumstances, especially in the case of abusive monopolies. Furthermore, there is an explicit research exemption.

The Chairman then asked the Japanese delegation to make a presentation on a report prepared by a group of experts for the JFTC entitled "Patent and Competition Policy in New Industries, With a Focus on Business Model Patents and Biotechnology Patents."

A member of the Japanese delegation stated that the study group issued its report in June 2002. In 1999, the JFTC had issued general guidelines for patent and know-how licensing agreements, which clarified that Japan's Antimonopoly Act would be applied to IP-related conduct that harms competition and departs from or contradicts the purpose of the IP system. However, the JFTC noticed afterward that new patents were being awarded in the biotechnology field that were previously outside the scope of patent protection, and that the JFTC did not yet have sufficient relevant expertise with regard to such patents. It was desirable to brainstorm with outside experts to anticipate the kinds of cases that might come in and how the JFTC should consider them from a competition policy point of view, therefore the study was commissioned.

The report deepened the JFTC's knowledge of competition issues related to biotechnology patents and gave a clear indication of what kinds of cases may arise. It also helped the JFTC to show players in the industry how the competition law would apply to anticompetitive conduct in new sectors such as biotechnology.

The delegate further explained that there have been no concrete, IP-related cases yet in the biotechnology area. He suggested that the JFTC might consider encouraging people in the industry to knock on their door for preliminary consultations so as to help prevent any problems that might otherwise occur.

In its contribution, Turkey suggests that competition authorities should take some *sui generis* conditions of biotechnology markets into account. He asked the delegation from Turkey to indicate which specific features of the biotechnology industry it thinks are relevant for competition analysis.

A delegate from Turkey responded that two characteristics of the biotechnology industry are particularly important. First, it is a very young industry relative to others. It nevertheless has a significant role in the economy, as well as for social welfare because it has introduced advanced technologies and innovations that meet social needs and solve significant problems. In particular, biotechnology has resulted in significant innovations in the pharmaceutical and agricultural industries. It is prudent for competition authorities to keep biotechnology's importance in mind. Second, it must be taken into account that patent protection is crucially important for the biotechnology industry. In a market-based economy, private undertakings must be given adequate incentives to innovate. IP rights are essentially a contract between society and inventors, and competition policy might be used as a tool to alter the balance in favour of innovators or against them. It must be acknowledged that the application of competition laws in industries that are especially dependent on IP might result in unwanted consequences. In the short run, enforcement that is too strict may have a convenient result for society, but in the long run it may result in greater harm than good by damaging the incentive to innovate. Therefore, the Turkish delegate stated, competition authorities should be very careful in the biotechnology industry.

The Chairman then noted that the contribution from the U.S. mentioned a white paper issued by the United States Patent and Trademark Office concerning patent pools in the biotechnology industry. He asked the U.S. delegation to describe the main points of the white paper and the specific features, if any, that should be taken into consideration when assessing the effect of patent pools in the biotechnology sector on competition.

A delegate from the U.S. explained that the paper was motivated by concerns that there are too many blocking patents in biotechnology. Its main recommendation was that well designed pooling arrangements

could often provide a solution to the problem. The authors also used guidelines and cases to suggest how pooling arrangements might be designed in a way that would be compatible with the competition laws. One notable feature of the paper is that it was written without any discussion, consultation, or collaboration between the competition agencies and the Patent and Trademark Office. One might think that its topic would have been an interesting basis for a conversation between sector regulators and competition officials. The delegate noted that the U.S. contribution states that such a dialog would be very productive.

The American delegate also stated that if competition agencies are going to make good policy in this area they have to increase their knowledge base, *i.e.*, they need to understand the technology and keep abreast of current business developments because the industry is so dynamic and the technology is so complex. This calls for doing good empirical research, which the Swiss mentioned, and using outside experts, as the Japanese did. Specifically, competition agencies could hold hearings and workshops and commission reports and studies. They could also improve the dialog between the patent office and the competition agencies in areas of shared policy concerns. Finally, the delegate recommended, it would be wise for agencies to change their own human capital.

The Chairman then called upon BIAC to discuss its views on whether more emphasis should be placed on competition during the patent examination process, whether competition authorities are using the right criteria to assess licensing practices, and whether the biotechnology industry has any special features that agencies should consider.

A BIAC delegate responded that BIAC's consistent message to the OECD has been that the key objective of IP policy should be to promote innovation, but that objective is perfectly consistent with the application of competition law policy to IP rights. BIAC's view was that it would not be appropriate for patent authorities to focus on competition issues when they review applications. Instead, patent authorities should more rigorously review applications to ensure that they meet patentability standards. That, in turn, would result in better incentives for innovation because it would reduce the costs and inefficiencies attendant to granting patents imprudently.

The BIAC delegate also urged that there should be no per se competition law liability with respect to patent pools. Rather, if pool members use reasonable means in advance to screen out invalid and non-essential patents and remove them, BIAC believed there should be no competition liability, even if it is later determined that patents within the pool are non-essential or invalid. Furthermore, BIAC was opposed to any requirements that would force patent pool members to license outside of the patent pool, although they should be free to do so if they wish. Compulsory licensing and enforcement actions for refusals to license have a chilling impact on all IP rights, the BIAC delegate said, because they create uncertainty about the true value of IP rights.

Finally, the BIAC delegate characterised judicial decisions on compulsory licensing as inadequate in both the U.S. and the E.U. because they lack clarity regarding the terms under which such licensing should be required.

At that point, the Chairman welcomed two members of DSTI's Biotechnology Unit, Ms. Chris Deane and Mr. Kenji Takezawa, who had been involved with a project to draft Best Practices Guidelines for the Licensing of Genetic Inventions. The Chairman asked Ms. Dean to briefly present the draft guidelines and encouraged the delegates to share any thoughts that they might have in response.

Ms. Deane gave a quick overview of biotechnology and described it as a powerful driver of economic growth. She noted that DSTI's Working Party on Biotechnology held an expert workshop on Genetic Inventions, IPR, and Licensing Practices in 2002. One of the key themes that emerged from that workshop was that licensing practices deserved particular attention and that best practices guidelines should be

drafted, which became an ongoing project. Ms. Deane noted that a summary of the expert group's discussions and the current draft of the guidelines are available on OLIS (DSTI/STP/BIO/M(2004)2). It was envisioned by the expert group that the guidelines would be presented to the OECD Council.

The Chairman then opened the floor for general discussion. A delegate from the United States began the discussion by asking the delegate from BIAC to clarify his criticism of U.S. law, particularly in light of the recent *Trinko* decision, which established firmly that there is no antitrust liability in the U.S. for unilateral refusals to license.

The BIAC delegate agreed with the U.S. delegate, but mentioned a lower court case that has been largely discredited but still has not been invalidated. It therefore leaves some uncertainty in the business community.

A delegate from Sweden commented that the Swedish competition authority does not receive any complaints or tips involving the biotechnology industry. This is not because participants are unaware of the agency, the delegate continued, but is probably because problems in this industry tend to be resolved by settlements. That may be due to the rapid pace at which the sector is developing, and a resulting unwillingness to wait for lengthy judicial procedures. Therefore, the delegate queried whether competition legislation is perhaps not the most appropriate legislation for a dynamic industry such as biotechnology, and if not, what should medium or small sized competition authorities do? In other words, what would be the most important area for competition authorities to work on?

A delegate from Italy posed two additional questions. First, he noted that despite the U.S. Supreme Court's *Trinko* decision, it is still the case in the U.S. that if a company has monopoly power or has an essential facility, then it is obliged to deal with competitors under some circumstances. Although patents do not necessarily confer monopolies, he continued, they might nevertheless lead to it in some instances, and thus there should be no reason why IP should not have to deal with competitors in some circumstances, as well. He therefore posed the question, are there any exceptional circumstances when a patent leads to monopoly power and a refusal to license can be a violation of antitrust law?

Second, the delegate from Italy asked the E.C. delegation whether, in mandatory licensing cases, merely requiring an IP owner to license is an adequate remedy. The licensor might achieve its exclusionary objective simply by setting an excessively high licence fee. Therefore, he asked whether the remedy should also have a pricing component.

A delegate from Spain then mentioned an interesting dilemma faced by the Spanish competition authority. It began to investigate a refusal to license case several years ago, but then the target of the investigation was acquired by another operator, which in turn was required to sell the patent in question as a condition for the approval of the merger. The patent therefore moved through three different companies after the initial refusal to license. This presents a philosophical problem of having to punish an entity that had nothing to do with the refusal to deal. Therefore, it can be seen that in the biotechnology industry, not only is patent development unusually dynamic, but the companies themselves are, as well.

A delegate from the U.S. then addressed the Italian delegate's first question. The American delegate agreed that *Trinko* does not specifically resolve the question of mandatory IP licensing. However, he added, many Supreme Court cases involving patent laws make it clear that the right to unilaterally withhold a licence is a core right of U.S. IP law. The relevance of *Trinko* is that it answers the question whether the narrow group of cases in which a monopolist has been held to have a duty to deal should be expanded. In the delegate's view, *Trinko* makes it clear that the Supreme Court would not use antitrust law to find a new duty to deal in the IP area when there are already so many cases construing IP law that hold otherwise. On the other hand, IP owners are not immune to antitrust laws. The *Microsoft* appeals court,

for example, found that argument to border on the frivolous. Nevertheless, the U.S. delegate stated that there is something different about IP, as opposed to generic monopoly power or an essential facility, because the very nature of a patent right is the right to exclude others from using it. It would make no sense for a patent system to encourage people to invent things that they can patent, only to find under the competition laws that if their inventions are necessary to some other commercial product then the right of exclusivity must be forfeited. That is the reason for sending a message to the IP community that they should fix the problems with their system that place too much of a burden on competition, because if they are not fixed with IP law, then there will be calls for antitrust authorities to do something about them.

A delegate from the E.C. disagreed with the view that there is something special about IP as opposed to other kinds of property, and was more inclined to see parallels between IP and essential facilities. Both types of property require sufficient incentives for making investments, whether they are investments in innovation or in building certain infrastructures. Therefore, the delegate said, even with patents there are situations where there may be a real abuse of monopoly power (if there is monopoly power in a particular market). With regard to the Italian delegate's second question regarding remedies, the E.C. delegate agreed that there may be difficulties with licensors who try to charge excessive fees, yet agencies must not rush to become regulatory authorities and thereby get involved in something that they cannot administer. The most important objective is to maintain the right balance between incentives for original innovation and incentives for follow-on research. But in any case, the delegate said, agencies cannot simply say that because the pricing and balancing issues are difficult, they will never intervene. Even so, intervention should be rare. Only in exceptional circumstances should governments wield the radical instrument of compulsory licensing.

Finally, a delegate from the U.S. noted that one of the fundamental challenges to the development of competition law was that it is a hopelessly anachronistic system, unable to keep pace with the quickly changing industrial landscape. The same questions about the adaptability of competition laws that are being raised now were also asked when the transportation and communications sectors were changing rapidly. But we have seen over time that the competition law concepts that we use have adapted fairly well. There is enough flexibility inherent in our systems to absorb new learning in law and economics. The delegate emphasised that the real challenge does not concern the adaptability of the concepts, but rather of the enforcement authorities and courts that apply them. Whether they are sufficiently adaptable is an open question. However, forging links with other institutions and investing in an increasing knowledge base was a key reason why the U.S. competition agencies decided to hold their IP hearings. A lesson from that experience is that, from an institutional prospective, to work effectively in areas like biotechnology, competition agencies have to change some of the ways that they apply their resources. Admittedly, that may involve very difficult resource allocation choices, but making those hard choices is one of the keys to adapting.

RÉSUMÉ DE LA DISCUSSION

Le Président ouvre le débat en faisant observer que les opinions diffèrent sur le rôle que devraient jouer les autorités de la concurrence dans la formulation et la mise en oeuvre de la politique relative à la propriété intellectuelle. Dans certains pays, l'autorité de la concurrence peut intervenir dans la formulation de cette politique, alors que dans d'autres elle n'y est pas autorisée. Il propose de commencer par examiner ces différents systèmes. Ensuite, il suggère que le Comité centre son attention sur deux des questions qui se situent à l'intersection du champ d'application du droit de la concurrence et des DPI – les refus unilatéraux de licence et l'exclusivité d'une part, les communautés de brevets d'autre part. La troisième question qu'il recommande d'aborder est l'interface PI/droit de la concurrence, notamment en ce qui concerne les biotechnologies. Il note que même si de nombreux pays n'ont guère d'expérience contentieuse en biotechnologies, plusieurs juridictions ont commandé des rapports d'experts pour évaluer l'efficacité de leur système de PI en biotechnologie et pour déterminer s'il débouche sur un secteur concurrentiel.

1. Le rôle que devraient jouer les autorités de la concurrence dans la formulation et la mise en oeuvre de la politique en matière de PI

Le Président attire l'attention sur la contribution des Etats-Unis, qui rend compte d'auditions conjointes du Ministère de la Justice et de la Federal Trade Commission tenues en 2002 sur le thème "Droit et politique de la concurrence et de la propriété intellectuelle dans l'économie fondée sur le savoir". Ce document mentionne l'interdépendance entre la politique de la concurrence et les systèmes de PI, et souligne l'importance des efforts destinés à combler les lacunes éventuelles de chaque régime. Il invite la délégation américaine à préciser quels sont les messages les plus importants à communiquer aux offices de brevets au sujet de cette interdépendance et à expliquer le rôle qu'elle souhaite voir jouer, le cas échéant, par les autorités de la concurrence dans la formulation et la mise en oeuvre de la politique relative à la PI.

Un délégué des Etats-Unis déclare que le fonctionnement du système de brevets a des effets importants sur le processus concurrentiel. Pour commencer, des brevets de mauvaise qualité (c'est-à-dire des brevets qui sont accordés alors même qu'ils ne remplissent pas les normes de brevetabilité définies dans le régime de brevets de la juridiction) peuvent avoir des effets préjudiciables à la concurrence de deux façons, premièrement lorsque le droit attaché au brevet crée un pouvoir de marché. Le délégué prend soin de signaler que les brevets en eux-mêmes ne créent pas directement un pouvoir de marché. Mais si un brevet accordé inconsidérément crée un pouvoir de monopole, alors son exploitation restreindra la concurrence.

Le deuxième effet est moins direct. Bien que cela ne soit pas prouvé de façon rigoureuse, l'expérience des Etats-Unis suggère que lorsqu'un office de brevets délivre des brevets faibles, la politique de la concurrence et le système juridique tendent à compenser cela en utilisant des principes du droit de la concurrence pour circonscrire les effets de brevets accordés inconsidérément. Malheureusement, la politique de la concurrence est dans ces circonstances un instrument trop grossier pour corriger les défaillances du système de brevets. Le rapport que la Federal Trade Commission a publié après les auditions conjointes suggère plusieurs moyens qui permettraient de rendre l'Office des brevets plus solide.

Premièrement, note le délégué des Etats-Unis, le système d'examen des brevets a besoin d'être financé de manière adéquate. Des domaines complexes, tels que les biotechnologies, nécessitent des spécialistes hautement qualifiés pour examiner et évaluer des brevets. Deuxièmement, le système des

brevets pourrait bénéficier de la mise en place de mécanismes plus rigoureux dans la période qui précède l'octroi du brevet afin de tester et d'évaluer l'application. Troisièmement, il faut une procédure plus efficace de contrôle après l'octroi du brevet. Une possibilité serait que les Etats-Unis adoptent la démarche que l'Union européenne a utilisée, notamment une procédure administrative pour évaluer la qualité du brevet a posteriori.

Le délégué des Etats-Unis souligne qu'il n'est pas en train de suggérer que les autorités de la concurrence soient impliquées dans l'évaluation des brevets. Il suggère simplement des mesures que l'Office des brevets lui-même pourrait prendre pour rendre l'évaluation des demandes plus efficace. Si les offices de brevets suivent ces suggestions, renforçant ainsi la solidité de leurs systèmes, les autorités de la concurrence et les tribunaux seront moins tentés de recourir à la doctrine de la concurrence pour corriger des problèmes.

Il serait souhaitable que les autorités de la concurrence fassent entendre davantage leur voix en établissant un dialogue interdisciplinaire avec les offices de brevet, ce qui favoriserait une meilleure compréhension mutuelle des domaines de chacun.

La contribution du Canada explique que le Bureau de la concurrence dispose de plusieurs moyens légaux pour intervenir dans la politique relative à la PI. Le Président demande à la délégation canadienne de parler de ces dispositions, de la fréquence à laquelle elles sont utilisées et de leur efficacité.

Un délégué du Canada répond que le Bureau de la concurrence s'est appuyé sur son droit statutaire de se présenter devant n'importe quel Conseil fédéral, commission ou autre tribunal pour témoigner par des faits ou commenter des problèmes de concurrence sur une question de propriété intellectuelle à deux occasions seulement. La première concernait une commission nommée par le gouvernement et chargée d'examiner l'impact du régime de licence obligatoire du Canada sur la fabrication de produits pharmaceutiques. Le Bureau a soumis des documents suggérant qu'à son avis il n'y avait aucun effet négatif dont on pouvait apporter la preuve sur le niveau de recherche-développement. La deuxième intervention était relative à la possibilité d'établir des sociétés de gestion des droits d'auteur pour administrer des droits dans un domaine, par exemple les photocopies. Dans les deux cas, les recommandations du Bureau ont été largement acceptées.

Le délégué du Canada explique aussi que l'article 32 de la loi canadienne sur la concurrence permet au Bureau de solliciter du Procureur général qu'il exerce un recours spécial auprès de la Cour fédérale dans les cas où l'exercice d'un droit de propriété intellectuelle entraînerait un amoindrissement de la concurrence. Les moyens peuvent être assez larges. Par exemple, ils permettent au tribunal d'ordonner la révocation du brevet. Ce n'est donc pas une procédure à employer à la légère. En fait il y a très peu de jurisprudence dans ce domaine. Les deux dernières affaires remontent au milieu des années 60 et ont été réglées. Le Bureau canadien de la concurrence a publié des lignes directrices concernant l'application de la loi sur la PI qui décrivent son interprétation de l'article 32 : il est clair que le Bureau n'utilisera cette disposition que lorsqu'une diminution de la concurrence résulte de l'exercice d'un DPI.

La contribution du Royaume-Uni indique « qu'en Australie et aux Etats-Unis on observe des tendances à mettre davantage l'accent sur la concurrence dans le processus d'octroi de brevets », mais elle précise que « au Royaume-Uni, nous avons préféré agir à l'inverse des initiatives récentes prises aux Etats-Unis et en Australie ». Le Président demande à la délégation du Royaume-Uni d'expliquer pourquoi le régime légal de ce pays a changé et de préciser si les autorités britanniques trouvent des avantages soit dans l'ancien, soit dans le nouveau système.

Un délégué du Royaume-Uni explique que le système de son pays a changé en mars 2000, lorsque la loi sur la concurrence de 1998 est entrée en vigueur, mettant la législation britannique de la concurrence en

conformité avec la législation communautaire. Auparavant, la loi sur les brevets traitait non seulement des questions de PI mais permettait aussi de faire certaines interventions si des brevets étaient exploités de manière déraisonnable. La loi sur la concurrence traite maintenant des problèmes de concurrence posés par l'exploitation.

Selon la contribution de la Nouvelle-Zélande, les critères légaux d'octroi de brevets en vertu de la loi sur les brevets (nouveauté, caractère non évident et utilité) sont techniques ; aucune considération explicite n'est accordée aux problèmes de concurrence, et la Commission du commerce n'est pas impliquée. Le Président demande si ce désintérêt à l'égard des problèmes de concurrence au niveau de la concession de licences est justifié.

Un délégué de la Nouvelle-Zélande répond qu'il y a en réalité une relation très étroite entre la politique de concurrence et la politique relative à la PI en Nouvelle-Zélande. Ces deux politiques sont gérées par la même branche du Ministère du développement économique. Une question de concurrence liée à la PI que la Nouvelle-Zélande prend très au sérieux est de savoir comment certaines nations ont réussi à conjuguer des DPI de plus en plus forts et le libre échange. En tant que pays importateur de technologie, la Nouvelle-Zélande n'accepte pas cette tendance. Elle considère que du point de vue de la concurrence, il y a un niveau optimal de protection qui a probablement été dépassé. Les écarts par rapport au niveau optimal réduisent l'efficience. En outre, on craint que dans certains domaines l'Office des brevets n'ait accordé des brevets trop larges. Le Ministère du développement économique a interrogé l'Office des brevets sur la façon dont sont examinés les brevets de gènes, par exemple. Sur la base de ces discussions, l'Office des brevets a accepté de revoir ses procédures. Enfin, le délégué a précisé que les détenteurs de brevets ne sont pas exemptés des aspects relatifs aux pratiques commerciales restrictives de la loi sur la concurrence. Cependant, il n'y a encore aucun exemple de poursuites engagées par la Commission du Commerce de Nouvelle-Zélande contre un détenteur de brevet.

La contribution de la Turquie indique que la participation des autorités de la concurrence au processus d'octroi de brevets et leur droit de remettre en cause la validité des brevets ne devraient pas être autorisés. Le Président invite la délégation de la Turquie à s'expliquer à ce sujet.

Un délégué de la Turquie répond que le processus d'examen des brevets nécessite des informations très techniques et détaillées et une grande spécialisation. L'autorité turque de la concurrence estime donc que si elle devait participer au processus d'examen, cela créerait pour elle une charge lourde et inutile. En outre, ce serait imprudent, car si l'autorité de la concurrence n'a déjà pas les ressources suffisantes pour faire face à ses responsabilités actuelles, elle n'en a pas pour prendre des responsabilités nouvelles. Pour le moment, il semble impossible d'obtenir un financement supplémentaire.

Le Président remarque que les participants ne voient pas tellement ce que les autorités de la concurrence devraient faire en termes de définition ou de remise en cause de la portée des DPI, à l'exception, dans une certaine mesure, du Canada. Cela ne veut cependant pas dire que les autorités de la concurrence n'ont pas de problèmes du fait de mauvais brevets.

2. Application du droit de la concurrence et droits de propriété intellectuelle

Le Président commence cette partie de la discussion en relevant les enjeux auxquels doivent faire face les pays qui se trouvent maintenant en situation de devoir adopter des réglementations internes compatibles avec les directives de l'UE dans ce domaine. Il appelle ensuite la Commission européenne à présenter son point de vue sur les problèmes d'application du droit de la concurrence et sur les droits de propriété intellectuelle.

Un délégué de la Commission européenne commence par faire remarquer que la Commission a entrepris récemment une révision complète de ses règles en vigueur, a réévalué les relations entre DPI et droit de la concurrence et, le 27 avril 2004, a publié une série entièrement nouvelle de règles sur les brevets, le savoir-faire et la cession sous licence de droits d'auteur sur les logiciels. Il s'agit essentiellement d'une réglementation prévoyant une exemption par catégories et d'une série de nouvelles lignes directrices sur les DPI. La démarche est la suivante : l'octroi de licences est en général favorable à la concurrence, de sorte qu'il y a clairement des zones de sécurité, et c'est également vrai en ce qui concerne les licences exclusives. Les nouvelles règles distinguent également pour la première fois les relations horizontales des relations verticales, de sorte qu'il est capital de savoir s'il s'agit d'accords conclus entre concurrents ou entre non concurrents avant de formuler des politiques. La Commission a entrepris de parvenir à un meilleur équilibre entre la protection des incitations à innover et les interventions nécessaires occasionnellement contre des accords de licence qui restreignent la concurrence.

Le délégué de la C.E. prend aussi deux exemples dans lesquels l'incitation à obtenir une licence avant tout et l'incitation à poursuivre la recherche doivent être équilibrées. Tout d'abord, dans le domaine des obligations de licences en retour, la Commission fait une distinction entre perfectionnements séparables et non séparables. Les perfectionnements séparables peuvent être exploités par le licencié sans porter atteinte à la technologie faisant initialement l'objet de la licence. Les nouvelles règles exemptent les licences en retour, y compris exclusives, d'innovations non séparables. En revanche, les licences en retour de perfectionnements séparables sont exemptées seulement si elles sont non exclusives, parce que ce cadre maintient l'incitation à effectuer des innovations de suivi qui sinon seraient retardées. C'est là un exemple, fait remarquer le délégué, de nouvelle réglementation qui change complètement les règles précédentes qui étaient beaucoup plus strictes, afin de parvenir à un équilibre différent.

Le deuxième domaine abordé par le délégué de la C.E. concerne les communautés de brevets. Reconnaissant les effets favorables et défavorables à la concurrence des communautés de brevets, la C.E. a mis au point un ensemble de règles qui finalement sont très convergentes avec la pratique américaine. En bref, les communautés sont bien accueillies si elles n'impliquent que des brevets complémentaires et essentiels. En revanche, si une communauté inclut des brevets qui peuvent se substituer les uns aux autres, cela crée un risque de collusion immédiat pour vendre conjointement des technologies concurrentes. La communauté violerait ainsi généralement l'article 81, mais il faudrait quand même procéder à une évaluation individuelle. L'inclusion de brevets non essentiels est aussi un problème, car ils risquent d'exclure des technologies de parties tierces. Dans ce domaine, toutefois, la CE est probablement moins stricte que les EU en ce sens que la CE effectue une analyse au cas par cas.

Le délégué de la C.E. passe ensuite aux refus unilatéraux de concession de licence. En principe, explique-t-il, il n'y a pas dans le droit de la concurrence de responsabilité pour refus de licence, même par une firme dominante. Il peut cependant y avoir des exceptions dans certaines circonstances. La décision *IMS* énonce trois conditions nécessaires. La première est qu'il doit s'agir d'une situation dans laquelle un concurrent essaie de développer un nouveau produit pour lequel il y a une demande potentielle des consommateurs. Deuxièmement, il doit s'agir d'une situation dans laquelle le refus de licence conduit à éliminer la concurrence sur un marché secondaire. Troisièmement, il n'est pas obligatoire qu'il y ait une justification objective du refus de licence. Là encore, on peut voir combien il est difficile de trouver un équilibre entre la protection de l'inventeur initial et les incitations à des innovations complémentaires.

A l'instar de la C.E., la Korean Fair Trade Commission a aussi promulgué des lignes directrices pour revoir l'exercice des DPI. Ces lignes directrices prévoient une « liste blanche » de pratiques qui ne sont pas considérées comme des violations du droit de la concurrence. Le Président demande à la délégation de Corée de préciser quelles pratiques sont sur la liste blanche et quelles pratiques sont sur la liste noire.

Un délégué de la Corée répond qu'il est stipulé à l'article 59 de la Monopoly Regulation and Fair Trade Act de Corée que le juste exercice des droits de PI est exempté du droit coréen de la concurrence. Cependant, si le comportement des détenteurs de brevets va au delà du but des DPI qui est de promouvoir les inventions et la créativité, alors ce comportement sera soumis au droit de la concurrence. Les lignes directrices de la KFTC interdisent en principe 17 types de comportement susceptibles de nuire à la concurrence lorsque le cédant d'un DPI impose indûment des restrictions portant sur certaines transactions avec les consommateurs, certaines quantités, régions de ventes ou améliorations technologiques. Cependant, il existe aussi une liste blanche de pratiques exemptées dont on peut prouver, après examen approfondi, qu'elles ne provoquent qu'une restriction infime de la concurrence ou même, dans certains cas, qu'elles augmentent la concurrence. Par exemple, la liste noire interdit aux cédants de restreindre les sources auprès desquelles une partie doit acheter des pièces de rechange et des équipements de véhicules à moteur. Cependant, la liste blanche autorise de telles restrictions si elles sont nécessaires pour garantir la qualité et la performance des biens cédés sous licence. Enfin, la subordination de vente est sur la liste noire, mais si elle est nécessaire pour maintenir la qualité des produits sous licence, ce comportement sera considéré aussi comme une pratique commerciale loyale.

3. Refus de licence unilatéraux/ licences exclusives

Le Président recentre ensuite la discussion sur les refus de licence et l'octroi de licences exclusives. Il note que la contribution de la Norvège examine un amendement récent à la loi norvégienne sur les brevets qui confère à l'autorité de la concurrence de ce pays le pouvoir d'accorder des licences obligatoires lorsqu'un brevet a été « négligé » pendant trois ans. Le Président appelle ensuite la délégation norvégienne à expliquer pourquoi la loi norvégienne a été modifiée, si l'autorité de la concurrence a eu un rôle dans l'application des amendements et quels critères sont utilisés pour décider qu'un brevet a été négligé.

Un délégué de la Norvège commence par noter que selon la loi norvégienne sur la concurrence, article 11, l'autorité de la concurrence avait déjà la capacité d'imposer des licences obligatoires dans des situations où il y avait abus de position dominante. Le nouveau pouvoir d'accorder une licence obligatoire selon la nouvelle loi vient de la mise en oeuvre de la directive européenne 98/44 CE sur la protection juridiques des inventions biotechnologiques. Il était nécessaire d'adopter des règles statutaires, dans le cadre de la législation norvégienne, concernant la concession de licences obligatoires pour des droits d'obtention végétale risquant de porter atteinte aux brevets existant déjà. Bien que la directive n'exige pas la mise en oeuvre d'autres dispositions relatives à la concession de licences obligatoires, les autorités norvégiennes ont choisi de saisir l'occasion d'apporter d'autres changements à la loi sur les brevets qui donnent à l'autorité norvégienne de la concurrence une capacité plus générale d'imposer des licences obligatoires dans certaines conditions. L'autorité norvégienne de la concurrence n'était pas à l'origine de ces modifications, mais elle les a approuvées dans ses commentaires.

La raison pour laquelle on a attribué ce nouveau pouvoir à l'autorité norvégienne de la concurrence réside dans son expérience acquise dans l'évaluation de problèmes de concurrence qui impliquent, dans de nombreux cas, des licences obligatoires. Cependant, ce nouveau pouvoir octroyé à l'autorité de la concurrence n'est encore qu'une alternative à une décision du tribunal. Afin de se voir accorder une licence obligatoire par l'autorité de la concurrence norvégienne, un demandeur doit remplir certains critères. Il doit avoir tenté de parvenir à un accord avec le détenteur du brevet sur une base concurrentielle, doit être capable d'exploiter l'invention de manière raisonnable, et le brevet doit avoir été négligé pendant trois ans. Ainsi, des tierces parties ont là un moyen d'accès aux inventions d'importance capitale pour la société. Cependant, dans chaque cas, l'autorité norvégienne de la concurrence doit contrebalancer la nécessité de stimuler les innovations originales par l'intérêt qu'a la communauté à avoir accès aux brevets laissés inexploités sans raison particulière.

Le Président note ensuite qu'il a l'impression qu'à la différence de ce qui se passe en Norvège, aux Etats-Unis la non utilisation unilatérale d'un brevet ne peut pas servir de fondement pour une action en responsabilité au titre du droit des ententes. Il demande à la délégation américaine si son impression est correcte et, dans l'affirmative, s'il serait possible d'indiquer les raisons de cette différence de politique.

Un délégué des Etats-Unis répond qu'en effet il est incapable de trouver un bon exemple de non utilisation d'un brevet pendant un certain temps. Cependant, il y a eu une affaire très controversée, présentée par la FTC, qui a été réglée dans les années 70, dans laquelle Xerox était impliquée. Cette société avait breveté la technologie de base de la photocopieuse papier ordinaire. La FTC prétendait que Xerox avait demandé à ses ingénieurs d'imaginer tout itinéraire possible qui pourrait être emprunté pour parvenir au même résultat et de breveter également ces technologies. Il y aurait eu ainsi une forteresse technologique à partir de laquelle des procès pourraient être intentés contre toute personne qui essaierait de faire concurrence à Xerox. Selon la FTC, Xerox n'aurait jamais souhaité exploiter ces technologies alternatives ; elle les aurait développées seulement pour créer des obstacles empêchant d'attaquer la technologie existante. Le règlement final a imposé à Xerox de concéder en licence les trois brevets en sa possession, sans redevances en contrepartie, ce qui n'a pas manqué d'inspirer à de nombreuses sociétés l'idée d'entrer sur le marché de la photocopie sèche sur papier dans les années 70 et 80. Le délégué a souligné encore une fois, cependant, que Xerox était une affaire extrêmement controversée qui n'a pas été portée devant les tribunaux. Elle a provoqué un très large débat dans la littérature spécialisée où l'on trouve posée la question fondamentale suivante : Quel est le taux de rendement approprié à attendre d'une technologie brevetée, et quelle est la redevance appropriée à fixer ? L'attaque la plus grave dans les publications spécialisées américaines est de dire que jusqu'à ce qu'on ait des certitudes en réponse à ces questions, on ne devrait pas pouvoir obliger une entreprise à utiliser ou à céder en licence cette technologie.

Contrairement aux Etats-Unis, fait remarquer le Président, le Royaume-Uni a connu un certain nombre d'affaires récentes en matière de concurrence, qui impliquent une forme ou une autre de refus unilatéral de céder en licence un produit dont la propriété intellectuelle est protégée. Le Président demande à la délégation américaine d'expliquer l'analyse qu'elle fait des refus de licence unilatéraux et de décrire l'affaire Synstar.

Un délégué du Royaume-Uni commence par noter que la première chose à faire est de savoir si la société qui refuse a la possibilité d'évincer les autres entreprises d'un marché ou de se livrer à d'autres pratiques anticoncurrentielles. Par conséquent l'analyse consiste essentiellement à savoir si la position est dominante et si cette position dominante est utilisée par le biais d'un DPI pour créer des conditions déloyales ou déraisonnables susceptibles de réduire la concurrence. L'affaire Synstar impliquait des contrats de maintenance portant sur du matériel informatique. Synstar prétendait qu'ICL, fournisseur d'ordinateurs à fonctionnalité centrale, avait refusé de fournir certains logiciels de diagnostic à des clients dont le matériel ne faisait pas l'objet de contrats de maintenance par ICL, empêchant ainsi d'autres prestataires de services de maintenance de lui faire concurrence pour des contrats d'entretien concernant des ordinateurs centraux ICL. Le marché primaire portait sur des équipements à vocation d'ordinateur central, et l'Office of Fair Trading a estimé qu'ICL ne dominait pas du tout ce marché. L'OFT a conclu ensuite que les services de maintenance n'étaient pas un marché séparé, parce que les clients qui achètent des ordinateurs centraux ont tendance à considérer que le coût des contrats de maintenance fait partie du coût global d'achat d'un ordinateur. Etant donné qu'il n'y avait pas de marché secondaire pertinent et qu'ICL n'était pas dominant sur le marché primaire, la plainte de Synstar était non fondée.

La contribution du Mexique examine une affaire dans laquelle la Commission fédérale de la concurrence (CFC) a conclu qu'une licence exclusive ne violait pas la loi fédérale sur la concurrence économique et qu'en fait elle avait pour effet de promouvoir la concurrence. Le Président invite la délégation mexicaine à fournir des détails sur l'affaire Punto-Flex.

Un délégué du Mexique explique que, d'après la constitution mexicaine, la PI est exemptée de la disposition générale contre la monopolisation. Cet état de fait a conduit de nombreux chercheurs et juristes à croire que la protection de la PI est complètement en dehors du droit de la concurrence. Cependant, la CFC a une interprétation différente, et cette affaire en est une bonne illustration. Comme au Royaume-Uni, la CFC doit montrer que le titulaire d'un DPI a une position dominante et qu'il abuse de cette position, par exemple en fermant le marché. Dans l'affaire Punto-Flex, une société avait inventé une façon très imaginative de distribuer de l'eau. La CFC a jugé que cette société n'avait pas une position dominante. En fait, la CFC a estimé que l'invention créait en réalité davantage de concurrence parce qu'elle donnait de nouvelles options au marché. Par conséquent, bien que le brevet ait été cédé en exclusivité, il n'était pas porté atteinte à la concurrence et l'affaire fut close.

Le Président appelle ensuite la délégation canadienne à expliquer les circonstances dans lesquelles il serait demandé au tribunal d'imposer des licences obligatoires.

Le Bureau de la concurrence examine les refus de licence en vertu de l'article 32, et son approche conformément à cette disposition est décrite dans ses lignes directrices visant à faire respecter la PI. Pour l'essentiel, l'examen comporte deux étapes. Tout d'abord, le Bureau détermine si le refus de licence a nui à la concurrence à un degré substantiel sur un marché pertinent qui est différent ou sensiblement plus grand que celui faisant l'objet de la PI. Lorsqu'il procède à cette détermination, le Bureau doit prendre en compte deux facteurs : le détenteur de la PI doit avoir une position dominante sur le marché en question, et la PI doit être une ressource essentielle pour les entreprises qui participent à ce marché. En d'autres termes, le refus doit empêcher d'autres firmes d'être effectivement en concurrence sur ce même marché ;

Si la première étape est réalisée, alors le Bureau détermine si le fait d'invoquer un recours spécial affecte les incitations des firmes à investir dans la recherche et développement. En conséquence, le Bureau déterminera si le titulaire du DPI aurait quand même effectué l'innovation s'il avait su à l'avance qu'une mesure spéciale serait imposée. Si la réponse est affirmative, cela suggère qu'il est souhaitable d'imposer une telle mesure.

4. Communautés de brevets

Le Président aborde ensuite les communautés de brevets et observe que la contribution qui traite le plus à fond de cette question est celle des Etats-Unis. Elle mentionne notamment une affaire de 1998 dans laquelle la FTC a donné des orientations sur les communautés de brevets. Le Président invite la délégation américaine à présenter son cadre d'analyse des communautés de brevets dans le contexte de l'affaire de 1998.

Un délégué des Etats-Unis répond que les communautés de brevets ont un fort potentiel pro-concurrentiel dans l'industrie des biotechnologies. Elles facilitent l'exploitation des technologies en supprimant les obstacles ayant un effet de blocage. Elles favorisent aussi l'intégration de technologies complémentaires et réduisent les coûts de transaction pour l'obtention des licences. En outre, les communautés de brevets sont considérées comme une approche beaucoup moins onéreuse de règlement de litiges que l'action en justice.

Le délégué des Etats-Unis explique que toutes ces justifications d'efficience étaient absentes dans l'affaire VISX/Summit. La technologie en question était destinée à permettre l'utilisation de la chirurgie au laser pour corriger la myopie. Seules deux firmes avaient l'approbation des autorités de contrôle de l'innocuité des produits alimentaires et des médicaments pour fournir la technologie en question, de sorte qu'il n'y avait pas d'autres brevets en dehors de la communauté de brevets. En effet, les deux sociétés avaient mis leurs brevets en commun. Selon la FTC, les technologies n'avaient pas du tout un effet de blocage, mais en fait elles pouvaient se substituer l'une à l'autre. L'affaire a été résolue par une décision de

dissolution de la communauté et d'autorisation de ceux qui avaient signé des contrats utilisant les licences préexistantes à les abandonner.

Le Président indique que les lignes directrices du Japon relatives aux accords de licence de brevets et de savoir-faire dans le cadre de la loi anti-monopoles traitent, entre autres choses, des communautés de brevets et indiquent quelles pratiques de mises en commun pourraient être considérées comme illégales. Il demande à la délégation japonaise de préciser si les lignes directrices font une distinction entre les communautés impliquant des technologies complémentaires et celles impliquant des technologies substituables.

Un délégué du Japon explique que les lignes directrices ne sont pas fondées sur les différences entre compléments et substituts. Les communautés de brevets peuvent avoir un effet pro-concurrentiel en termes d'accroissement de l'utilité des brevets mis en commun, et elles peuvent aussi promouvoir l'échange de technologies parmi les détenteurs de DPI. Cependant, si une communauté de brevets impose des restrictions mutuelles à ses membres en ce qui concerne le prix de vente, le volume de fabrication ou le volume des ventes par exemple et, ce faisant, restreint sensiblement la concurrence, cela devient problématique par rapport à la législation japonaise anti monopoles. C'est pourquoi, en vertu de ces lignes directrices, la FTC du Japon examine au cas par cas si chaque communauté de brevets est anticoncurrentielle et ne se contente pas de se poser la question des substituts et des compléments.

Le Président appelle ensuite la délégation du Taipei chinois à commenter une affaire sur laquelle la FTC de Taiwan a travaillé ces cinq dernières années et concernant le marché de la technologie des disques compacts réinscriptibles. Selon la contribution du Taipei chinois, l'affaire touche à bon nombre des sujets examinés lors de cette table ronde, notamment aux communautés de brevets.

Un délégué du Taipei chinois déclare que l'affaire des CD implique trois concédants qui sont des firmes connues au plan international. Plusieurs licenciés taiwanais se sont plaints à la FTC que deux des cédants avaient constitué une communauté de brevets anticoncurrentielle. La FTC de Taiwan a examiné la nature des différents brevets impliqués pour voir s'ils étaient tous essentiels, et a trouvé que certains des brevets n'étaient pas vraiment liés à la technologie en question. En outre, les trois grands cédants avaient conclu un arrangement exclusif tel que toute firme rivale aurait eu des difficultés à leur faire concurrence.

Un autre facteur intéressant, explique le délégué, concerne le taux de redevance. En 1996, lorsque les parties ont constitué la communauté de brevets, il y avait une formule qui faisait référence soit à un pourcentage du prix moyen de vente, soit à 10 yens japonais (montant le plus élevé des deux). En 1996, le taux de redevance semblait raisonnable. Mais en 2000, lorsque le marché fut très concurrentiel, le prix de vente moyen du produit baissa de façon spectaculaire. Le taux de redevance basé sur le prix de vente n'était plus applicable et on utilisa le taux minimum de 10 yens. En conséquence, les fabricants taiwanais devaient payer une redevance relativement élevée qui représentait presque 18 pour cent de l'ensemble de leurs coûts. Cela soulève une question intéressante et difficile : faut-il considérer cette redevance en tant qu'accord de fixation du prix ? Finalement, la FTC de Taiwan a estimé que la communauté de brevets violait la Loi sur le commerce loyal en fixant conjointement un taux de redevance qui n'avait pas été approuvé au préalable par la FTC, abusant d'une position monopolistique en maintenant un taux de redevance qui a porté préjudice à la concurrence en aval, et associant des brevets valables, essentiels et complémentaires avec des brevets non valables, non essentiels, substituables et non pertinents, ce qui constituait une disposition contractuelle illégale.

Le Président note que plusieurs contributions mentionnent en tant que préoccupation particulière la possibilité qu'un détenteur de brevet utilise son brevet pour prendre une position dominante sur un marché sans lien avec le brevet. Il invite la délégation française à parler de cette préoccupation.

Un délégué de la France commence par souligner que les restrictions associées à la propriété intellectuelle peuvent être justifiées si elles contribuent au progrès économique, notamment en assurant la promotion de nouvelles technologies ou de nouveaux produits. De sorte que les DPI doivent être protégés. La loi sur la concurrence ne peut mettre en question l'existence de droits de propriété intellectuelle exclusifs, mais elle peut en interdire l'abus. Le délégué donne ensuite un exemple faisant référence aux sanctions imposées à Sandoz-Novartis en 2003. Sandoz produisait et vendait deux médicaments brevetés dérivés de la cyclosporine. Ces médicaments étaient vitaux pour des patients qui avaient subi des greffes d'organe ou de moelle épinière.

En 1994, Sandoz a lancé une politique de marketing en direction de la clientèle hospitalière fondée sur un système de fidélité et de rabais. Elle offrait des remises sur les médicaments à base de cyclosporine, à condition que les hôpitaux achètent aussi sept autres produits Sandoz, alors qu'il y avait des produits concurrents sur le marché. Le Conseil de la concurrence a conclu que Sandoz, qui jouissait d'une position dominante sur le marché de la cyclosporine, avait abusé de sa position pour vendre les sept autres produits.

5. L'interface propriété intellectuelle / droit de la concurrence en biotechnologies

Le Président fait remarquer qu'il est frappant de constater, d'après les contributions, que les autorités de la concurrence ont examiné très peu d'affaires dans le secteur des biotechnologies. Néanmoins, un certain nombre de pays ont fait des tentatives pour examiner l'interface entre les DPI, la compétitivité et la concurrence dans le domaine des biotechnologies. Plusieurs rapports ont été commandés par des autorités de la concurrence et des offices de brevets. Le Président appelle la délégation suisse à parler d'une étude de l'Institut fédéral suisse de la propriété intellectuelle intitulée « Recherche et concession de brevets en biotechnologies, étude réalisée en Suisse ».

Un délégué de la Suisse précise que ce rapport s'explique du fait que la loi suisse sur les brevets subit actuellement une réforme partielle. Certaines préoccupations apparaissent, notamment dans le domaine des biotechnologies, auxquelles le rapport tente de répondre. Ses objectifs sont d'améliorer la compréhension des aspects économiques de la concession de brevets, de tous problèmes concrets, pratiques, et des lacunes de la législation suisse actuellement en vigueur.

L'étude n'a trouvé aucune faille ni abus systématique dans le système de brevets applicable actuellement aux inventions biotechnologiques en Suisse. Le problème de « l'anti-commun » n'était pas censé exister à ce moment là. En outre, l'étude a découvert que les communautés et consortiums de brevets ne sont pas très utilisés actuellement, bien que les délégués les recommandent en tant que remèdes aux problèmes de transfert de technologie et d'exploitation, notamment pour les universités. Le délégué considère donc les communautés de brevets plus comme une solution que comme un problème.

La qualité et la portée des brevets posent en revanche davantage de problèmes. C'est pourquoi dans les réformes on a demandé la divulgation concrète des fonctions des brevets d'ADN. Les licences obligatoires sont possibles dans certaines circonstances, notamment dans le cas d'abus de situation de monopole. En outre, il y a une exemption explicite en faveur de la recherche.

Le Président demande ensuite à la délégation japonaise de faire un exposé sur un rapport préparé par un groupe d'experts de la FTC du Japon intitulé « Patent and Competition Policy in New Industries, With a Focus on Business Model Patents and Biotechnology Patents. »

Un membre de la délégation japonaise précise que le groupe d'étude a publié son rapport en juin 2002. En 1999, la FTC du Japon avait fait paraître des lignes directrices générales relatives aux accords de licence concernant les brevets et le savoir-faire, qui précisaient que la loi japonaise anti monopoles serait appliquée aux comportements liés à la PI qui portent atteinte à la concurrence et s'opposent à ou

contredisent le but du système de protection de la PI. Cependant, la FTC japonaise a remarqué après coup que de nouveaux brevets étaient accordés dans le domaine des biotechnologies qui se trouvaient précédemment hors du champ de protection des brevets, et que cette même FTC n'avait pas encore acquis suffisamment d'expertise par rapport à ces brevets. Il était souhaitable de faire appel à des experts extérieurs pour anticiper les types d'affaires qui risquaient de se présenter et la façon dont la FTC devrait les aborder du point de vue de la politique de la concurrence. L'étude a donc été commandée.

Le rapport permettait à la FTC japonaise d'approfondir ses connaissances sur les questions de concurrence liées aux brevets biotechnologiques et indiquait clairement quels types de cas étaient susceptibles de se présenter. Il aidait aussi la FTC à montrer aux acteurs comment la loi sur la concurrence s'appliquerait aux comportements anticoncurrentiels dans de nouveaux secteurs tels que les biotechnologies.

Le délégué explique aussi qu'il n'y a pas eu encore de cas concret lié à la PI dans le domaine des biotechnologies. Il suggère que la FTC du Japon envisage d'encourager les personnes qui travaillent dans ce secteur à frapper à sa porte pour des consultations préliminaires, afin de tenter de prévenir tout problème qui pourrait survenir.

Dans sa contribution, la Turquie suggère que les autorités de la concurrence prennent en compte certaines conditions *sui generis* des marchés biotechnologiques. Il demande à la délégation de la Turquie d'indiquer les caractéristiques spécifiques de l'industrie biotechnologique qu'elle pense pertinentes pour l'analyse de la concurrence.

Un délégué de la Turquie répond que deux caractéristiques sont particulièrement importantes. Premièrement, il s'agit d'une industrie très jeune par rapport aux autres. Elle a néanmoins un rôle important dans l'économie ainsi que pour le bien-être social, parce qu'elle a introduit des technologies avancées et des innovations qui répondent aux besoins sociaux et résolvent des problèmes importants. En particulier, la biotechnologie a débouché sur des innovations importantes dans les secteurs pharmaceutiques et agricoles. Il est prudent que les autorités de la concurrence gardent à l'esprit l'importance de la biotechnologie. Deuxièmement, il faut tenir compte du fait que la protection des brevets est d'une importance capitale pour l'industrie biotechnologique. Dans une économie de marché, il faut donner aux entreprises privées les incitations adéquates pour qu'elles innovent. Les droits de propriété intellectuelle sont essentiellement un contrat entre la société et des inventeurs, et la politique de la concurrence pourrait être utilisée comme outil pour modifier l'équilibre en faveur des personnes qui innovent ou contre elles. Il faut reconnaître que l'application des lois sur la concurrence dans des industries qui sont particulièrement dépendantes de la PI pourrait avoir des conséquences non voulues. A court terme, une application trop stricte peut avoir un résultat opportun pour la société, mais à long terme le remède risque d'être pire que le mal en portant préjudice à l'incitation à innover. C'est pourquoi, comme l'indique le délégué turc, les autorités de la concurrence doivent être très prudentes dans le domaine des biotechnologies.

Le Président note ensuite que la contribution des Etats-Unis fait mention d'un livre blanc publié par l'Office des brevets et marques des Etats-Unis concernant les communautés de brevets dans l'industrie biotechnologique. Il demande à la délégation américaine de décrire les principaux points du livre blanc et les caractéristiques spécifiques qu'il faudrait, le cas échéant, prendre en considération pour évaluer l'effet des communautés de brevets dans le secteur des biotechnologies sur la concurrence.

Un délégué des Etats-Unis explique que le document était motivé par la crainte qu'il y ait trop de brevets bloquants en biotechnologie. La principale recommandation qu'il contient est que des arrangements bien conçus en matière de communautés de brevets peuvent souvent offrir une solution au problème. Les auteurs font aussi référence aux lignes directrices et aux procès pour laisser entendre que de

tels arrangements pourraient être conçus de manière à être compatibles avec les lois sur la concurrence. On remarquera que le document a été rédigé sans qu'il y ait la moindre discussion, consultation ou collaboration entre les autorités de la concurrence et l'Office des brevets et des marques. On pourrait penser que ce thème aurait pu constituer une base de discussion intéressante entre autorités chargées de la réglementation du secteur et fonctionnaires de la concurrence. Le délégué rappelle que dans la contribution des Etats-Unis, il est dit qu'un tel dialogue serait très productif.

Le délégué américain ajoute que si les autorités de la concurrence veulent mener une bonne politique dans ce domaine, elles doivent accroître leur base de connaissances, c'est-à-dire qu'elles doivent comprendre la technologie et rester au courant des derniers développements, parce que la branche est très dynamique et la technologie très complexe. Ceci implique de faire une bonne recherche empirique, nécessité que les Suisses ont mentionné, et de recourir à des experts extérieurs, comme l'ont fait les Japonais. Plus précisément, les autorités de la concurrence pourraient tenir des auditions, animer des ateliers et commander des rapports et des études. Elles pourraient aussi améliorer le dialogue entre l'office des brevets et l'autorité de la concurrence dans les domaines où les préoccupations sont partagées. Enfin, selon la recommandation du délégué, il serait sage que les autorités renouvellent leur propre capital humain.

Le Président en appelle ensuite au BIAC pour qu'il fasse savoir si, à son avis, il convient de mettre davantage l'accent sur la concurrence durant le processus d'examen des brevets, si les autorités de la concurrence utilisent les bons critères pour évaluer les pratiques en matière d'octroi de licences, et si l'industrie des biotechnologies possède des caractéristiques spéciales à prendre en compte.

Un délégué du BIAC répond que le message du BIAC à l'OCDE est le suivant : la politique en matière de PI devrait avoir pour principal objectif de promouvoir l'innovation, mais cet objectif est parfaitement compatible avec l'application de la politique et du droit de la concurrence aux DPI. De l'avis du BIAC, il n'est pas souhaitable que les autorités en matière de brevets se concentrent sur les problèmes de concurrence lorsqu'elles examinent les demandes. Ces autorités devraient plutôt procéder à ces examens avec plus de rigueur pour s'assurer que les demandes répondent aux normes de brevetabilité. Cela se traduirait par de meilleures incitations à l'innovation, parce que les coûts et les inefficacités liés à la concession imprudente de brevets s'en trouveraient réduits.

Le délégué du BIAC insiste aussi pour dire qu'il ne devrait pas y avoir de responsabilité automatique au titre du droit de la concurrence en ce qui concerne les communautés de brevets. Si les membres d'une communauté utilisent à l'avance des moyens raisonnables pour éliminer les brevets non valables et non essentiels, il ne devrait pas y avoir de problème de concurrence, selon le BIAC, même s'il s'avère ultérieurement que certains brevets de la communauté sont non essentiels ou non valables. En outre, le BIAC est opposé à tout ce qui obligerait les membres d'une communauté de brevets à concéder des licences en dehors du pool, mais ils devraient être libres de le faire s'ils le souhaitent. La concession de licences obligatoires et les mesures de répression pour refus de licences ont un impact très négatif sur tous les DPI, déclare le délégué du BIAC, parce que cela crée une incertitude au sujet de la vraie valeur des droits de propriété intellectuelle.

Pour finir, le délégué du BIAC qualifie d'inadéquates les décisions judiciaires sur les licences obligatoires, aussi bien aux Etats-Unis que dans l'Union européenne, parce qu'elles ne disent pas clairement dans quelles conditions ces licences devraient être accordées.

Le Président souhaite alors la bienvenue à deux membres de l'Unité biotechnologie de la DSTI, Ms. Chris Deane et M. Kenji Takezawa, qui ont participé à un projet de rédaction de Principes directeurs concernant les meilleures pratiques en matière de licences sur les inventions génétiques. Le Président

demande à Ms Dean de présenter brièvement le projet de principes directeurs et encourage les délégués à partager les réactions que cela leur inspire.

Ms. Deane donne un bref aperçu des biotechnologies qu'elle décrit comme un moteur puissant de croissance économique. Elle rappelle que le Groupe de travail sur la biotechnologie de la DSTI a tenu un atelier d'experts sur les inventions génétiques, les DPI et les pratiques en matière de licences en 2002. L'un des thèmes clés qui ressort de cet atelier est que les pratiques en matière de licences méritent une attention particulière et qu'il faut rédiger des Principes directeurs concernant les meilleures pratiques, ce qui est devenu un projet en cours. Ms Deane note qu'un résumé des discussions du groupe d'experts et le projet actuel des Principes sont disponibles sur OLIS (DSTI/STP/BIO/M(2004)2). Il est envisagé par le Groupe d'experts que les Principes directeurs soient présentés au Conseil de l'OCDE.

Le Président laisse place ensuite au débat général. Un délégué des Etats-Unis entame la discussion en demandant au délégué du BIAC de clarifier sa critique de la législation américaine, à la lumière notamment de la récente décision *Trinko* qui a fermement établi qu'il n'y a pas de responsabilité au titre de la législation contre les ententes aux Etats-Unis pour les refus de licence unilatéraux.

Le délégué du BIAC est d'accord avec le délégué des Etats-Unis, mais mentionne une affaire portée devant un tribunal de rang inférieur, qui a été largement discréditée, mais la décision n'a pas encore été invalidée. Elle laisse donc planer une certaine incertitude dans les milieux d'affaires.

Un délégué de la Suède indique que l'autorité de la concurrence de ce pays n'a reçu aucune plainte ni informations impliquant l'industrie de la biotechnologie. Ce n'est pas parce que les participants ne connaissent pas l'existence de l'autorité, poursuit le délégué, mais probablement parce que dans cette branche les problèmes ont tendance à se résoudre à l'amiable. Cela peut s'expliquer par le rythme rapide auquel le secteur se développe et donc par le peu d'empressement à se lancer dans de longues procédures judiciaires. Le délégué se demande donc si la législation sur la concurrence ne serait pas la législation la plus appropriée pour une branche dynamique comme la biotechnologie, et si non, que devraient faire des autorités de la concurrence de petite ou moyenne dimension ? Autrement dit, quel serait le domaine de travail le plus important pour les autorités de la concurrence ?

Un délégué de l'Italie pose deux questions supplémentaires. Premièrement, il note que malgré la décision de la Cour suprême américaine dans l'affaire *Trinko,* il n'en demeure pas moins qu'aux Etats-Unis, si une société a un pouvoir de monopole ou une facilité essentielle, elle est obligée de traiter avec ses concurrents dans certaines circonstances. Bien que les brevets ne confèrent pas nécessairement des monopoles, poursuit-il, ils pourraient conduire à cela dans certains cas, et donc il n'y a pas de raisons que le détenteur d'un DPI ne soit pas obligé aussi de traiter avec des concurrents dans certaines circonstances. Il pose donc la question suivante : y a-t-il des circonstances exceptionnelles dans lesquelles un brevet entraîne un pouvoir de monopole et un refus de licence peut constituer une violation de la législation contre les ententes ?

Deuxièmement, le délégué de l'Italie demande à la délégation de la C.E. si, dans les cas de licences obligatoires, le simple fait de demander au détenteur du DPI d'accorder une licence est le bon remède. Le cédant pourrait réaliser son objectif d'exclusion en fixant simplement une redevance de licence excessivement élevée. Il demande donc si le remède comporterait aussi un élément de prix.

Un délégué de l'Espagne mentionne alors un dilemme intéressant qui se pose à l'autorité de la concurrence de son pays. Cette dernière a commencé à enquêter sur une affaire de refus de licence il y a plusieurs années, mais ensuite la cible de l'enquête a été acquise par un autre opérateur qui, à son tour, a dû vendre le brevet en question comme condition d'approbation de la fusion. Le brevet est donc passé entre les mains de trois sociétés différentes après le refus de licence initial. Cela pose un problème théorique :

faut-il sanctionner une entité qui n'avait rien à voir avec le refus de traiter ? On peut donc voir que dans le secteur de la biotechnologie, non seulement le développement de brevets est plus dynamique qu'ailleurs, mais que les sociétés le sont aussi.

Un délégué des Etats-Unis aborde ensuite la première question du délégué italien. Le délégué américain reconnaît que *Trinko* ne résout pas particulièrement la question des licences obligatoires en matière de PI. Cependant, ajoute-t-il, beaucoup d'affaires de la Cour Suprême dans lesquelles intervient la législation sur les brevets montrent clairement que le droit de retenir unilatéralement une licence est un droit essentiel de la législation américaine en matière de PI. La pertinence de l'affaire *Trinko* est qu'elle répond à la question de savoir s'il convient d'élargir le groupe étroit des cas dans lesquels un monopole a été considéré comme ayant l'obligation de traiter. De l'avis du délégué, *Trinko* fait apparaître clairement que la Cour Suprême n'utiliserait pas la législation contre les ententes pour instaurer une nouvelle obligation de traiter dans le domaine de la PI quand il y a déjà de si nombreux jugements interprétant la législation sur la PI qui vont dans le sens opposé. En revanche, les titulaires de DPI ne sont pas exempts des lois contre les ententes. Le tribunal ayant jugé le recours de Microsoft, par exemple, a estimé que l'argument était futile. Néanmoins, le délégué des Etats-Unis déclare qu'il y a quelque chose de différent au sujet de la propriété intellectuelle, contrairement au pouvoir générique d'un monopole ou à une facilité essentielle, parce que la nature même d'un brevet est le droit d'exclure les autres de son utilisation. Cela n'aurait pas de sens pour un système de brevet d'encourager des gens à inventer des choses qu'ils ne peuvent breveter, seulement pour découvrir que, d'après les lois sur la concurrence, si leurs inventions sont nécessaires pour quelque autre produit commercial, alors il leur faut renoncer au droit d'exclusivité. C'est la raison pour laquelle le message envoyé aux détenteurs de DPI est qu'ils devraient régler les problèmes qui tiennent à leur système et qui pèsent trop lourd sur la concurrence, parce que s'ils ne sont pas réglés par la législation sur la PI, il faudra faire appel aux autorités de la concurrence pour qu'elles fassent quelque chose.

Un délégué de la C.E. n'est pas d'accord avec l'idée qu'il y a quelque chose de spécial dans la PI qui la distingue d'autres types de propriété ; il est plus enclin à faire un parallèle entre la PI et les facilités essentielles. Les deux types de propriété nécessitent des incitations suffisantes pour réaliser des investissements, que ce soit en innovant ou en construisant certaines infrastructures. C'est pourquoi, selon le délégué, même avec les brevets il y a des situations dans lesquelles il peut y avoir réellement abus de pouvoir de monopole (s'il y a un pouvoir de monopole sur un marché particulier). En ce qui concerne la deuxième question du délégué italien concernant les remèdes, le délégué de la C.E. reconnaît qu'il peut y avoir des difficultés avec des cédants qui essaient d'imposer des redevances excessives, mais les organismes ne doivent pas s'empresser de devenir des autorités réglementaires et participer ainsi à quelque chose qu'ils ne peuvent pas administrer. L'objectif le plus important est de maintenir le juste équilibre entre les incitations en faveur d'une innovation originale et les incitations à poursuivre la recherche. Quoi qu'il en soit, déclare le délégué, les organismes ne peuvent pas se contenter de dire qu'ils n'interviendront jamais parce que les problèmes de prix et d'équilibrage sont difficiles. Même ainsi, les interventions devraient être rares. C'est seulement dans des circonstances exceptionnelles que les gouvernements devraient brandir l'instrument radical des licences obligatoires.

Enfin, un délégué des Etats-Unis note que l'un des enjeux fondamentaux pour le développement du droit de la concurrence est qu'il s'agit d'un système totalement anachronique, incapable de suivre les changements que subit le paysage industriel. Les mêmes questions au sujet de l'adaptabilité des lois sur la concurrence qu'on se pose maintenant étaient aussi évoquées lorsque les secteurs des transports et des communications évoluaient rapidement. Mais nous avons vu avec le temps que les concepts du droit de la concurrence que nous utilisons se sont assez bien adaptés. Il y a suffisamment de flexibilité inhérente à nos systèmes pour absorber de nouveaux apprentissages en droit et en économie. Le délégué souligne que l'enjeu réel ne concerne pas l'adaptabilité des concepts, mais plutôt les autorités et les tribunaux chargés de les appliquer. Sont-ils sont suffisamment adaptables ? Cependant, c'est essentiellement en forgeant des

liens avec d'autres institutions et en investissant dans une base de connaissances croissantes que les autorités américaines de la concurrence ont décidé d'organiser leurs auditions sur la PI. L'expérience nous apprend que, d'un point de vue institutionnel, pour travailler efficacement dans des domaines tels que la biotechnologie, les autorités de la concurrence doivent changer certaines de leurs façons d'appliquer leurs ressources. Certes, cela peut passer par des choix de répartition de ressources très difficiles, mais faire des choix difficiles est l'une des clés de l'adaptation.