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# Report to Fiscalía Nacional Económica on Settlement with G.D. Searle
# Filed by Distinguished Professor Michael A. Carrier

## Credentials

1. I am a Distinguished Professor at Rutgers Law School, New Jersey, USA, and Co-Director of the Rutgers Institute for Information Policy and Law. I am a leading authority on the intersection of competition and intellectual property ("IP") law, serving as a co-author of the leading treatise, IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW; the author of INNOVATION FOR THE 21ST CENTURY: HARNESSING THE POWER OF INTELLECTUAL PROPERTY AND ANTITRUST LAW (Oxford University Press 2009, paperback 2011); and the editor of CRITICAL CONCEPTS IN INTELLECTUAL PROPERTY LAW: COMPETITION (Edward Elgar Publishing 2011). In addition, I have written more than 85 articles and book chapters in leading journals, including many on the intersection of the IP and competition laws.
2. I have particular expertise on IP/competition issues in the pharmaceutical industry, having written more than 35 articles and book chapters addressing issues such as settlements, "product hopping," citizen petitions, and other types of conduct. I have given more than 50 talks (including in Canada, China, England, and Israel) related to patents and competition in the drug industry. In 2013, I testified to the U.S. Senate Judiciary Committee on these issues.
3. My work has been cited in numerous courts, including the U.S. Supreme Court, California Supreme Court, U.S. federal appellate and district courts, International Trade Commission, and Federal Trade Commission, as well as in congressional hearings, government officials' speeches, and congressional and government agency reports.
4. I am a member of the Board of Advisors of the American Antitrust Institute; have served as chair of the Executive Committee of the Antitrust and Economic Regulation section of the Association of American Law Schools; and have written and submitted friend-of-the-court briefs on behalf of antitrust/consumer organizations and hundreds of professors in the U.S. and California Supreme Courts and numerous federal appellate courts.
5. I have served as an expert and consultant on projects related to the intersection of the IP and competition laws, including as an advisor to the Canadian Competition Bureau on its revision of the IP Enforcement Guidelines.

**Facts of case**

6. In my expert opinion, the Fiscalía Nacional Económica ("FNE") has a strong case that G.D. Searle ("Searle") breached article 3, subsections 1 and 2(b), of Decree Law ("DL") 211 by impeding, restricting, or hindering competition, or setting out to produce such effects, in the market for drugs containing the active ingredient Celecoxib, which is used to treat inflammation and chronic pain from osteoarthritis and rheumatoid arthritis, as well as acute pain management. Complaint ¶ 4. The FNE's complaint against Searle filed in the Tribunal for the Defense of Free Competition ("TDLC") describes a vast array of conduct harming competitors, consumers, and the market as a whole. Paragraphs 7 to 13 below detail the evidence supporting a finding of abuse of a dominant position breaching article 3, subsections 1 and 2(b).

7. From January 9, 2003 through November 14, 2014, Searle was able to exploit a patent on the compound Celecoxib as a chemical formula (the "Primary Patent"). *Id.* ¶ 6. But just as the Primary Patent was about to expire, Searle obtained a second patent on a pharmaceutical composition based on Celecoxib and the process for obtaining it (the "Secondary Patent"). *Id.* ¶ 7. This patent became effective on May 5, 2014 and is scheduled to expire in 2029. *Id.* Searle's delaying tactics were at least partially responsible for a period of more than 14 years (far longer than the typical period) from the filing date of the Secondary Patent to approval. *Id.* ¶¶ 9, 12.

8. FNE also pointed to evidence of inequitable conduct, as Searle, in support of its Secondary Patent application, disclosed to the National Institute of Industrial Property ("INAPI") a European Patent but failed to disclose that that patent was later revoked. *Id.* ¶ 17. Searle also did not disclose to INAPI the "Karim Document," a scientific study it co-authored, that played a role in the patent revocations by the European Patent Office and INAPI. *Id.* ¶¶ 18-20.

9. When the Primary Patent was due to expire, competitors were expected to enter the market. In 2012, the Ministry of Health ("Minsal") issued Exempted Decree No. 981/12, which required bioequivalence of the compound Celecoxib and mentioned CELEBRA® as a reference drug. *Id.* ¶ 25. At least 4 laboratories invested in bioequivalence research and obtained the relevant registration from the sanitary authority. *Id.* ¶ 26. Searle had an incentive to delay competition given its knowledge that competitors were expected to enter the market following the expiration of the Primary Patent.

10. Although drug companies often attempt to justify product switches by pointing to innovative aspects of the reformulated version, such a justification is not persuasive in this case since the drug covered by the Secondary Patent

was "[e]xactly the same" and "[t]here were no changes" in the drug. *Id.* ¶ 29. In fact, Searle never applied for a new sanitary registration, confirming that the two patents covered the same drug. *Id.* ¶ 30.

11. Searle sent 14 warning letters to competitors requesting that they not sell, commercialize, or exploit the Celecoxib composition protected by the Secondary Patent until 2029. *Id.* ¶¶ 32-33. A Pfizer senior executive also called the general managers of laboratories that had entered the market, offering them the chance to avoid a lawsuit if they entered into a settlement. *Id.* ¶ 37.

12. Searle filed a lawsuit against a competitor, Synthon, and when its request for an injunction was denied, filed an unfair competition claim. *Id.* ¶¶ 34-35.

13. Searle's conduct resulted in two laboratories not being able to offer their products through Cruz Verde, an important pharmacy chain. *Id.*¶ 40.

14. FNE makes a strong case that the array of conduct described in paragraphs 7 through 13 above not only raises significant concerns about anticompetitive behavior but also had an effect on the market, which consists of drug products with the active ingredient Celecoxib. *Id.* ¶ 49. Drug prices tend to fall significantly when multiple generics enter the market. But in contrast to these substantial reductions, the price of drugs containing Celecoxib fell only 6% to 13% when generic competitors entered the market. *Id.* ¶ 57.

**Legal precedent**

15. My expectation is that the application of Chilean competition law in this case would be robust based on (1) the close connection to European competition law, which falls on the more-interventionist side of the case law; (2) the "unusually broad" nature of DL 211; and (3) Chilean courts' acceptance of the ambitious "essential facilities" doctrine requiring monopolists to share facilities essential to competition. Javier Tapia C., "*Tell Me What You Brag About and I'll Tell You What You Lack": The Jurisprudential Treatment of Abuses of Dominance in Chile*, pp. 11-13, 20, 23-24, 26. Because there has not yet been a competition-law case in Chile challenging pharmaceutical conduct, it is helpful to briefly consider the law of other jurisdictions.

16. In a leading case addressing the intersection of IP and competition law, the European General Court upheld the European Commission's findings that AstraZeneca abused its dominant position through (1) representations that resulted in patent offices granting Supplemental Protection Certificates

(providing an additional period of patent protection) to which AstraZeneca was not entitled, which led to a "restriction or elimination of competition"; and (2) deregistering capsule marketing authorizations to "delay and make more difficult" generic marketing. *The General Court essentially upholds the decision of the Commission which found that the AstraZeneca Group abused its dominant position by preventing the marketing of generic products replicating Losec*, Press Release No. 67/10, 1 July 2010; Case T-321/05, *AstraZeneca v. Comm'n*, July 1, 2010, ¶ 361, *available at* http://curia.europa.eu ("T-321/05"). The court explained that companies with a dominant position have a "special responsibility" and thus, in the absence of legitimate justifications, "cannot . . . use regulatory procedures in such a way as to prevent or make more difficult the entry of competitors on the market." C-457/10 P, *AstraZeneca AB v. European Commission*, ¶ 134, 6 Dec. 2012.

17. Providing another example of a court punishing conduct similar to that presented in this case, the Italian Council of State found an abuse of dominance when Pfizer engaged in conduct including "[a]busive litigation against generic suppliers" and the sending of "information to generic suppliers . . . to warn them not to enter the market prior to the patent expiry." *Roundtable on Role of Competition in the Pharmaceutical Sector and its Benefits for Consumers*, SEVENTH UNITED NATIONS CONFERENCE TO REVIEW THE UN SET ON COMPETITION POLICY, at 7, July 6-10 2015 (Statement by Italy). Pfizer's strategy "created . . . uncertainty about the possibility for competitors to enter the market," which made it "more difficult" to enter. *Id.* And even though "only lawful proceedings were used by Pfizer," abuse of dominance, "as abuse of right in a broader sense, does not require unlawful behaviours" but instead can be based on "the existence of rights that are misused, *i.e.*, rights whose exercise is formally lawful, but factually breaches the law." *Id.* at 7-8. The Council of State concluded that Pfizer's conduct revealed "a clear and persistent anti-competitive intent . . . aimed at delaying the marketing of generic drugs." *Id.* at 9.

18. In addition to these rulings, other courts consistently have recognized that competition law plays a role even for granted patents. In other words, just because conduct is allowed under patent law does not mean it is exempt from the application of competition law. In one of the most important IP/competition cases in recent years, the U.S. Supreme Court held that antitrust analysis applies to pharmaceutical settlements. It found that the existence of a patent did not immunize the agreements, as it "would be incongruous to determine antitrust legality by measuring [a] settlement's anticompetitive effects solely against patent law policy, rather than by

measuring them against procompetitive antitrust policies as well." *FTC v. Actavis*, 133 S. Ct. 2223, 2231 (2013).

19. To similar effect, the European General Court has held that "the illegality of abusive conduct . . . is unrelated to its compliance or non-compliance with other legal rules" and "in the majority of cases, abuses of dominant positions consist of behaviour which is otherwise lawful under branches of law other than competition law." C-457/10 P, *AstraZeneca AB v. European Commission*, ¶ 132, 6 Dec. 2012. And the TDLC has explained that "the exercise of an IP right could illegitimately affect competition when its exercise is abusive and the owner of the privilege has market power." Decision No. 130, Case C 239-12, *Lawsuit by Beatriz Zuberman Comercializadora E.I.R.L. against One Smart Star Number Chile S.A.* (7th Recital).

**Terms of settlement**

20. The array of cases discussed in paragraphs 15 through 19 above, together with the conduct described in paragraphs 7 through 13 above, provides the context in which to consider the terms of the proposed settlement.
21. The settlement provides important benefits to generic laboratories that are not yet on the market as well as those that are already on the market. For the first category, it allows the competitors to enter the market immediately, and to stay on the market through the duration of the Secondary Patent term. The settlement offers a type of license that is strongly procompetitive in nature, as it is (1) nonexclusive, offered to all potential rivals; (2) irrevocable, not able to be taken away by Searle; and (3) royalty-free, ensuring that all potential competitors will not face cost issues. RELEVANT CLAUSES OF FNE / G.D. SEARLE L.L.C. SETTLEMENT, *Open License Agreement*.
22. These benefits also apply to generic laboratories that are already on the market, as their access to a license for the duration of the Secondary Patent term gives them the certainty of knowing that Searle will not sue them for infringement. To similar effect, the settlement provides that Searle will withdraw its claim against Synthon, *Open License* ("Withdrawal"), and end the royalty-based agreement with Saval, *id.* ("Notice of disposition to terminate the untitled agreement that is assimilable to a license granted to Saval").
23. Additional clauses in the license confirm its procompetitive nature. For starters, competitors obtain the rights they need to fully exploit the patent, including rights to develop, commercialize, distribute, use, offer for sale, sell, and import the drug. *Open License Agreement*. In addition, the license

anticipates that competitors can sublicense the rights, ensuring the continuation of the settlement's procompetitive effects. *Id.* Finally, the license can only be terminated at the licensee's discretion, which removes the potential anticompetitive possibility of Searle terminating the license. *Open License* ("License Termination and Term").

24. It also bears mention that the settlement will not have effects on countries other than Chile as it is limited to Chile. *Id.* ("Territory of the License"). Moreover, the arbitration provisions offer an efficient mechanism for addressing disputes between the parties. *Id.* ("Arbitration").

25. In addition to the benefits offered by the license, other aspects of the settlement promise important benefits for competition. Of particular assistance is Searle's agreement to cease promotional activities in connection with "second brands" including VALDYNE® and CAPSURE®. *Id.* ("Medical Promotion"). Such a cessation will last for 2 years, which should allow new generic laboratories to obtain a foothold in the market and existing competitors to gain additional market share. *Id.* The promise also covers samples and promotional objects including gimmicks, which often encourage doctors to prescribe medications. *Id.* Finally, Searle will ensure that VALDYNE® and CAPSURE® are not included in promotional lists of products. *Id.*

26. Further increasing the effectiveness of the agreement, Searle promises to notify "the general public, drug distributors, and pharmacies" of the execution and approval of the settlement. *Id.* ("Duty of Disclosure"). The notification consists of two publications in two diverse nationally circulated newspapers, and also will be sent to 25 organizations, including generic laboratories, drug distributors, and pharmacies. *Id.* Increasing exposure to the agreement raises awareness of generic alternatives to Searle's products, making it more likely that these alternatives will be used.

27. In addition to the specific promises in relation to licensing, litigation, and marketing, Searle offers helpful general guarantees, agreeing to "refrain from incurring or participating . . . in any event, act or agreement that could impede, restrict or hinder competition" or "that tends to produce such effects" in connection with the relevant patent. *Id.* Relatedly, Searle promises that no individual in the company "is authorized to lead, request or suggest to any member of the company to take actions contrary to antitrust law." *Open License Agreement*.

28. In fact, Searle's commitment in the settlement is based not only on its compliance with the agreement's legal requirements but also on its "assurance that the preservation of a competitive economy is essential to [] Searle's welfare, to that of its clients, and to the economy in general." *Open License*

("Statement of Commitment to Respect Competition to be included in the Agreement's Recitals").

**General settlement analysis**

29. The provisions described in paragraphs 21 through 28 above make up a strong settlement that is beneficial for competition in Chile. It allows FNE to obtain most of what it could have obtained through litigation, as well as benefits it could not have received through its lawsuit.

30. Most notably, the settlement promises to significantly increase generic competition. Generic laboratories not on the market, as well as those on the market, receive a license from Searle, thereby reducing the uncertainty about facing a patent lawsuit. The license itself lasts for the duration of the Secondary Patent, and provides the necessary rights, as well as the right to sublicense. And it provides nonexclusive, royalty-free terms, which are unambiguously procompetitive because they allow all competitors to enter the market and do not impose any limitations, cost or otherwise.

31. Searle's 2-year restriction on marketing and promotion of its secondary brands also is valuable. Marketing and promotion have a powerful effect in the pharmaceutical industry, with many doctors deciding which medications to prescribe because of the activity. Even if FNE won its lawsuit, Searle would still be able to engage in marketing and promotion of its secondary brands, which would make it more difficult for generic laboratories to gain a foothold in the market. In contrast, this provision, which gives even stronger protection than FNE could have obtained through its lawsuit, promises significant benefits for consumers.

32. The provision by which Searle must communicate the settlement to 25 organizations, including generic laboratories, drug distributors, and pharmacies, ensures that it will be widely known and provides another benefit that might not have been available as a result of a successful lawsuit. And the inclusion in newspapers makes it more likely that the public will be aware of the settlement and (together with the notices to the other stakeholders) be more likely to purchase lower-priced drugs containing Celecoxib.

33. In addition to these benefits, the settlement increases generic competition since Searle has agreed to discontinue its existing action against Synthon and drop its demands for royalties from Saval.

34. Although I believe there is a strong likelihood that FNE would have been successful in its case against Searle under article 3, subsections 1 and 2(b), this

is not a 100% likelihood of success. Searle filed a 61-page opposition to the complaint, vigorously contesting FNE's claims. It is possible that FNE might not have emerged victorious in its challenge.

35. For FNE, there are multiple important benefits to the settlement: (1) addressing the conduct described above in paragraphs 7 through 13; (2) unleashing immediate competition through a nonexclusive, royalty-free license for generic laboratories that have not yet entered the market; (3) removing the uncertainty facing generic laboratories already on the market; (4) obtaining concessions on secondary brands beneficial to both groups of laboratories; (5) obtaining notifications and promises to comply with competition laws; and (6) putting other drug companies on notice that behavior similar to Searle's could lead to a case for breaching article 3, subsections 1 and 2(b), of DL 211.

36. Even though FNE would not be able to obtain a finding of a competition-law violation or a payment of fees, that appears to be a worthwhile sacrifice given the certainty of achieving all of the significant benefits outlined in paragraph 35 above.

37. Searle also would benefit from the settlement by avoiding the conclusion that it engaged in anticompetitive acts and eliminating the possibility of being required to pay fees. RELEVANT CLAUSES OF FNE / G.D. SEARLE L.L.C. SETTLEMENT, *Statement setting forth that the Settlement does not signify an acknowledgement of liability*.

**Conclusion**

38. In my expert opinion, FNE has a significant chance of success in its claim. But Searle also has a chance of success. Like all effective settlements, this agreement offers something for both sides: FNE obtains most of what it was seeking through the lawsuit, and Searle avoids a finding of anticompetitive acts as well as a payment of fees.

39. Just as important, the settlement provides significant benefits for competition and consumers in Chile. For the many senior citizens who need to take drugs containing Celecoxib every day, the settlement promises to reduce price and increase usage.

40. In short, the settlement presents a thoughtful, comprehensive resolution of an important case at the intersection of IP and competition law. It puts future companies on notice that FNE will be carefully scrutinizing behavior (including that which may be lawful under patent law) similar to that presented in the case. And it increases generic competition in an important market, allowing consumers to benefit from affordable medications offered by a range of generic laboratories. Thank you for your consideration of this report.

Sincerely yours,

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