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- Contribution from Chile -

7-8 October 2025

This attached document from Chile is circulated to the Latin American and Caribbean Competition Forum (LACCF) FOR DISCUSSION under Session II at its forthcoming meeting to be held on 7-8 October 2025 in Asunción, Paraguay

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Session II: Competition and Intellectual Property

- Contribution from Chile –

Executive Summary

The interaction between intellectual property (IP) and competition law has gained increasing relevance in Chile, particularly in light of the expanding role of intangible assets and the growing complexity of digital and innovation-driven markets. Chile's National Competition Authority (Fiscalía Nacional Económica, FNE), the Competition Tribunal (Tribunal de Defensa de la Libre Competencia, TDLC) and the Chilean competition system as a whole have become increasingly active in IP-related matters, which has allowed them to accumulate valuable experience in this arena. Issues related to the interface between IP rights and competition have been addressed through enforcement, merger control, advocacy, and inter-agency cooperation.

Chilean competition law, governed by Decree Law No. 211 of 1973, fully applies to markets involving IP. No exemptions or special rules are in place, and the open-textured nature of the law allows authorities to address a wide range of anticompetitive conduct related to IP rights. The FNE and the Competition Tribunal have dealt with relevant cases involving abuse of dominant position and unfair competition related to patents and trademarks. Notable examples include proceedings against G.D. Searle LLC (Pfizer), involving evergreening practices with secondary patents, and the CCU case, where trademark registrations were allegedly used to block market entry and parallel imports.

In merger control, IP rights have been central in assessing potential harm and designing remedies. In the *Abbott/CFR* merger, concerns about market dominance and entry barriers in the valproic acid market led to the imposition of structural remedies involving the divestiture and licensing of IP assets. Similarly, the *Bayer/Monsanto* merger involved global divestitures of IP portfolios in herbicides and seeds to address horizontal overlaps.

The FNE has also engaged in competition advocacy on IP-related issues. Its 2016 *Study on the Supplementary Protection System for Patents* raised concerns about the risk of excessive extensions of exclusivity through formalistic granting procedures. Its 2020 *Market Study* on *Pharmaceuticals* identified systemic problems, such as lack of transparency, delayed patent grants, and misuse of secondary patents to block generics.

Finally, the FNE and INAPI (Chile's IP agency) have maintained a long-standing cooperation agreement since 2011, enabling joint initiatives in information exchange, research, training, and public outreach. This collaboration has supported a coherent institutional approach to the interaction between competition and intellectual property law.

1. Introduction

1. In recent decades, intellectual property (IP) rights have acquired a significant and increasingly expansive role in economic activity and market competition. The importance of intangible assets and digital markets has grown, and the interaction between competition and IP law has accordingly become more prominent.

2. Over this period, the Chilean competition authority (Fiscalía Nacional Económica, or FNE) and the Chilean competition system as a whole have become increasingly active in IP-related matters, which has allowed them to accumulate valuable experience in this arena.

3. This contribution provides an overview of the main policy principles and approaches to competition law enforcement, advocacy, and intellectual property (IP) protection currently followed in Chile. Section II offers a brief description of the relevant institutional framework, while Section III presents the general principles governing the interaction between both domains. Sections IV and V analyse the main competition cases related to IP issues, in the areas of anticompetitive conduct and merger control, respectively. Finally, Section VI addresses efforts in competition advocacy and institutional collaboration related to intellectual property protection.

2. Competition & IP: Institutional Framework

4. Chile's institutional framework for competition law enforcement is characterized by a bifurcated model, with a clear separation between the investigative and prosecutorial body —the FNE— and the adjudicative or judicial body —the Tribunal de Defensa de la Libre Competencia (TDLC)—. The Supreme Court of Justice also plays a role in this design, acting as the body that reviews TDLC decisions. This division of functions seeks to ensure impartiality, efficiency, and specialization in the enforcement of antitrust rules.

5. The FNE is the Chilean agency responsible for the enforcement and advocacy of competition in all markets and productive sectors of the Chilean economy. It is an arm's length body —a decentralized public agency, with legal personality and its own assets, independent from any other body or service—, subject to governmental oversight through the Ministry of Economy, Development, and Tourism.

6. To fulfil its mandate, the FNE investigates any act, conduct, or agreement that prevents, restricts, or hinders free competition, or tends to produce such effects. Its investigative priorities include cartels and collusive practices, abuse of dominant position, and mergers that may substantially lessen competition.

7. In turn, the TDLC is a special and independent judicial body subject to the directive, disciplinary, and financial oversight of the Supreme Court. Its function is to prevent, correct, and sanction infringements of free competition in the country. The Supreme Court serves as the final judicial review instance for TDLC decisions, hearing and ruling on appeals against the judgments and resolutions issued by the Tribunal.

8. Both the organizational structure and powers of the FNE and TDLC, as well as the substantive rules of Chilean competition law, are established under Decree Law No. 211 of 1973 ("DL 211" or the "Competition Act"). The foundational elements of Chile's current institutional framework for competition law were established in 2003, followed by significant legislative reforms enacted in 2009 and 2016.

9. In the field of IP, the institutional design encompasses the National Institute of Industrial Property (INAPI), the Industrial Property Court (TDPI), and the Supreme Court of Justice.

10. INAPI is a decentralized public agency with a technical mandate, subject to governmental oversight by the Ministry of Economy, Development, and Tourism. It was created by Law No. 20.254 and began operations in 2009. Its main functions include administering the industrial property system in Chile and granting rights over trademarks, patents, utility models, industrial designs and drawings, layout designs of integrated circuits, geographical indications, and designations of origin.

11. The TDPI, in turn, is a collegiate judicial body that hears appeals in second instance concerning substantive decisions issued by INAPI in trademark and patent matters.

12. Lastly, the Supreme Court plays a role at a later stage, as part of the judicial review system for TDPI decisions, hearing and deciding on cassation appeals—both on procedural and substantive grounds—against its rulings.

3. Policy principles and approaches to competition and IP

13. There are no specific exceptions in Chile regarding the application of competition law within the realm of IP protection. The behavioural rules of Chilean competition law apply in full to markets related to IP.

14. Indeed, the open-textured nature of the behavioural provisions of the Chilean Competition Act—which, in the first paragraph of Article 3, sets out a general clause on anticompetitive conduct, followed by specific examples included in the second paragraph[1]—enables the prosecution of a wide range of anticompetitive behaviours across all types of markets, including, to be sure, those involving the intensive use of IP rights.

15. Given the inherently dynamic nature of the markets in which IP rights are most relevant, there have frequently arisen practices that, while not expressly listed among the examples set out in subparagraphs (a)-(d), paragraph two, of Article 3, Competition Act, are clearly encompassed by the general clause in Article 3, paragraph one—for instance, the creation of artificial barriers to entry through the instrumental use of procedural rights in trademark law (see below).

16. From a reconstructive perspective of current practice, the interaction between competition and intellectual property can be understood through the idea of *complementarity*. While intellectual property is grounded in the idea that innovation is not possible without incentives to capture exclusive rents, competition law assumes that incentives to innovate do not exist without competitive pressure. Thus, although the substantive analysis of intellectual property matters falls under the purview of INAPI, the Industrial Property Court (TDPI), and the Supreme Court, this does not mean that behaviours involving the abusive exercise of IP rights fall outside the scope of application of the Competition Act.

[1] Article 3 Competition Act, paragraph 1: *"Article 3°.- Whosoever should execute or enter into, individually or collectively, any deed, act or agreement that impedes, restricts or thwarts competition, or tends to produce such effects, will be sanctioned with the measures established in article 26 of this law, notwithstanding the application of the preventive, corrective or restrictive measures ordered with respect to such deeds, acts or agreements in each particular case […]".*

17. This complementarity also manifests at the substantive level. On the one hand, IP protection promotes innovation by safeguarding new products and/or technological improvements; on the other hand, competition law ensures that these incentives do not translate into abuses by economic agents holding IP rights.

4. Anti-competitive behaviour involving IP-related business practices

18. At the national level, the FNE and the country's courts have had the opportunity to address some of the most significant points of interaction between competition law and the exercise of intellectual property rights in a broad sense. These issues have arisen primarily in the context of investigations and proceedings concerning abuse of dominant position (Article 3, second paragraph, letter b of Decree-Law No. 211) and acts of unfair competition (Article 3, second paragraph, letter c of the same statute). The most relevant cases can be grouped into two main categories: (i) cases involving competition and patents, and (ii) cases involving competition and trademarks.

4.1. Competition and Patents

19. A landmark case reviewed by the Chilean Competition Tribunal in this area arose from a lawsuit filed by the FNE against G.D. Searle LLC, a subsidiary of Pfizer[2]. Following an extensive investigation, the FNE accused the defendant of engaging in evergreening practices by making instrumental use of a secondary patent with the aim of restricting and hindering the entry of competitors into the market for medicines containing the active ingredient Celecoxib (primarily indicated for the treatment of inflammation and chronic pain associated with osteoarthritis and rheumatoid arthritis).

20. According to the FNE, the purpose of this conduct was to disproportionately extend the period of exclusivity for the commercialization of the drug, thereby preventing the entry of competitors offering bioequivalent products already authorized by the health authority. This strategy also included the sending of a series of warning letters to competitors, claiming that the commercialization of the product was prohibited due to the existence of the secondary patent, as well as the initiation of legal actions with the same objective.

21. The case ultimately concluded with a settlement agreement with the FNE, under which G.D. Searle committed to granting a free, non-exclusive, and irrevocable license for its secondary patent on Celecoxib to any current or potential competitor operating in Chile. In addition to other commitments, the company also undertook not to obstruct or take legal action against competitors in relation to this patent, and to withdraw the lawsuits it had initiated against one of its rivals.

22. Another relevant case involving patents was decided by the TDLC in 2013, on a claim brought by Actigen Nova S.A. against Bioagro S.A [3] In that case, the TDLC emphasized that it is the patent itself that grants the exclusive right to exploit the invention for a defined period, and thus non-compete clauses would be unnecessary to safeguard such exploitation. Accordingly, and considering the broad scope of the clauses at issue in the case—which lacked geographical, temporal, or personal limitations—the Tribunal held that these provisions could potentially affect product markets beyond those analysed in the judgment. In other words, through the non-compete clause, the defendant company may

[2] TDLC. Case No. C-310-16: *"Requerimiento de la FNE contra G.D. Searle LLC".*

[3] TDLC. Ruling No. 127/2013, Case No. C-238-16: *"Demanda de Actigen Nova S.A. contra Bioagro S.A."*

have been attempting to extend the market power conferred by the patent into other markets where it held no such protection.

23. In addition, the TDLC has reviewed a number of claims involving acts of unfair competition related to the exercise of patent rights. Notably, the Tribunal addressed these issues in the following cases:

- *Recalcine v Novartis*.[4] The TDLC dismissed a complaint filed by Laboratorios Recalcine S.A. against Novartis Chile S.A., finding that the actions taken by Novartis to prevent Recalcine from obtaining sanitary registrations for a drug similar to one previously patented by Novartis were based on a reasonable doubt concerning the composition of the product. This decision was upheld by the Supreme Court.
- *Tecnofarma v Sanofi*.[5] The TDLC dismissed a claim by Tecnofarma S.A. against Sanofi, finding that a series of warning letters aimed at preventing the commercialization of a similar product did not ultimately prevent Tecnofarma's market entry.
- *Isracom v OSS*.[6] The TDLC upheld a claim by Isracom against OSS for unfair competition, holding that discrediting campaigns and legal actions based on the alleged abusive use of a patent on an abbreviated dialling system were not covered by the defendant's industrial property rights). This case upheld by the Supreme Court (although it reduced the fine imposed by the TDLC).
- *Laboratorios Chile and Sanofi-Aventis' Settlement*.[7] Settlement agreement between Laboratorios Chile and Sanofi-Aventis (which concluded a claim in which Laboratorios Chile had alleged that the defendant carried out discrediting actions aimed at preventing the entry of generic drugs competing with Eloxatin, a drug whose patent protection had already expired).

24. Another, more recent case adjudicated by the TDLC concerning unfair competition in the context of patents is *Morales v. Trefimet*.[8] In this case, the claimant alleged that Trefimet had abused its dominant position as a manufacturer and producer of "thermal lances" (tools primarily used in the mining industry for melting ferrous and non-ferrous materials), by sending letters urging its clients not to purchase the claimant's product on the grounds that it allegedly infringed Trefimet's patents.

25. The TDLC ruled in favour of the claimant, finding that the communications sent by Trefimet (which held a dominant position) had the primary aim of diverting the claimant's customer base through false and inaccurate assertions; the Tribunal held that such conduct did not constitute a proportionate means of enforcing the legal rights afforded by its patents. However, the Supreme Court, in judgment No. 26525-2018, overturned the

[4] TDLC. Ruling No. 46/2006. Case No. C-078-05: *"Demanda de Recalcine S.A. contra Novartis Chile S.A."*

[5] TDLC. Ruling No. 52/2007. Case No. C-115-06: *"Demanda de Tecnofarma S.A. contra Sanofi Aventis".*

[6] TDLC. Ruling No. 130/2013. Case C-239-12: "Demanda de Beatriz Zuberman Comercializadora E.I.R.L. contra One Smart Star Number Chile S.A."

[7] Settlement between Laboratorios Chile and Sanofi-Aventis (7 June 2011). TDLC. Case No C-215-2010: *"Demanda de Laboratorio Chile S.A. contra Sanofi-Aventis de Chile S.A. y otros".*

[8] TDLC. Ruling No. 164/2018. Case C-333-2017. *"Demanda de Óscar Morales L. contra Trefimet S.A."*

TDLC's decision, holding that the contents of Trefimet's letters were related to a plausible allegation of patent infringement and, therefore, it was not within the TDLC's jurisdiction to assess the veracity of such claims.

4.2. Competition and Trademarks

26. Another area of interaction between intellectual property and competition law lies in the registration and use of trademarks. In particular, at the national level, cases have arisen involving the use of trademark registrations as barriers to entry for the legitimate owner of a distinctive sign or name, as well as in relation to third parties seeking to import original goods lawfully acquired abroad—a practice commonly referred to as 'parallel imports'.

27. *Trademark registrations used as barriers to entry for the legitimate owner*. A good example of this type of conduct is FNE's complaint against CCU (*FNE v CCU)*.[9] In that case, the National Economic Prosecutor's Office alleged that the company had maintained unused trademark registrations corresponding to products of current or potential foreign competitors. The FNE further claimed that CCU held trademark registrations covering generic beer varieties used to distinguish different types of beer for consumers, as well as registrations covering Chilean geographical indications that served to differentiate the product's place of origin.

28. In addition, CCU had initiated a number of administrative and judicial proceedings and sent warning letters to potential competitors with the purpose of preventing the advertising and/or active commercialization of products—particularly by foreign competitors. In its complaint, the FNE argued that all these actions were undertaken with the aim of hindering the expansion or entry of current or potential competitors of the CCU group.

29. The case was resolved through a settlement agreement with the FNE, approved by the Competition Tribunal in May 2014.[10] Under the agreement, CCU undertook not to oppose the use by third parties of its registered trademarks that served to inform consumers about the geographic origin of beer. Among other commitments, the company also agreed to cancel trademarks corresponding to generic beer varieties and to request the cancellation of trademarks associated with competitor brands (Antártica, Andes, and Victoria) if those products were not commercialized in the domestic market within a five-year period.

30. *FNE v CCU* was a significant factor in prompting the modernization of industrial property legislation in the area of trademarks. In line with international trends, the Ministry of Economy, Development, and Tourism promoted a legislative reform that culminated in the enactment of Law No. 21.355, which amended Law No. 19.039 on Industrial Property and Law No. 20.254, which created the INAPI. The new law entered into force in May 2022.[11]

31. Essentially, the reform aimed to strengthen the alignment between the protection of industrial property rights and the promotion of competition by introducing a *use requirement* for maintaining the validity of a trademark. This requirement helps prevent

[9] TDLC. Case No. C-263-13: *"Requerimiento de la FNE contra Compañía Cervecerías Unidas S.A. y otra".*

[10] Settlement between the FNE and CCU (28 May 2014). TDLC. Case No. C-263-13: *"Requerimiento de la FNE contra Compañía Cervecerías Unidas S.A. y otra".*

[11] Law No. 21.355 (published 5 June 2022). Available at: https://www.bcn.cl/leychile/navegar?idNorma=1162253 [last accessed: July 2025].

the proliferation of exclusive rights over signs that do not actually perform the essential function of a trademark—namely, to distinguish products and services in the market as a result of their use. At the same time, the reform discourages the proliferation of so-called "defensive" or "paper" trademarks, which served exclusively as entry barriers for competitors seeking to offer goods or services under those signs, despite not being effectively used in the market.

32. *Parallel imports*. The FNE has also emphasised the relevance of antitrust scrutiny in the exercise of industrial property rights in Chile in the context of parallel imports. Specifically, the agency recently closed an investigation against Hewlett Packard Inc. Chile Comercial Ltda. (HP Chile) concerning the imposition of vertical restraints affecting wholesale and retail clients in the printing supplies market. The investigation had been initiated due to concerns about HP Chile's "Qualified Distribution Program," which the company ultimately agreed to terminate.[12]

33. HP's program consisted of a selective distribution system for printer supplies and consumables bearing the HP brand. It imposed restrictions that, among other effects, significantly reduced the number of actors allowed to commercialize HP products in Chile, limiting consumer choice and creating risks to competition.

34. The FNE considered HP Chile's commitment to end the Qualified Distribution Program—whose restrictive provisions had triggered the investigation—as an appropriate measure to mitigate the identified risks and promote competition in the distribution of these products. The measure directly benefits consumers and establishes clearer limits on the use of vertical restrictions in distribution policies. Furthermore, the commitment explicitly preserved the legality of parallel imports of products lawfully acquired abroad, in accordance with Article 19 bis (e) of DFL No. 4 of 2022, issued by the Ministry of Economy, Development, and Tourism, which consolidated, coordinated, and systematized the text of Law No. 19.039 on Industrial Property.

35. *Unfair competition*. Finally, the TDLC has reviewed a number of unfair competition cases related to the registration and/or use of trademarks. Notably, the Tribunal addressed these issues in the following cases:

- *El Golfo v Capuy*.[13] The TDLC upheld a claim by El Golfo S.A. against Capuy S.A. for unfair competition consisting in obstructing the use of the generic name of the food product "Kamikama" through a trademark registration.
- *Sociedad Hemisferio Izquierdo v Soler*.[14] The TDLC partially upheld a complaint filed by Sociedad Hemisferio Izquierdo Ltda. against José Soler, finding that actions taken to prevent the use of the term "Executive Search" —generically associated with personnel recruitment services—constituted an attempt to exclude competitors from the market; and

[12] FNE. Investigation No. 2577-19 FNE: *"Investigación en la distribución de insumos marca HP".* Final decisión (11 March 2025).

[13] TDLC. Ruling No. 30/2005. Case No. C-058-04: *"Demanda de El Golfo Comercial S.A., en contra de Capuy S.A."*

[14] TDLC. Ruling No. 50/2007. Case No. C-093-06: *"Demanda de Hemisferio Izquierdo Consultores contra don José Soler Lertora".*

- *Rivas v American British School*.[15] The TDLC partially upheld a complaint by María Luz Rivas against Sociedad Educacional American British School. The Tribunal held that the trademark registration of the school's name and insignia did not justify the imposition of bidding conditions for the manufacture of school uniforms that aimed to exclude bidders other than the school's affiliated company. This decision was upheld by the Supreme Court.

5. IP-related issues in merger control

5.1. Competition concerns related to IP rights in recent merger cases

36. *Abbot/CFR*.[16] In the context of the *Abbott/CFR* merger, the FNE identified several factors indicating that the entity resulting from the transaction would have the ability to unilaterally and significantly increase the prices of products containing valproic acid as their active ingredient. These factors included: (i) the acquisition by Abbott of a dominant position in the Chilean market for valproic acid following the transaction; (ii) the acquisition by Abbott of its closest competitor in the national market for valproic acid; and (iii) the existence of significant barriers to entry in the valproic acid market, particularly related to the time required to carry out product development studies, obtain regulatory approvals from the health authority, and build brand recognition and market presence in Chile.

37. *Bayer/Monsanto*.[17] Subsequently, in the context of Bayer Aktiengesellschaft's (Bayer AG) acquisition of Monsanto Company (Monsanto), the FNE approved the transaction subject to the implementation of specific mitigation measures offered by the parties, some of which had a global scope and others that were tailored to the Chilean market.

38. In Chile, the parties' activities overlapped in the seeds and agrochemicals sector, particularly in the markets for vegetable seeds and non-selective herbicides, where Monsanto had an indirect presence by distributing its products through a third party. This overlap raised potential horizontal risks stemming from the creation of an entity with a dominant position in those markets.

[15] TDLC. Ruling No. 62/2008. Case No. C-122-06: *"Demanda de María Rivas Morel contra American British School"*.

[16] Settlement between the FNE and Abbot Laboratorios de Chile, CFR Pharmaceuticals *et al.* Approved by the TDLC in Case No. AE-09-2014: *"Acuerdo Extrajudicial N°9/2014: Acuerdo Extrajudicial entre la FNE, Abbott Laboratorios de Chile Ltda, Abbott laboratories , Holdco SpA. y CFR Pharmaceuticals S.A."* (The current merger control procedure in Chile, under the responsibility of the FNE, was established in 2016. Prior to that, in the absence of a mandatory pre-merger control system, the FNE would typically investigate proposed mergers by exercising its general investigative powers. In that context, it was not uncommon for mergers that could otherwise substantially lessen competition to be approved through out-of-court agreements between the FNE with the parties, which could include structural remedies, as occurred in this case.

[17] FNE. *"Notificación de la Operación de Concentración entre Bayer AG y Monsanto Company"*. 25 May 2018. Case FNE No. F97-2017.

5.2. Remedies

39. Remedies related to IP rights can be imposed and have indeed been imposed in Chile, including remedies that involve the sale or licensing of IP rights. Two cases are pertinent to mention in this regard.

40. Firstly, in *Abbott/CFR*,[18] Abbott and CFR agreed to divest brands, formulas, process technologies, rights, contracts, and all other assets necessary for the successful participation of a viable, effective, and independent competitor in the business of manufacturing, marketing, promoting, and distributing valproic acid-based products in Chile.

41. Specifically, the divestiture included, among others: (i) the transfer—at Abbott's discretion—of all products currently marketed by either Abbott or CFR whose active ingredient, according to the records of the Public Health Institute (ISP), is valproic acid in any of its formulations, including the associated brands, IP licenses, dossiers, marketing authorizations, and any other elements needed for their successful commercialization in Chile (the "Divested Business"); (ii) the granting of a non-exclusive license for Chile over the trade secrets and know-how necessary to develop and manufacture the divested products in the national territory; (iii) the transfer or licensing to the acquirer of the Divested Business of all assets, rights, contracts, and agreements required to operate viably and competitively in Chile; and (iv) the conclusion of service and supply agreements with the acquirer of the Divested Business for the provision of inputs and products necessary to ensure viable and competitive operations in Chile.

42. Secondly, in *Bayer/Monsanto*,[19] the notifying parties offered to divest Bayer AG's global businesses in herbicides—specifically Glufosinate Ammonium (including its herbicide Basta®)—as well as its Annual Seeds, Traits, and Vegetable Seeds businesses, including watermelon, melon, onion, pepper, lettuce, and cucumber seeds.

43. In the first case, this entailed the transfer to a third party, BASF SE, of all exclusive intellectual property owned by Bayer that was used in the global Glufosinate Ammonium business to be divested, as well as any IP shared under licensing agreements. In the second affected market, the divestiture involved the transfer of the entire Bayer Vegetable Seeds (BVS) intellectual property portfolio, including germplasm, traits, markers, cell biology information, patent rights, trademarks, licensing agreements, plant variety protection rights, and relevant know-how.

[18] Above, note 15.

[19] Above, note 16.

6. Competition advocacy and institutional co-operation

6.1. Competition advocacy related to IP rights

44. The FNE has undertaken specific advocacy efforts in the area where competition law intersects with intellectual property. Two examples are particularly noteworthy.

45. Firstly, through its *Study on the Supplementary Protection System for Patents in Chile and Its Effects on Competition* (2016).[20] This study examined the competition-related effects arising from the introduction of the supplementary protection system for invention patents, established by Law No. 20.160 to bring domestic legislation into line with the free trade agreements and association agreements signed by Chile with the United States and the European Union. In the pharmaceutical sector in particular, the study highlighted that conducting a purely formal review when assessing applications for supplementary protection of an already granted patent—without regard to timing, procedural factors, or substantive considerations—has the potential to unduly extend the effective protection period, thereby hindering or preventing market entry by competitors.

46. Secondly, through its *Market Study on Pharmaceuticals (EM03-2018)*,[21] the FNE conducted a thorough and comprehensive review of the pharmaceutical industry, covering the entire chain from production to the sale of medicines, and including all relevant stakeholders and regulators. In the course of this work, it was found that competition in this market was primarily taking place through marketing rather than price, a dynamic that was facilitated, among other factors, by certain regulatory issues related to the intersection between competition and IP. The findings related to patents can be summarised as follows:

- *Lack of transparency:* There is no public information linking patents to sanitary registrations, which hinders competitor entry.
- *Delays in granting patents:* The average time to grant a patent is eight years, which delays the entry of medicines into the market.
- *Limited entry after patent expiry:* In many cases, active ingredients with expired patents still have no registered competitors, which is related, in part, to the lack of public information about the set of active patents (and their expiration dates) associated with a given active ingredient.
- *Use of secondary patents as an instrument to block competitors:* The existence of multiple secondary patents may hinder the entry of generics.
- *Problems with data exclusivity:* The limitations imposed on data exclusivity are not always observed, affecting the protection of test data.

47. To address these problems and other issues identified, the FNE proposed a comprehensive package of regulatory reforms, consisting of fifteen measures aimed at improving competition in this industry. These measures included, among others: (i) introducing improvements to the process for registering and certifying the bioequivalence

[20] FNE. *Study on the Supplementary Protection System for Patents in Chile and Its Effects on Competition* (2016). Available at: https://www.fne.gob.cl/wp-content/uploads/2016/02/FNE-Proteccion-suplementaria.pdf [last accessed: July 2025]. This study was carried out before the FNE had explicit powers to conduct market studies and request information from private parties for that purpose—powers that were incorporated into the Competition Act in 2016.

[21] FNE. *Market Study on Pharmaceuticals (EM03-2018)*. Final report published in January 2020. Available at: https://www.fne.gob.cl/fne-publica-informe-final-de-estudio-de-mercado-sobre-medicamentos/ [last accessed: July 2025].

of medicines; (ii) establishing a faster mechanism for registering medicines that are already sold in other countries and have certified bioequivalence; (iii) introducing a requirement to inform the health authority about patents in force that are associated with a given active ingredient (and including such information in a public registry); (iv) establishing a reward for the first generic medicine to enter the market; (v) increasing the number of interchangeable medicines; and (vi) improving information dissemination policies.[22]

6.2. Cooperation with the IP Agency

48. The National Institute of Industrial Property (INAPI) and the FNE have maintained a close institutional partnership for over a decade. In 2011, the two agencies entered into an inter-agency cooperation agreement that has enabled them to collaborate on matters relating to industrial property and competition laws.

49. This agreement established a mutual commitment to exchange information—subject to applicable legal provisions on confidentiality and data protection—in order to identify matters of relevance to the investigations or actions carried out by either institution. It also contemplated joint training initiatives and advocacy activities aimed at promoting more effective use of both legal systems.

50. The agreement established expedited communication channels between the agencies, which facilitated, in the short term, the development of joint research documents examining the relationship between intellectual property and competition law, particularly in connection with entrepreneurship, innovation, and economic growth in Chile. A notable example is the 2016 study on the supplementary protection system for patents and its effects on competition, in which INAPI contributed by providing relevant data on pharmaceutical patents included in the FNE's analysis.

51. Moreover, the agreement has made it possible to organize joint training sessions for third parties and other outreach activities aimed at promoting the principles and rules of industrial property and competition law, as well as raising awareness among consumers and users regarding the respective roles of INAPI and the FNE.

[22] Some of the proposals made by the FNE were incorporated at different stages of the legislative debate of a bill aimed at introducing various regulatory changes in this industry (Boletín Nº 9914-11, known as *"Ley de Fármacos II"*). Yet, the legislative discussion of this bill has extended over several years and has faced some difficulties, with many of the proposed regulatory changes still awaiting approval by Congress.