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- Contribution from Brazil -

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Session II: Competition and Intellectual Property

– Contribution from Brazil –

Legal Framework, Enforcement, and Advocacy[1]

1. Introduction

1. The relationship between intellectual property rights and competition policy has long been the subject of legal, economic, and institutional debate. On the one hand, intellectual property (IP) rights confer exclusivity to foster innovation and creativity by ensuring that inventors, artists, and businesses can appropriate the returns from their investments. On the other hand, these exclusive rights — if exercised abusively or without adequate limits — can harm competition, restrict access to essential goods, and diminish social welfare.

2. This tension is particularly pronounced in developing economies, such as Brazil, whose competition authorities and policymakers must balance the need to promote innovation and attract investments with the imperative of ensuring access to affordable goods and services, fostering competitive markets, and preventing undue market power. The Brazilian legal system, through its Constitution, competition law, and intellectual property statutes, expressly recognizes both the value of protecting creativity and the necessity of curbing abuses that undermine competition.

3. This paper examines how Brazil's Administrative Council for Economic Defense (CADE) has approached the intersection of intellectual property and competition law. It analyzes CADE's decisions and advocacy efforts in key areas, including merger control, the assessment of anticompetitive conducts, and competition advocacy, with a focus on cases involving trademarks, patents, industrial designs, copyrights, and data exclusivity.

4. Through an in-depth review of CADE's jurisprudence and advocacy positions, the article illustrates how competition enforcement and advocacy can complement intellectual property protection by preventing its overextension, safeguarding consumer welfare, and promoting dynamic and inclusive markets.

2. Conceptual Framework

5. In Brazil, the legal foundation for intellectual property (IP) protection lies primarily in the Industrial Property Law (Law 9279/1996), which covers trademarks, patents, industrial designs, and geographical indications, and in the Copyright Law (Law 9610/1998), which regulates the protection of intellectual works in the literary, artistic, and scientific domains.
Additionally, Decree 75541/1975 promulgated the Convention Establishing the World Intellectual Property Organization (WIPO), signed in Stockholm on July 14, 1967.

[1] This paper was written by Ricardo Medeiros Castro, Head of the Advisory Unit of the Office of the President of CADE, and proofread and edited in English by Izabel Cristina Medina Brum and Nathália Oliveira Silva, in-house translators at the International Unit of CADE.

According to this statutes, intellectual property encompasses rights relating to literary, artistic, and scientific works; artistic performances and executions; phonograms and broadcasts; inventions in all fields of human endeavour; scientific discoveries; industrial designs and models; industrial, commercial, and service marks; trade names and business designations; protection against unfair competition; and all other rights resulting from intellectual activity in all the aforementioned fields.

6. Denis Barbosa (2003) [2] and Bettina Augusta Amorim Bulzico (2007) [3] observe that this branch of law is highly internationalized. Indeed, one of the most influential international instruments on intellectual property is the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), an international treaty concluded under the World Trade Organization (WTO), in 1994, as part of the outcome of the Uruguay Round of the GATT. TRIPS sets minimum standards of protection for various types of intellectual property that the WTO member states are obliged to implement in their domestic legislation. In addition to harmonizing substantive rules, the Agreement provides mechanisms for enforcement and for resolving disputes between states in cases of violation.

7. However, unlike other forms of property, Luís Otávio Pimentel (2005) [4] points out that "among the common or core elements of all intellectual property are the incorporeal nature of its object and the limited duration of its protection." From another perspective, Carol Proner (2007) [5] emphasizes that the concept of 'intellectual property' should be understood as a category that reflects the economic and political stimuli of each historical period. [6]

8. On this economic dimension, Afonso Paula Pinheiro Rocha (2008)[7] analyses intellectual property by highlighting the unique characteristics of intellectual goods and the challenges of their legal protection. As he explains, intellectual goods: (i) are non-rival — consumption by one individual does not diminish the possibility of consumption by others — and (ii) are often non-excludable, since once a creation is disclosed, it is difficult to prevent third parties from using it without legal protection mechanisms.

9. These features align intellectual goods with so-called public goods, which are enjoyed collectively without depletion or immediate exclusion, such as the light from a lighthouse or the national defence.

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[2] BARBOSA, Denis Borges. *Uma Introdução à Propriedade Intelectual*. 2. ed. Rio de Janeiro: Lumen Juris, 2003. v. 1, p. 5.

[3] BULZICO, Bettina Augusta Amorim. *Evolução da Regulamentação Internacional da Propriedade Intelectual e os Novos Rumos Para Harmonizar a Legislação*. Revista Direitos Fundamentais & Democracia, Unibrasil, v. 1, 2007.

[4] PIMENTEL, Luís Otávio. *Propriedade Intelectual e Desenvolvimento*. In: Propriedade Intelectual – Estudos em Homenagem à Professora Maristela Basso. Curitiba: Juruá Editora, 2005. p. 46

[5] PRONER, Carol. *Propriedade Intelectual: Para uma outra ordem jurídica possível*. São Paulo: Cortez Editora, 2007. p. 3

[6] From this economic perspective, Robert Sherwood identifies eight common elements of intellectual property rights: the concept of an exclusive right; the mechanism for creating the exclusive right; the duration of the exclusive right; the public interest associated with the exclusive right; the negotiability of this right; the informal agreements and understandings among nations; the enforceability of the exclusive right; and the transactional arrangements for market purposes. SHERWOOD, Robert M. *Propriedade Intelectual e Desenvolvimento Econômico*. São Paulo: Edusp, 1992. p. 37.

[7] ROCHA, Afonso de Paula Pinheiro. Propriedade intelectual e suas implicações constitucionais: análise do perfil constitucional da propriedade intelectual e suas inter-relações com valores constitucionais e direitos fundamentais. 2008. 287 f.: Dissertação (mestrado) - Universidade Federal do Ceará, Faculdade de Direito, Programa de Pós-Graduação em Direito, Fortaleza/CE, 2008.

10. This peculiar nature raises classic economic problems, such as free riding, where individuals benefit from a creation without contributing to its production. To prevent this disincentive to innovation, exclusive rights such as patents, copyrights, and trademarks are justified. Nevertheless, excessive exclusivity can sometimes produce undesirable effects. Hoarding such property — as in the failure to produce essential medicines — can lead to public health problems. Similarly, the creation of monopolies, particularly if unjustified, can artificially restrict supply and raise prices, reducing allocative efficiency and social welfare.

11. Accordingly, intellectual property must be fairly regulated, ensuring sufficient incentives to foster creativity and technological development, but without imposing disproportionate barriers to access, competition, and collective welfare. This is where the role of a competition authority, such as CADE in Brazil, becomes crucial: to monitor potential abuses of exclusive rights, prevent anticompetitive practices, and ensure that the protection of creativity does not become an unjustified obstacle to free competition.

12. In this respect, the 1988 Brazilian Constitution establishes the foundations of competition policy. Article 173, Paragraph 4, provides that "The law shall repress the abuse of economic power aiming at dominating markets, eliminating competition and increasing profits arbitrarily." More broadly, Article 170 stipulates that the Brazilian "economic order" shall be "founded on the valorisation of human labour and free enterprise," observing principles such as "free competition," "the social function of property," "consumer protection," and "private property." In addition, Law 12529/2011 structured the Brazilian Competition Defense System (SBDC), assigning CADE responsibility for implementing and enforcing competition policy.

13. As Commissioner Mauricio Oscar Bandeira Maia insightfully noted in his opinion in Administrative Proceeding No. 08012.002673/2007-51, there is no inherent antagonism between intellectual property and competition law. According to him, both branches were designed to coexist harmoniously: while intellectual property protects creativity and provides incentives for innovation, competition law ensures that such rights are not used to illegitimately exclude competitors or harm the market and consumers.

14. This complementarity seeks to ensure that prices remain competitive, that firms are motivated to innovate, and that consumers enjoy greater welfare. Although both rights have constitutional foundations, it is the role of ordinary legislation to set forth mechanisms to curb abuses and ensure that the privileges granted to holders of intellectual rights serve the social interest and economic development, and not as tools of anticompetitive exclusion.

15. In this sense, it is worth examining how CADE has addressed intellectual property issues.

3. CADE's decisions

3.1. Mergers and Intellectual Property

16. In several merger transactions reviewed by CADE, intellectual property assets — notably trademarks — have played a crucial role in identifying and mitigating competitive risks.

17. In Merger Case No. 08012.005846/1999-12, involving the merger of Companhia Cervejaria Brahma and Companhia Antarctica Paulista Indústria Brasileira, which resulted in the creation of AMBEV, it was found that the transaction would lead to a significant concentration in the markets for bottled water, soft drinks, and beer across different regions.

Given the high likelihood of market power being exercised in the beer segment due to the merger, CADE imposed various remedies, including the divestiture of the "Bavária" brand, explicitly recognizing the relevance of intangible assets and intellectual property to competition in the sector. The rationale was to preserve rivalry in the relevant market by transferring economically significant brands to a third-party competitor, thereby ensuring that the new market structure would not become excessively concentrated nor deprive consumers of meaningful choices.

18. This concern is consistent with economic analysis grounded in models such as Bertrand competition with product differentiation. In this model, the presence of highly differentiated brands confers a certain degree of market power on enterprises: products are not perfect substitutes, and consumers exhibit specific preferences, reflected in lower price elasticity of demand for particular brands. In technical terms, brands enhance a product's "attractiveness" relative to its competitors, enabling an enterprise to charge higher prices without losing a significant portion of its customer base..

19. Another example involving remedies related to trademark issues occurred in 2004, when CADE ruled on Merger Case No. 08012.000212/2002-30, in which PepsiCo Inc. licensed the rights to produce, market, and distribute the Gatorade-related brands to Companhia Brasileira de Bebidas (CBB), which owned the isotonic beverage brand Marathon. Considering that the transaction would lead to excessive concentration in the isotonic beverages market, CADE conditioned the transaction's approval on the sale of the Marathon brand to a competitor. The parties auctioned the brand and presented Energia On Line as the winning bidder. Accordingly, CADE required the execution of a Performance Commitment Agreement (TCD) in 2006, under which Energia On Line undertook to enter the isotonic market effectively and to submit periodic reports on its activities related to the Marathon brand.

20. Similarly, on September 14, 2016, CADE approved the acquisition of the Olla, Jontex, and Lovetex brands — previously owned by Hypermarcas — by Reckitt Benckiser (Merger Case No. 08700.003462/2016-79). As a condition for antitrust approval, the acquiring company agreed to divest the K-Y brand in Brazil, which was previously part of its portfolio. The markets affected by the merger were those for male condoms and personal lubricants. After the transaction, Reckitt would hold the leading brands in both product categories — already owning Durex and K-Y — which raised competitive concerns.

21. Also notable is Merger Case No. 08700.001097/2017-49, involving Monsanto Company and Bayer Aktiengesellschaft. The transaction was conditionally cleared with the signing of a Merger Control Agreement (ACC) proposed by the parties before CADE's Tribunal. In this transaction, Bayer acquired sole control over Monsanto. The case raised particular concerns regarding the concentration of intellectual property assets — including patents on genetically modified seeds, germplasm banks, know-how, among others. In response, the companies proposed a set of remedies to address the competitive concerns identified. The principal structural remedy consisted of divesting all assets currently held by Bayer relating to soybean and cotton seed businesses, as well as the business of non-selective herbicides based on glufosinate ammonium.

22. In addition to these structural remedies, Bayer and Monsanto also proposed behavioural commitments, which included transparency in commercial policies, prohibition of exclusivity in sales channels, prohibition of tying and bundling practices, and broad, non-discriminatory licensing of their products. Notably, these behavioural remedies also involved intellectual property assets. Such remedies aim to restore competitive conditions in the relevant market.

23. These examples illustrate just a few ways in which intellectual property assets are considered from a structural analysis perspective in merger control.

3.2. Anticompetitive conduct and Intellectual Property

24. The Competition Authority also addresses a wide range of issues concerning the analysis of conduct, specifically, the assessment of potential abuses of market power in the context of intellectual property. Pursuant to Article 36, Paragraph 3, item XIX of Law 12529/2011, the abusive exercise of industrial, intellectual, technological or trademark rights may constitute a violation of the economic order. Due to the misuse of such rights, competitors can be excluded from the market through various illicit practices, such as fraud in obtaining intellectual property registration, tying the sale of a patented product to an unprotected one, sham litigation (abusive lawsuits), among others.

25. Such conduct can raise transaction costs for subsequent innovators, hinder competition and the dissemination of knowledge, trigger the proliferation of strategic litigation — such as those conducted by patent trolls — and restrict incremental creativity, which depends on access to prior creations (POSNER, 2006).[8]

26. CADE has reviewed several cases involving intellectual property conduct. For example, in Administrative Proceeding No. 08012.004283/2000-40, CADE analysed the behaviour of Box 3 Vídeo e Publicidade Ltda. and Léo Produções e Publicidade Ltda., companies operating in the television sales programming market, particularly through the format known as "Shop Tour." The defendants filed multiple lawsuits against direct competitors, alleging copyright infringement of the format based on a registration with the Brazilian National Library Foundation. However, the document presented did not confer exclusive rights, as it was merely declaratory, without substantive analysis of the originality or protectability of the registered work. Nevertheless, the companies used this registration to support a series of lawsuits, obtaining preliminary injunctions that temporarily removed competitors from the market. CADE concluded that such conduct constituted an abuse of the right to petition — known as sham litigation — because the lawsuits contained false information, lacked legitimate grounds, and were strategically employed to exclude rivals and consolidate a monopolistic position in the market.

27. In this context, it is also important to highlight Administrative Proceeding No. 08012.011508/2007-91, filed by Pró Genéricos against Eli Lilly and Company and Eli Lilly do Brasil Ltda. The defendants were accused of abusing their exclusive market rights related to the drug Gemcitabine. Marketed under the brand name Gemzar, among others, Gemcitabine is a chemotherapy agent used in the treatment of several types of cancer, including breast, ovarian, non-small cell lung, pancreatic, and bladder cancers. It is administered through slow intravenous infusion.

28. Gemcitabine was first patented in 1983 and approved for medical use in 1995. Over the years, several patents were granted relating to the drug, including the following:

- Patent 4.526.988- EliLilly - USPTO, 1983
- Patent 4.692.434- EliLilly - USPTO, 1984
- Patent 4.808.614- EliLilly - USPTO, 1987

[8] POSNER, Richard A. Do We Have Too Many Intellectual Property Rights? *Marquette Intellectual Property Law Review*, v.9, n.2, p.173–?, 2006. Available at: https://chicagounbound.uchicago.edu/journal_articles/195/.

- Patent 5,015,743- EliLilly - USPTO, 1989
- Patent 5,118,820 - EliLilly - USPTO, 1991
- Patent 4,965,374 - EliLilly - USPTO, 1989
- Patent 5,223,608 - EliLilly - USPTO, 1990

29. Thus, when Eli Lilly filed the Brazilian patent application PI9302434-7 in 1993, it was already aware that Gemcitabine was not a new invention. Moreover, PI9302434-7 specifically concerned a production process — a method for producing Gemcitabine in a purer and cleaner form. Therefore, even though the active ingredient itself was already known, there was still the possibility of seeking protection for innovative production methods of Gemcitabine.

30. However, at the time, Article 9(c) of Brazilian Law 5772/71 explicitly prohibited patents for pharmaceutical products. Only in 1995, Article 70.8 of the TRIPS Agreement imposed an obligation to provide patent protection for pharmaceutical products — though notably, this obligation did not extend to patents covering merely the production processes of such products.

> ART. 70.8 - Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical **products** commensurate with its obligations under Article 27, that Member shall:
>
> *(a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;*
>
> *(b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and*
>
> *(c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b). (emphasis added)*

31. Since PI9302434-7, filed in 1993, concerned only a production process, it was not eligible for protection under Article 70.8 of the TRIPS Agreement. Even if that were not the case — that is, even if PI9302434-7 had claimed a pharmaceutical product — Eli Lilly would still not have been entitled to patent protection, as Gemcitabine was already being commercially marketed in the United States, which was expressly prohibited under Article 230 of Brazilian Law 9279/96.

32. The problem arose when the Brazilian Intellectual Property Office (INPI) rejected Eli Lilly's patent application, stating that the company had no legal right to that. After this rejection, however, Eli Lilly attempted to transform its limited "production process patent" into a "pharmaceutical product patent," falsely claiming that it was merely clarifying the original claims, even though it was in fact altering and expanding them to cover something that was already in the public domain.

33. In addition, Eli Lilly petitioned a federal judge to suspend the INPI's decision-making process. At the same time — before a different federal judge who was unaware of the prior request — Eli Lilly complained that the INPI was taking too long to issue a final

decision on its application. On this basis, Eli Lilly invoked the protection provided by Article 70.9 of the TRIPS Agreement.

> *9. Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member.*

34. Article 70.9 of the TRIPS Agreement serves as a safeguard against undue delays by intellectual property authorities. It grants the applicant exclusive marketing rights for a period of up to five years, or until the patent is granted or denied, whichever occurs first. In this case, however, the delay was caused by Eli Lilly itself.

35. A second federal judge granted Eli Lilly exclusive marketing rights for gemcitabine for the treatment of breast cancer. Nonetheless, Eli Lilly subsequently approached a third Brazilian judge and misrepresented the scope of these rights, claiming entitlement to unrestricted exclusive marketing rights for gemcitabine covering all types of cancer. This manoeuvre resulted in an injunction that extended protection for an additional eight-month period, during which the pharmaceutical company Sandoz was prohibited from offering its competing product, Gemcit, for three months. During this period, Eli Lilly charged BRL 540 in public procurement bids — more than double the price (BRL 189) it charged after the injunction was overturned.

36. For these reasons, CADE concluded that Eli Lilly had abused its patent rights through a strategy of *sham litigation*. The agency imposed a fine of BRL 36.6 million. This decision is significant not only for the specific case, but also as a clear signal to other companies that such illicit and deceptive strategies will not be tolerated and will be sanctioned under the Brazilian legal system.

3.3. Competition Advocacy and Intellectual Property

37. CADE is also active in competition advocacy in the field of intellectual property. It contributes to legislative debates and collaborates with the Interministerial Intellectual Property Group, having played a pivotal role in ensuring that the National Intellectual Property Strategy incorporates a dedicated chapter addressing concerns about the anticompetitive overuse of intellectual property rights.

38. Below are three cases adjudicated by CADE in which, although the conduct was ultimately granted immunity—as in the case related to the Central Office for Collection and Distribution of Copyrights (ECAD)—or not convicted—as in the Industrial Design and Lundbeck cases—, it is illustrated how there is still room to make the legal framework more pro-competitive.

3.3.1. Copyrights

39. On March 20, 2013, CADE ruled in Administrative Proceeding No. 08012.003745/2010-83, imposing a fine of approximately BRL 38 million on ECAD and its affiliated associations for cartel practices. The decision recognized that the associations, which should potentially compete, were jointly fixing the prices of the musical repertoire and imposing contractual clauses that functioned as barriers to the entry of new associations into the collective management market. CADE considered these practices an

abuse of dominant position and an overextension of intellectual property rights, resulting in harm to competition and consumers.

40. However, just months after CADE's decision, the Brazilian legislature enacted Law 12853/2013, which amended the Copyright Act (Law 9610/1998) and paradoxically legalized the violation by stipulating, in Article 98, Paragraph 8, that associations must unify the price of their repertoires through the collecting entity. Although this legal change improved artists' representation in ECAD's decisions, it eliminated competition among associations and entrenched the monopoly on collection and price setting — clearly at odds with CADE's jurisprudence and competitive analysis.

41. As a result, the Brazilian model was characterized by a legalized monopoly, in which ECAD, a private entity, unilaterally sets copyright fees without any competitive (due to the absence of inter-association competition) or regulatory constraint (due to the lack of state price oversight). This arrangement exacerbates the overutilization of intellectual property rights by concentrating all market power in a single agent, to the detriment of negotiations between rights holders and users.

42. This scenario stands in stark contrast to solutions adopted in other jurisdictions. In the United States, for instance, there is competition among private entities (ASCAP, BMI, and SESAC), which manage distinct repertoires and compete for affiliates and clients. Moreover, following antitrust proceedings by the Department of Justice (DOJ) against ASCAP and BMI in the 1940s and 1950s, Consent Decrees were established to curb their market power, prohibiting practices such as exclusivity, price discrimination, and unjustified refusals to license. The "court rate" mechanism was also created, allowing courts to set reasonable licensing fees when parties cannot reach an agreement. This system combines competition among associations with judicial oversight to prevent abuses.

43. In Europe, there is strong regulation of collective management organizations, with rules prohibiting abusive statutory clauses, ensuring fair distribution of revenues, and enhancing authors' mobility and autonomy. Landmark cases such as *GEMA I* and *Phil Collins v. Imtrat* reflect European concern with democratizing associations and safeguarding fair conditions for authors and users. Other initiatives, such as the IFPI Simulcasting Agreement and Directive 2014/26/EU, aim to foster multi-territorial licensing and competition in the digital environment.

44. Brazil, by contrast, has remained distant from these models, with a system that lacks both competition among associations and effective price regulation. It is necessary to correct these distortions by fostering greater competition, transparency, and user participation in pricing and strategic decisions — either through legislative or regulatory reform aligning the Brazilian system with the international best practices—.

3.3.2. Industrial Design and the Anfape Case

45. Administrative Proceeding No. 08012.002673/2007-51, adjudicated by CADE, originated from a complaint by the National Association of Auto Parts Manufacturers (ANFAPE) against automakers Volkswagen do Brasil, Fiat Automóveis, and Ford Motor Company Brasil. ANFAPE alleged that the respondents abused industrial design registrations to monopolize the automotive aftermarket, excluding independent manufacturers and imposing high prices on consumers.

46. After extensive proceedings, including opinions from the Office of Superintendent General at CADE, the Office of the Attorney General, and the Federal Prosecutor's Office, the automakers were acquitted by majority vote. However, even the majority acknowledged that the case revealed significant distortions in the secondary market and pointed to the need for legislative reforms to safeguard competition in the aftermarket. Although some

commissioners expressed reservations about the adequacy of the current legal framework, they acknowledged that the enforcement of industrial design rights in the secondary market did not, in itself, constitute an antitrust infringement.

47. The case exposed the need to rethink Brazil's industrial design protection system. Registrations, often granted without substantive merit examination by the INPI, were used by automakers to exclude competitors through litigation. For instance, judges granted injunctions allowing automakers to seize independent manufacturers' parts, even when the INPI later found the designs lacked the novelty and originality required by law.

48. The Office of the Superintendent General at CADE noted that the automakers' judicial victories evoked "considerable discomfort" among judges, who voiced the view that unrestricted protection of industrial designs in the auto parts sector effectively created a monopoly in the replacement market, undermining competition and consumer interest.

49. Although CADE did not find the automakers guilty, it highlighted the urgent need for legislative reform to address these abuses and protect competition in the aftermarket. One possible solution discussed in the record was to establish by law the ineffectiveness of industrial design registrations against independent manufacturers in the replacement market, as well as to eliminate criminal sanctions in such cases.

50. Thus, despite not sanctioning any company, CADE signalled a meaningful path forward in terms of competition advocacy.

3.3.3. Lundbeck´s case

51. The Lundbeck case addresses a broader issue related to "data protection" and "data exclusivity" for undisclosed data generated in the process of obtaining marketing approval for pharmaceutical products. Before delving into the specifics of the case, it is important to contextualize this debate within the international arena, particularly the pressures Brazil has faced on this topic.

52. Under Section 301 of the U.S. Trade Act of 1974, the United States may impose trade sanctions or initiate dispute settlement proceedings at the World Trade Organization (WTO) against countries deemed to "fail to respect intellectual property rights," effectively placing them on a so-called blacklist (Watch List or Priority Watch List). At present, Brazil remains on the U.S. Watch List.

53. One of the reasons mentioned by the U.S. administration for including Brazil on this list is the allegation that Brazil does not adequately provide "protection against unfair commercial use of undisclosed test and other data generated to obtain marketing approval for veterinary and agricultural chemical products (...) as well as for pharmaceutical products."

> *While Brazilian law and regulations provide for protection against unfair commercial use of undisclosed test and other data generated to obtain marketing approval for veterinary and agricultural chemical products, they do not provide similar protection for pharmaceutical products. The United States encourages Brazil to provide transparency and procedural fairness to all interested parties in connection with potential recognition or protection of GIs including in connection with trade agreement negotiations with other countries.*[9] *(301 Report of 2018, p.80)*

54. Thus, the United States seeks to enforce Article 39.3 of the TRIPS Agreement through the use of Section 301 of the U.S. Trade Act of 1974. However, it is inaccurate to

[9] See https://ustr.gov/sites/default/files/files/Press/Reports/2018%20Special%20301.pdf, http://www.ustr.gov/sites/default/files/2012%20Special%20301%20Report.pdf

claim that Brazil violates the TRIPS Agreement merely because it adopts a broader interpretation of Article 39.3. Moreover, this does not constitute a fair or legitimate reason for the United States to single out Brazil for discriminatory treatment among other countries.

55. Article 39.3 of the TRIPS Agreement sets out obligations regarding how States should handle "data exclusivity" and "data protection" for "new chemical entities" in the pharmaceutical industry.

56. As noted by Palmedo (2013):

> *Data exclusivity is a form of intellectual property (IP) protection required by many trade agreements that protects the data submitted by pharmaceutical and chemical firms to regulatory authorities for marketing approval. The pharmaceutical industry argues it is an important form of IP protection needed to support further investment in new medicines. However, advocates for access to medicines have warned that it delays generic competition and therefore raises prices of drugs. When a branded firm applies for marketing approval from a regulator like the U.S. Food and Drug Administration, it must present clinical test data to regulators showing that the drug is safe and effective. The process of obtaining the clinical trial data is very expensive, risky, and time consuming. Studies of the cost of drug development find that the majority of the cost of bringing a new drug to market is conducting the clinical trials.*
>
> *If generic firms needed to reproduce the same data, the high expenses would require them to charge prices nearly as high as the innovator. Additionally, it would violate international ethical standards that prohibit doctors from conducting experiments on humans in situations where the results are already known. Therefore, most nations' regulatory authorities grant generic firms marketing approval based on bioequivalence data, which shows that their products are chemically the same, and are absorbed into the body the same way, as the originators' products. Generic firms rely on the clinical trials conducted by the originator firms for proof their products' safety and efficacy.*
>
> *Data exclusivity establishes a period of time (generally 5-10 years for small-molecule drugs) during which generic firms cannot win marketing approval based on the clinical data submitted by brand name producers. It can keep generics off the market even in cases where there is no patent in place, or when a compulsory license has been issued.*[10]

57. However, data exclusivity is not synonymous with data protection. Pursuant to Article 39.3 of the TRIPS Agreement, member countries are required to protect such data from disclosure, except when necessary to safeguard public interests or where adequate measures are adopted to prevent unfair commercial use. Notably, the TRIPS Agreement does not impose any obligation on countries to grant exclusivity — and, consequently, market power — to originator firms.[11]

[10] See PALMEDO, Michael, Do Pharmaceutical Firms Invest More Heavily in Countries with Data Exclusivity? (2013). Currents International Trade Law Journal, Summer 2013, Available at SSRN: https://ssrn.com/abstract=2259797 https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2259797

[11] *"It must be admitted that the following of Article 39.3 does not, from a prima facie reading, appear to impose data exclusivity during a certain period of time. This lack of clarity is the obvious result of a difficult negotiation process where divergences of views arose between developing and industrialized countries as to the necessity of EC/U.S. like type of data protection as well as among industrialized countries on the length of the data exclusivity period" (EU, 2001, p. 3).* Protection Of Data Submitted For The Registration Of Pharmaceuticals:

58. The WTO, itself, recognizes that the TRIPS Agreement does not require "exclusive" rights to protect test data:

> *Article 39.3 of the TRIPS Agreement leaves considerable room for Member countries to implement the obligation to protect test data against unfair competition practices. The Agreement provides that "undisclosed information" is regulated under the discipline of unfair competition, as contained in article 10 bis of the Paris Convention. With this provision, the Agreement clearly avoids the treatment of undisclosed information as a "property" and* ***does not require granting "exclusive" rights to the owner of the data.***[12] *(emphasis added)*

59. The U.S. position advocating for the implementation of "data exclusivity," which would compel other firms wishing to enter the market either (1) to repeat clinical trials or (2) to respect the originator's market power during the exclusivity period — even in the absence of a patent — can have serious social consequences. Typically, the efficacy of a medicine is demonstrated using the econometric method known as "difference-in-differences analysis," where the treatment group receives the actual drug being tested, while the control group receives a placebo or palliative treatment. Deaths or deterioration in the health of the control group relative to the treatment group determine the drug's effectiveness. If efficacy is already well-established, repeating such trials would only subject the control group to unnecessary harm without yielding any additional substantive knowledge about the drug's effectiveness in a given treatment.

60. Despite such concerns, data exclusivity is recognized in several jurisdictions, granting temporary market power in exchange for the submission and retention of research data by other authorities (European Union, United States, Japan, China, Canada, among others).

61. Conversely, countries such as South Africa, Brazil, and Israel have no specific legislation guaranteeing data package protection for those who conducted the pre-clinical and clinical studies required for regulatory approval.

62. Unlike the U.S. and EU, Brazil does not disclose the originator's research data at all and has no law granting data exclusivity. Moreover, research data submitted to the regulatory authority (ANVISA) are never made public, at least in Brazil. Nevertheless, some companies have brought lawsuits arguing that, due to the Brazilian lack of specific legislation regulating and delimiting data exclusivity, such exclusivity should be recognized without limits — including no temporal limitation.

63. Such an interpretation, however, raises serious concerns, as it could effectively result in a level of protection even greater than that afforded by patents, by establishing a form of perpetual monopoly. This would not only conflict with the constitutional principles governing the temporary nature of intellectual property rights in Brazil, but also risk undermining access to generic medicines and free competition in the pharmaceutical market.

64. These firms have claimed that generics could be indefinitely barred from the market because they could not legally rely on the originator's data to demonstrate the safety and efficacy of their products — regardless of whether the drug is a "new chemical entity" or any other relevant factor, and notwithstanding the fact that ANVISA's records are never

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Implementing The Standards Of The Trips Agreement. 2002. According to *http://apps.who.int/medicinedocs/en/d/Jh3009ae/12.html*

[12] See https://www.wto.org/english/tratop_e/trips_e/paper_develop_w296_e.htm

disclosed. In many jurisdictions, data exclusivity is granted only for new chemical entities, for a limited period, and in exchange for the publication of the supporting research.

65. Supposing this litigation strategy succeeds and is applied broadly, it could effectively dismantle Brazil's generics policy or, at minimum, create significant risks for the generics market. This would harm competition, as generics — the most aggressive competitors, or *mavericks*, within their therapeutic classes — offer patients and pharmacists alternatives once a prescription for a reference medicine is written. According to Brazilian Law 6360/1976 (Art. 3, Item 21) and ANVISA Resolution RDC 16/07, only the corresponding generic can replace the prescribed reference medicine at the pharmacy counter. Forcing generics to redo all the studies and prohibiting them from referencing the originator's product undermines the sole mechanism of interchangeability and substitutability at the pharmaceutical level, effectively removing generics from the market.

66. Beyond the anticompetitive effects, this approach represents a flawed mechanism for protecting investments in molecules not eligible for patent protection. In other words, even where the originator has not invented anything worthy of a patent, this distorted interpretation enables firms to protect their investments merely through perpetual exclusive sales of certain molecules or by harming patients by subjecting them to unnecessary duplicative trials — which, even if conducted, would not expand interchangeability or substitutability under Brazil's regulatory framework.

67. It is also noteworthy that, when negotiating "free trade" agreements with other nations, the United States has made data exclusivity a precondition for concluding such treaties. As Shaffer & Brenner (2009)[13] observe:

> *Millions of people lack access to affordable medicines. The intellectual property rules in the Central America Free Trade Agreement (CAFTA) provide pharmaceutical companies with monopoly protections that allow them to market some drugs without competition by less costly generics (…) Our study suggests that CAFTA's intellectual property rules on data exclusivity and patents are responsible for the removal of several lower-cost generic drugs from the market in Guatemala and for the denial of entry to a number of others. (…). The U.S. Congress removed the data-exclusivity provision of the trade agreement with Peru in May 2007, recognizing potentially negative consequences for lower-income countries. As an initial step, the U.S. Trade Representative and the Department of Commerce should extend this recognition to all CAFTA countries. It should assert its intention not to implement the data-exclusivity provisions of CAFTA and should proactively cooperate with Central American governments that take action not to implement these provisions. A more limited reform proposal, generated prior to the Peru policy, would require generic producers to pay a small sum for the use of pharmaceutical test data, rather than the present system of establishing exclusive rights to protect investments in the data.*

68. Thus, when the United States places Brazil on the Watch List under Section 301 of the U.S. Trade Act of 1974, the unfairness of such a measure becomes evident. If Brazil were to comply fully with the demands made by the U.S., there would be a significant risk of replicating what has already occurred in other countries — namely, the removal of numerous affordable generic medicines from the market without valid justification.

[13] SHAFFER ER, BRENNER JE. A trade agreement's impact on access to generic drugs. Health Aff (Millwood). 2009 Sep-Oct;28(5):w957-68. doi: 10.1377/hlthaff.28.5.w957. Epub 2009 Aug 25. PMID: 19706626.

69. It is important to clarify that Brazil does not disclose any test results submitted to ANVISA for the approval of generic medicines; however, generics are allowed to enter the market following the approval and commercialization of the reference drug.

70. In this context, CADE analysed a case to determine whether certain companies had abused their intellectual property rights by claiming before the judiciary that (i) their data had been improperly used by ANVISA and (ii) that they were entitled to indefinite data exclusivity as a means of recouping their investments. [Administrative Proceeding No. 08012.006377/2010-25; Plaintiff: Pró Genéricos; Defendants: H. Lundbeck A/S and Lundbeck Brasil Ltda.; Conduct under investigation: Abuse of data protection rights concerning Lexapro (an antidepressant) to prevent generic market entry.]

71. Lundbeck filed lawsuits against manufacturers of generic versions of escitalopram, which is not a new chemical entity, despite holding no patent or any other enforceable intellectual property right over the substance — aside from a controversial claim to data exclusivity, a form of protection that is clearly not recognized under Brazilian law.

72. According to Lundbeck's own 2000 Annual Report, the development and market launch of Lexapro (escitalopram) were significantly faster and less costly than those of other drugs, largely because the company was able to rely on existing clinical data related to citalopram, its predecessor. Specifically, Lundbeck stated that developing a new drug typically takes 5 to 6 years, but the development of Lexapro was expedited thanks to the extensive knowledge already available from citalopram.

73. Citalopram had been on the market since 1989 and had been used by over 28 million people, which allowed Lundbeck to bypass Phase I and Phase II clinical trials, saving both time and resources. The company, in collaboration with Forest Laboratories Inc., initiated clinical trials of escitalopram in August 1999 and completed Phase III in under a year, submitting the results to Swedish health authorities in 2001.

74. This demonstrates that Lundbeck relied on information from a drug that had long been available on the market—data that could not be protected through exclusivity rights. This situation arose because escitalopram is the chiral (S-isomer) version of citalopram, a substance whose safety profile was already well established, thereby reducing the need to replicate much of the clinical research.

75. As it does not qualify as a new chemical entity, it would not be entitled to exclusive market rights — even in jurisdictions that recognize such intellectual property protection.

76. Although Lundbeck did not initially request a time limitation, the Brazilian judiciary ruled in its favour and established an exclusive market right ex post for a limited period of ten years. In practice, this meant that if a generic had lawfully entered the market during this ten-year period, it would still be required to pay compensation to Lundbeck — the amount of which remains unclear.

77. CADE concluded that it was not supposed to punish a company merely for seeking protection through the Brazilian judicial system against practices it deemed unfair. Based on the principles of free speech and unrestricted access to the judiciary, the originator company was entitled to petition the courts for data exclusivity, even in this conditions.

78. It is worth noting, however, that Commissioner Polyanna Ferreira Silva Vilanova disagreed with Lundbeck's interpretation of intellectual property law. Nevertheless, her dissenting opinion did not lead to the discover of antitrust violations. According to Commissioner Vilanova:

> I find it extremely important to note that such a finding does not mean CADE's unrestricted *agreement with Lundbeck's argument. As well pointed out by the*

SG / CADE, the conclusion by the absence of antitrust tort does not refute the fact that the debate over data package protection may have important competitive implications. I believe that the position advocated by ANVISA - the possibility of basing itself on the product package of the reference product in the registration process of generic / similar medicines - favours the entry of generic / similar drugs, which would result in increased competition and more access of consumers to lower-cost drugs. Too broad protection of data package exclusivity rights may have competitive impacts, as it would become more costly and time-consuming to enter generic / similar products, with clear impacts for the generic policy and for the drug market in Brazil. For this reason, it is recommended that the Judiciary and the Legislative Branch to consider the existence of these competitive impacts when making decisions on this topic. However, in my view, it is not for CADE to arbitrate which understanding should prevail. Even in the event of any discrepancy by the competition authority in relation to the argument put forward by Lundbeck, it is not sufficient to characterize the conduct of the Representative as anticompetitive. (loose translation, emphasis added)

79. Datapackage was not the only issue debated in the *Lundbeck* case. There were other allegations that were likewise deemed insufficient to warrant a sanction. Nevertheless, although CADE did not impose any penalties on Lundbeck, this case illustrates how there is an appropriate and necessary space for broader competition advocacy efforts in Intellectual Property cases.

4. Conclusion

80. The Brazilian experience at the intersection of intellectual property and competition law demonstrates the importance of maintaining a delicate balance between fostering innovation and preserving competitive market structures. CADE's jurisprudence and advocacy illustrate that intellectual property rights, while legitimate and necessary to incentivize creativity, are not absolute and must be exercised within the boundaries of the public interest and economic order.

81. The cases analysed reveal that the misuse of intellectual property — whether through sham litigation, abusive licensing practices, unjustified exclusivity claims, or strategic litigation to foreclose competitors — can undermine competition, restrict consumer choice, and inflate prices, thereby frustrating the very objectives that intellectual property is intended to serve. At the same time, they also reflect CADE's institutional restraint in recognizing the rightful place of the judiciary and the legislature in defining the scope of such rights, and its focus on ensuring that enforcement actions are proportionate and grounded in evidence of competitive harm.

82. In light of Brazil's constitutional commitment to both the social function of property and the principle of free competition, CADE's role as a guardian of competitive markets remains essential. As new challenges emerge — such as those posed by digital markets, biopharmaceutical innovation, and the globalization of trade and intellectual property regimes — the need for a coherent, balanced, and forward-looking approach becomes even more urgent.

83. Ultimately, Brazil's approach, as exemplified by CADE's actions, reinforces the notion that intellectual property and competition are not inherently antagonistic, but rather complementary tools for promoting innovation, efficiency, and social welfare.

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