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Research Report

Competition law and access to medicines: Lessons from Brazilian regulation and practice

Research Paper, No. 142

Provided in Cooperation with:

South Centre, Geneva

Suggested Citation: Falcão, Matheus Z.; Gondo, Mariana; Navarrete, Ana Carolina (2022) : Competition law and access to medicines: Lessons from Brazilian regulation and practice, Research Paper, No. 142, South Centre, Geneva

This Version is available at:

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Research
Paper

4 January 2022

Competition Law and Access to Medicines: Lessons from Brazilian Regulation and Practice

Matheus Z. Falcão, Mariana Gondo and
Ana Carolina Navarrete




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RESEARCH PAPER

142

COMPETITION LAW AND ACCESS TO MEDICINES: LESSONS FROM BRAZILIAN REGULATION AND PRACTICE

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4 JANUARY 2022

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ABSTRACT

Competition law may play an important role in drug pricing control by containing high prices derived from economic violations. Since the use of competition tools is not limited by the TRIPS Agreement or other international binding disciplines, there is ample policy room to explore how countries, especially in the Global South, can benefit from strengthening their jurisdiction on that matter. This article briefly explains the Brazilian Competition System by describing the structure of the Brazilian competition authority (CADE – Administrative Council for Economic Defense) and the main economic violations set forth by Brazilian law. It describes the convergence of competition with the consumer protection system. It also discusses three relevant pharmaceutical market cases examined by the competition authority (sham litigation, overpricing and economic abuse, buy-and-raise and exclusionary practices). Finally, it presents some lessons from the Brazilian case on the challenges of using competition law to confront abuse or misuse of intellectual property rights in the pharmaceutical market, with lessons to other developing countries

Le droit de la concurrence peut jouer un rôle important dans le contrôle des prix des médicaments en limitant les prix élevés découlant de violations économiques. Étant donné que l'utilisation des outils de la concurrence n'est pas limitée par l'Accord sur les ADPIC ou d'autres mesures internationales contraignantes, il existe une grande marge de manœuvre pour étudier comment les pays, en particulier ceux du Sud, peuvent bénéficier d'un renforcement de leur juridiction en la matière. Cet article explique brièvement le système brésilien de la concurrence en décrivant la structure de l'autorité brésilienne de la concurrence (CADE – Conseil administratif de défense économique) et les principales infractions économiques établies par la loi brésilienne. Il décrit la convergence de la concurrence avec le système de protection des consommateurs. Il aborde également trois affaires pertinentes relatives au marché pharmaceutique examinées par l'autorité de la concurrence (litiges fictifs, fixation de prix excessifs et abus économiques, achats et hausses de prix et pratiques d'exclusion). Enfin, il présente quelques leçons du cas brésilien sur les défis de l'utilisation du droit de la concurrence pour faire face à l'abus ou à la mauvaise utilisation des droits de propriété intellectuelle dans le marché pharmaceutique, avec des leçons pour d'autres pays en développement.

El derecho de la competencia puede desempeñar un papel importante en el control de los precios de los medicamentos, al contener los precios elevados derivados de violaciones económicas. Dado que el uso de las herramientas de la competencia no está limitado por el Acuerdo sobre los ADPIC u otras disciplinas internacionales vinculantes, existe un amplio margen político para explorar cómo los países, especialmente en el Sur Global, pueden beneficiarse del fortalecimiento de su jurisdicción en esa materia. Este artículo explica brevemente el sistema de competencia brasileño, describiendo la estructura de la autoridad de competencia brasileña (CADE – Consejo Administrativo de Defensa Económica) y las principales infracciones económicas establecidas por la legislación brasileña. Describe la convergencia de la competencia con el sistema de protección al consumidor. También discute tres casos relevantes del mercado farmacéutico examinados por la autoridad de la competencia (litigios falsos, sobreprecio y abuso económico, compra y aumento y prácticas de exclusión). Por último, presenta algunas lecciones del caso brasileño sobre los desafíos de utilizar la ley de competencia para enfrentar el abuso o el mal uso de los derechos de propiedad intelectual en el mercado farmacéutico, con lecciones para otros países en desarrollo.

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INTRODUCTION

The international discussion on using competition law for promoting access to life-saving treatments by decreasing prices, especially in the Global South, is a key issue in the debate on broader access to health technologies. Competition law is one of the TRIPS flexibilities and has been indicated by important international^{1,2} and intergovernmental organizations³ as one path for dealing with monopoly-driven economy practices that raise prices.

A rising number of cases in the field reveals the competition law potential on that matter, such as the Hazel Tau case in South Africa,⁴ the Avastin-Lucentis case in Italy⁵ and in the European Union jurisdiction, the Aspen case in Italy,⁶ and the Pfizer-Flynn case in the United Kingdom,⁷ among others.

This discussion also considers the infraction of excessive pricing on pharmaceutical markets, i.e., how can a price be deemed so high that it can be sanctioned as an economic infraction. An OECD 2018 report⁸ on that matter highlights the relevance of this discussion, although it fails to address how to apply competition law doctrines on patented medicines. The tension between IP rights and access to medicines is particularly important in Global South countries,⁹ and therefore it is an important matter for competition authorities.

For many diseases, drug treatment is the only or the most effective response, which makes access to medicines an essential component of the right to health. As such, adequate policy and drug pricing regulations (and avoiding abusive pricing practices) are key elements for expanding access to life-saving medicines. And because the global medicine market is highly concentrated and subject to various market failures and potential anti-competitive practices, competition law is an important tool to promote access and welfare, thus playing a key role in fulfilling the right to health.

The 1988 Constitution of the Federative Republic of Brazil acknowledges the right to health. According to its art. 196,¹⁰ health is a right of all and a state's duty, which must develop social and economic policies aimed at reducing the risk of disease and providing universal and equitable access to health services.

¹United Nations Development Programme (UNDP). *Report of the United Nations Secretary-General High-Level Panel on Access to Medicines. Promoting innovation and access to health technologies*. (New York, UNDP 2016). Available from www.unsgaccessmeds.org.

²United Nations Development Programme (UNDP). *Using Competition Law to Promote Access to Medicine*. New York: UNDP, 2014. Available from <https://www.undp.org/publications/using-competition-law-promote-access-medicine-0>.

³Vitor Henrique Pinto Ido, *Designing Pro-Health Competition Policies in Developing Countries*, Research Paper No. 125 (Geneva, South Centre, December 2020).

⁴Hazel Tau & others v. GlaxoSmithKline, Boehringer Ingelheim & others, 2002 (South African Competition Commission, Competition Commission Case No. 2002Sep226). For a summary, see: UNCTAD Case Law Database. Available from

<https://unctad.org/ipccaselaw/sites/default/files/ipccaselaw/2020-12/Hazel%20Tau%20SA%20Competition%20Commission%20v.%20GSK%20BI%20et%20al%202002.pdf>.

⁵https://ec.europa.eu/competition/ecn/brief/02_2014/it_roche.pdf.

⁶[https://one.oecd.org/document/DAF/COMP/WD\(2018\)106/en/pdf](https://one.oecd.org/document/DAF/COMP/WD(2018)106/en/pdf).

⁷CMA, "CMA publishes a full decision in phenytoin case", 15 June 2017. Available from: <https://www.gov.uk/government/news/cma-publishes-full-decision-in-phenytoin-case>.

⁸OECD. Excessive prices on pharmaceutical markets. Available from: [https://one.oecd.org/document/DAF/COMP\(2018\)12/en/pdf](https://one.oecd.org/document/DAF/COMP(2018)12/en/pdf).

⁹Mohammed El Said and Amy Kapczynski, "Access to medicines: The role of intellectual property law and policy", Working Paper prepared for the Third Meeting of the Technical Advisory Group of the Global Commission on HIV and the Law, 7–9 July 2011.

¹⁰Brazil. Constitution of the Federative Republic of Brazil, 1988. Available from: http://www.planalto.gov.br/ccivil_03/constituicao/constituicao.htm. Accessed 15 July 2021.

For the full attainment of this right, the adoption of a set of state actions is essential. In cases where the onset of the disease or health condition has already occurred, it is important that individuals arrange all the necessary measures to give access to existing treatments. The federal government, state-level governments and municipalities are responsible for procurement of health technologies. The federal government carries out strategic procurement programs, such as for HIV/AIDS and Hepatitis C. When it comes to other high-priced medicines, e.g., monoclonal antibodies, federal and state governments generally share procurement procedures.¹¹

In this context, this paper discusses three pharmaceutical market cases analyzed by the Brazilian competition authority (CADE – Administrative Council for Economic Defense). It offers reflections and inputs on the prospects and challenges of the use of competition law in situations of abuse or misuse of intellectual property rights.

The first section of this article describes the Brazilian Competition Defense System by presenting the main legal provisions that define both CADE's organizational structure and its scope. Then, the article addresses the points of convergence between the Brazilian Consumer Protection Code and competition law. The subsequent sections present cases related to the violation of the right of access to medicine resulting from illegal practices of pharmaceutical companies in the country. The second section provides a discussion of sham litigation in Eli Lilly's case. The third section presents the Roche Pharmaceuticals case, one related to overpricing and economic abuse. The fourth section presents the ongoing Sofosbuvir case. This case deals with alleged buy-and-raise and exclusionary practice. Finally, the article shares lessons learned that might be useful for other developing countries.

¹¹ For further knowledge: Fabiola Sulpino Vieira, "Assistência farmacêutica no sistema público de saúde no Brasil", *Revista Panamericana de Salud Pública*, vol. 27, (2010) pp. 149–156.

1. BRAZILIAN COMPETITION DEFENSE SYSTEM

The Brazilian competition authority, CADE was created in 1962 by Law n. 4.137 of 1962.^{12,13} At this time, CADE was an agency with little autonomy linked to the Ministry of Labor and it was responsible for overseeing the economic management and accounting system of companies. The Law 8.884 of 1994¹⁴ created the structure closer to its current form, which is an autarchy (“autarquia” in Portuguese), i.e., an administrative body with technical, administrative and financial autonomy, linked to the Minister of Justice and competent to oversee mergers and acquisitions and to take action against anti-competitive acts.

The Law 12.529 of November 30, 2011—currently in effect—replaced the former law and established the Brazilian Competition Defense System, as it is known today, by defining both institutions and economic infractions. According to the legal provision, CADE is a special body and is composed of the Administrative Court of Economic Defense, the General Superintendence and the Department of Economic Studies.

When the new Law 12.529/2011 came into force, CADE gained more autonomy and became responsible for instructing administrative proceedings for the investigation of violations of the economic order, as well as processes for analyzing mergers, competences that belonged to Offices of the Ministry of Justice prior to that.

CADE structure is as follows: CADE Administrative Tribunal shall deliver judgements on matters involving competition after considering a General Superintendent’s report on the case. The Administrative Tribunal is composed of the president and six other directors, with significant legal or economic knowledge.¹⁵ Its competences are preventive, repressive and educational. The Superintendence, on the other hand, has the role of instructing processes, i.e., initiating administrative procedures to investigate abusive conduct and carrying out the initial investigation of the case. The Economic Law Department assists CADE with sectoral studies.

Law 12.529/2011 provides that CADE is responsible for ensuring the prevention of infractions against the economic order. This performance must be guided by the constitutional dictates of economic liberty, free competition, the social function of property, consumer protection and repression of abuse of economic power. It is noteworthy that, according to article 170 of the Brazilian Constitution, the economic order aims at ensuring a dignified existence for all, in accordance with the dictates of social justice and the observance of progressive principles such as reducing inequalities and protecting the environment.

Therefore, by constitutional imperative, the defense of the economic order should not only aim at the economic maximization of efficiencies. There is a set of principles (among them, freedom of enterprise and free competition) that must be harmonized to maximize social welfare. Law 12.529/2011 itself establishes that the “society” as a collectivity is the holder (i.e.,

¹² Brazil. Law No. 4,137/1962 of September 10, 1962. Regulates and suppresses the abuse of economic power. Brasília, DF, Jun 1994. Available from: http://www.planalto.gov.br/ccivil_03/leis/1950-1969/l4137.htm. Accessed 22 September 2021.

¹³ In the Brazilian system, the word “Law” also refers to a parliamentary act.

¹⁴ Brazil. Law No. 8,884/1994 of June 11, 1994. Transformation of the Administrative Council for Economic Defense (CADE) into an independent agency, provides for the prevention and repression of infractions against the economic order, and other measures. Brasília, DF, Jun 1994. Available from http://www.planalto.gov.br/ccivil_03/leis/l8884.htm. Accessed 15 July 2021.

¹⁵ Brazil. Law No. 12,529, of 30 November 2011. Structure of the Brazilian Competition Defense System; provides for the prevention and repression of violations against the economic order, Brasília, DF, Nov 2011. Available from http://www.planalto.gov.br/ccivil_03/ato2011-2014/2011/lei/l12529.htm. Accessed on 15 July 2021.

the key stakeholder) of the legal interests protected by the competition law, and not individual competitors.¹⁶ In other words, the act considers that society as a whole is a rights-holder protected by the Brazilian Competition Defense System (and not solely the private sector). Accordingly, CADE must act to prevent infractions against the economic order for the benefit of the entire community.

Art. 36 of Law 12.529/2011 defines a set of economic infractions that include limiting free competition or freedom of enterprise, dominating the relevant market of goods or services, and arbitrarily increasing profits and abusive economic practices. It is noteworthy that the law establishes that the existence of intentional conduct is not necessary for the configuration of the infraction. In addition, for the configuration of illegality, Brazilian legislation considers the effects produced by the conduct, even if potentially.

Economic infractions can be committed either horizontally (between competitors or against one of them) or vertically (along the production chain). One of the infractions, specifically defined in item XIX, is the abusive exploitation of intellectual, industrial, technology or trademark rights.¹⁷ In addition, still on the subject of intellectual property, the law defines, in Article 38, IV, a, compulsory license¹⁸ as a possible sanction to be applied by CADE to abuse of intellectual property rights. This rule has been incorporated in the Brazilian legal system since Law 8.884/1994 but has never been put into practice. In addition, art. 61, §2, V, of Law 12.529/2011 also provides for compulsory licensing as a possible measure to mitigate the harmful economic effects of approval of mergers on the relevant affected markets.

It is noteworthy that the Brazilian Constitution attributes a social function to property. This means that the grant of patents and the exercise of patent rights should comply with the fundamental principles of the Brazilian state as well. Thus, patent holders' rights are circumscribed by the limits of their economic and social function. The normative provision of the abuse of patent rights as an infringement against the economic order reveals that patent rights have their legitimacy as much as they lend themselves to constitutional aims, rather than being a natural individual right.¹⁹

In addition, Brazil has a Consumer Defense Code (Law 8.078/1990²⁰). The approval of this law is the result of the country's re-democratization process and its provisions reflect a strong character of guaranteeing rights. Far from being just an instrument that exclusively seeks to ensure better prices for consumers, the Brazilian Consumer Protection Code establishes that one of the basic rights is the right to health. In addition, the Code creates the National Policy on Consumer Relations. This policy must be executed in observance of the principle of making consumer protection compatible with the need for economic development in order to

¹⁶ Law 12,529/2011, Article 1 – Structures the Brazilian Competition Defense System and provides for the prevention and repression of infraction against the economic order, guided by the constitutional dictates of freedom of enterprise, free competition, social function of property, consumer protection and repression of abuse of economic power. Sole paragraph – The society is the holder of the legal interests protected by this Law.

¹⁷ Law 9,279, of 14 May 1996 regulates the rights and obligations related to industrial property in Brazil. According to that law, industrial property rights can be enforced by i) the granting of patents for invention and utility model; ii) the granting of registration of an industrial design; iii) the granting of trademark registration; and iv) repression of unfair competition.

¹⁸ In Brazil, compulsory licensing is provided for in both competition law and industrial property law. According to competition law, in cases where there is an infringement against competition related to the use of intellectual property rights, depending on the seriousness of the facts or the general public interest, CADE may recommend to the competent public bodies the granting of a compulsory license. According to industrial property law, a compulsory license may be granted in cases of i) national or international emergency; ii) declaration of public interest by law or by the Federal Executive Branch; iii) recognition of a state of public calamity nationwide by the National Congress. The compulsory license is temporary and remunerates the patent holder with a percentage of the net sales price defined by law.

¹⁹ Paula Andrea Forgioni, *The Fundamentals of Antitrust*. 7th ed. (São Paulo: Editora Revista dos Tribunais, 2014).

²⁰ Brazil. Law No. 8078/1990 of 11 September 1990 provides for consumer protection and other measures. Brasília, DF, Sep 1990. Available at: http://www.planalto.gov.br/ccivil_03/leis/l8078compilado.htm. Accessed 15 July 2021.

implement the principles of the economic order – the ultimate objective of which, as mentioned above, is human dignity. The restraint and repression of all abuses practiced in the consumer market that may cause harm to consumers is also a principle established by law. Therefore, the principle of “consumer protection” that guides the Brazilian Competition Defense System should not be restricted to guaranteeing better prices, but to guaranteeing an economic order that promotes health and human dignity for Brazilian consumers.

To summarize, since 1994, there has been a normative provision for the Brazilian competition agency to operate in accordance with the constitutional dictates of freedom of initiative, free competition, consumer protection, repression of abuse of economic power and the social function of property, as noted above. Competition law in Brazil sets forth the possibility of compulsory licensing of intellectual property rights. These principles converge with the consumer protection law, which also recognizes the right to health and mandates a similar comprehensive view of the economic order, as per the federal constitution. Although there is room for improvement, Brazilian competition law and policy are important instruments that can be used to guarantee access to medicines. With this background, the following sections provide an overview of some of the most important cases judged by or submitted to CADE involving patented medicines and the right to health.

2. ELI LILLY CASE: SHAM LITIGATION

To date, there is a single case where the Brazilian competition authority has condemned a pharmaceutical company for an IPR-related economic infraction.²¹ In June 2015, the CADE Court imposed an R\$ 36.6 million fine against the pharmaceutical company Eli Lilly of Brazil and its American parent company, Eli Lilly Inc., for the practice of “sham litigation.” This practice consists of pursuing objectively baseless lawsuits, concealing an attempt to interfere directly with the business relationship of a competitor.²²

Although it is difficult to distinguish the legitimate use of the litigation process from strategic attempts to use the process in order to restrict competition, legal and economic literature, as well as the courts, have come up with operational tests enabling them to determine the boundaries of this category.²³

In September 2007, the Brazilian Association of Generic Medicines Industries (“Pró Genéricos”) filed a complaint to the Economic Law Secretariat (an entity that at that time played the role currently exercised by the General Superintendence). In this case, CADE concluded that contradictory administrative processes and lawsuits filed by Eli Lilly in the Federal Court of Rio de Janeiro, the Federal District and in the State Court of São Paulo were baseless and aimed to restrict competition, featuring predatory behavior. Due to these lawsuits the company obtained the *de facto* exclusive commercialization of gemcitabine hydrochloride – marketed under the Gemzar brand – used in oncology.

On December 22, 2004, the INPI (Industrial Property National Institute, i.e., Brazilian IPR office) published in the Industrial Property Magazine 1722 that it was proceeding with the merit analysis of the patent application filed by Eli Lilly on Gemzar (gemcitabine), a drug used to treat cancer. However, on February 17, 2005, the INPI issued a technical opinion indicating that the patent application did not meet the technical requirement for an inventive step, therefore it was not eligible for patent protection.

On April 7, 2005, the company appealed to the INPI administrative division, while also expanding the claims in the patent application, so that the patent protection would cover additional processes and substances. In June of the same year, the institute decided on the patent application, maintaining its initial position not to grant a patent, thus keeping the patent only process-related.

In the same month, the company filed a lawsuit in the Federal Court of Rio de Janeiro²⁴ against the INPI requesting that the institute’s decision be nullified, the patent granted and the administrative process suspended due to the lawsuit. In August, the company appealed once more to the INPI against the institute’s previous decision, and in September it also filed a revised patent application that further extended the patent claims, this time including the active

²¹ Cf. Administrative Procedure 08012.011508 / 2007-9.1.

²² For more complete definitions about sham litigation see Salgado and Zuccolotto. “Study on the Anti-competitive enforcement of intellectual property (IP) rights: Sham Litigation”, Committee on Development and Intellectual Property (CDIP) Ninth Session (Geneva, May 7 to 11, 2012). Available from: https://www.wipo.int/edocs/mdocs/mdocs/en/cdip_9/cdip_9_inf_6_rev.pdf. Accessed on: July 15, 2021.

²³ Ioannis Lianos and Pierre Regibeau, “‘Sham’ litigation: When can it arise and how can it be reduced?”, *The Antitrust Bulletin*, vol. 62, No. 4, (2017) pp. 643–689.

²⁴ Even though Brazil’s capital city has been Brasília (located in the Federal District) since 1960, there are several federal bodies which remained in the city of Rio de Janeiro from the time that city was the country’s capital. The INPI is one of them, thus it is simple to understand why the company has filed a lawsuit against the Institute in this jurisdiction. The National Medicines Agency, ANVISA, on the other hand, is based in the Federal District.

ingredient molecule that was in the public domain and thus not patent-eligible subject matter. In October, it presented the same demand in the lawsuit.

On 13 October 2005, the first court decision of the case was published, in which the Federal Court of Rio de Janeiro denied the amendment of the initial petition to expand the patent claims. However, the court suspended the patent claim administrative process, prohibiting the INPI from following the procedure.

Around a year later, in November 2006, the company filed a new lawsuit, now against the drug market approval authority ANVISA (Health Surveillance National Agency) in the Federal Court of the Federal District. In this litigation, Eli Lilly presented the same demand, as previously done at the Rio de Janeiro court. The company added an urgent request that the court in the Federal District grant the exclusive right to commercialize the drug in the country, which would prohibit ANVISA from registering any generic drug from another manufacturer until the INPI made a decision on the granting of the patent.

As one can see, the two legal proceedings are contradictory. The company demanded in the Federal District a preliminary injunction until a final decision by the INPI was taken, suspending the possibility of commercialization by competitors. However, the same company had asked the Rio de Janeiro court to overturn the administrative process at the INPI. It therefore filed two contradictory court orders and did not notify the Federal District's judicial body of the existence of a suspension of the INPI's administrative procedure by court decision in Rio de Janeiro, nor that its patent application had already been denied several times, both administratively and judicially.

In the second instance, the Federal Regional Tribunal of the Federal District issued two decisions in the proceedings. The first, in November 2006, denied Eli Lilly's request for exclusive marketing rights (EMR). There are no provisions for the grant of exclusive marketing rights under Brazilian IP Law. In the second ruling, in June 2007, the same judge reformulated the understanding and accepted the request for exclusive marketing rights, which, as just noted, are a TRIPS-Plus provision not integrated in Brazilian law, conditioning this final decision to an INPI opinion on claims 15 and 16, the last to be included in the claim table in the patent application.

It is relevant to note that the regulation of patents in Brazil treats products and processes differently. In this case, the judge requested the INPI to comment on whether the company sought to patent a molecule (product) or a synthesis procedure (process). If the application concerned a process, the judge held the view that the patent should be granted; if it were a product, it should not. Even so, the INPI was still prevented from taking a decision due to the other lawsuit in Rio de Janeiro, which suspended the administrative proceedings.

In other words, Eli Lilly was able to benefit from an exclusivity market right (EMR) which does not exist under Brazilian law and also created a situation where it benefited from a monopoly after the patent had been denied, using various court proceedings to achieve such an outcome. The company also benefited from the situation by filing a third lawsuit at São Paulo court against a generic manufacturer (Sandoz) demanding the suspension of the generic drug registry.

Such a decision would only be revoked in March 2008, by the subsequent court of appeals under Brazilian law, the Superior Court of Justice (STJ), at the request of the Pró-Genéricos association. Thus, for approximately one year, Eli Lilly maintained a commercial monopoly of the active principle and the supply of the drug due to a court decision.

The set of contradictory actions and the constant requests to expand the scope of the claims in the patent application were the basis for CADE to impose on the company a fine of R\$ 36.6

million. The period of about nine months in which the company held the irregular monopoly was enough to harm public healthcare, as Eli Lilly was able to sell the drug with a price about 280 per cent²⁵ above the full competition scenario, when a generic company registered in Brazil, Sandoz, would have been able to manufacture and sell it as well during the full period if it were not stopped by the lawsuits by Eli Lilly.

There are some important conclusions to be drawn from this case. Primarily, it is useful to understand the ways in which pharmaceutical companies might push the system to extend monopoly rights in order to identify similar patterns and prevent abuses. In that case, Eli Lilly deliberately misled the judicial system into enforcing a right it did not have, raising the relevance of a deep knowledge of the patent system by courts and transparency on the granting of patents.

²⁵ According to CADE and the Minister of Health, during the monopoly period the unit price of gemcitabine hydrochloride was R\$ 540,00, which decreased to R\$ 189,00 immediately after barriers to competition were lifted.

3. ROCHE PHARMACEUTICALS CASE: EXCESSIVE PRICING AND ABUSIVE ECONOMIC PRACTICE

Another Brazilian case of interest is that of the monoclonal antibody Trastuzumab,²⁶ developed by the American company Genentech and later purchased by the Swiss company Roche. Its indication is for the treatment of breast cancer. Trastuzumab has already sparked important civil society campaigns for access to medicines around the world, for example, in India and South Africa.²⁷ It was the first of bio therapeutics included in the list of pre-qualified drugs by the World Health Organization (WHO).²⁸

Trastuzumab was a medicine incorporated into the Brazilian universal healthcare system (SUS) for the treatment of breast cancer. However, its indication, according to the Clinical Protocol and Therapeutic Guideline (PCDT) of SUS, included two stages of the pathology, but not the terminal phase of the HER2 positive type (HER2 +), which is a specific type of cancer that develops faster (the acronym HER2 + indicates the high presence of a protein found in this type of tumor). Thus, several users of the system filed right to health-based lawsuits against the state demanding Trastuzumab provision, which forced the local and regional healthcare public managers to purchase the medicine outside the public procurement framework of the Ministry of Health.

The Trastuzumab case is an ongoing legal case,²⁹ with the potential to become an example of using competition law to reduce drug prices and access. A public civil action was filed by the Public Prosecutor's Office (MPF, in the Portuguese acronym) based on a report developed by the Law and Poverty Research Group from the Faculty of Law of the University of São Paulo (USP).³⁰ In summary, the lawsuit claims that the pharmaceutical company Roche practiced excessive pricing and IP rights abuse by charging different prices on state level public procurements of its drug Herceptin (Trastuzumab), as it achieved better values in the negotiation.

Within the context of these purchases, the Law and Poverty Research Group report identified that the company practiced considerably different prices between each sale transaction, which could qualify as an excessive price. The charged price was considerably higher than that offered to the Ministry of Health for the same medicine. The study estimated a loss of R\$ 107 million and harm to 11 of the 27 Brazilian federative units. It also highlighted a variation of 300 per cent from Trastuzumab prices on federal procurements.

²⁶ In Brazil, Trastuzumab was one of the medicines which had a pipeline patent, a special provision of Brazilian law that resulted in a questioning in the Supreme Federal Court regarding its constitutionality. The action, proposed by a civil society organization in 2007, is still under discussion in Direct Action of Unconstitutionality n. 4234. The Brazilian Industrial Property Law (Law 9729/96), which incorporated the TRIPS Agreement into the internal system, defined a temporary mechanism, in Article 230, for the automatic granting of patents already approved in foreign trademark and patent offices in agreement with Brazil. This instrument, which became known as "pipeline patents", would last one year and thus exempted the applicant from demonstrating novelty, inventiveness and application of its application (the three requirements for registering a patent), which, in theory, had already been analyzed by a foreign entity. The law establishes as the initial term for granting the patent its deposit abroad.

²⁷ For further knowledge: <https://section27.org.za/2017/06/coalition-welcomes-landmark-competition-commission-probe-into-prices-of-cancer-medicines>.

²⁸ For further knowledge: <https://www.who.int/news/item/18-12-2019-who-prequalifies-first-biosimilar-medicine-to-increase-worldwide-access-to-life-saving-breast-cancer-treatment>.

²⁹ This is Judicial Proceeding n. 33778-19.2016.4.01.3400, originated from Civil Inquiry n. 1.16.000.000699/2015-87 of the MPF.

³⁰For further knowledge: https://00b9f5d9-efc5-42db-80ec-1bbdbf542ad1.filesusr.com/ugd/2b9b36_e64e538cd0894a6d84b093c0921b76c0.pdf.

Based on this complaint, the MPF filed a lawsuit demanding that the company refund the state and charge the same price as it did to the Ministry of Health. The lawsuit demanded compulsory licensing of the drug, based on Brazilian competition law's provision that allows for this sanction in case of intellectual property abuse. The lawsuit was filed not only against Roche but also against the INPI and the Federal Government—demanding that the latter proceed with a compulsory license for government use. Both public parties (the INPI and the federal government) responded by suggesting their removal from the case based on procedural law.

Roche claimed that the price differences were due to logistical reasons: for example, the difference between cost of segmented sale and sale in scale and the longer delivery time. Roche also claimed that prices, although different, were always within the limit regulated by the Pharmaceutical Market Regulation Chamber (CMED), which sets a price-cap regulation model for drug prices.

This last point by Roche, regarding the drug's patent, was related to another legal proceeding in progress concerning the patent for the production of monoclonal antibodies.³¹ In this lawsuit, Genentech, a Roche subsidiary that developed the drug, demanded that its patent term should be counted not from the filing abroad, but from the filing in Brazil, which would extend several years of commercial patent exclusivity in the country.

This demand, however, contradicted all the jurisprudence of the Superior Court of Justice (STJ) on the subject, as recognized by the company itself in its initial petition. The process is still pending at the STJ and the company's request has so far been rejected in all decisions. It is notable that this company was also at the center of the Avastin & Lucentis case at the European Union, which, although distinct, contains similar behavioral patterns.³²

The Trastuzumab public civil action is now awaiting a second instance trial. The sentence, a final lower court decision, did not accept MPF's requests, based on two theses. First, that a compulsory licensing would be a measure of great impact, including international, and that a court should not decide in this sense; second, and more prominently, that the pharmaceutical market is regulated price-wise, and that the prices charged by Roche were all established within the price cap limits set by the regulatory authority, CMED.

Drug pricing regulation is a key instrument for governments to contain high prices on the pharmaceutical market. The Brazilian model was created in 2002 and works with a price cap methodology in which the national authority sets a maximum price for each product. The authority, the Pharmaceutical Market Regulations Chamber, is an inter-ministerial body enrolling the ministries of economics, justice and health and the medicines agency, ANVISA, which hosts the Chamber's Secretariat.

Even though there is evidence supporting the relevance and effectiveness of CMED's regulation on containing increases in drug prices,³³ there is also a strong criticism raised by civil society organizations and accounts overseeing bodies in Brazil that the price caps are too high, therefore allowing companies to charge extra amounts on transactions.³⁴

³¹ This is case number 0804078-49.2011.4.02.5101, which is currently being processed at the Superior Court of Justice (Superior Tribunal de Justiça) under the identification AREsp 1178467 / RJ (2017 / 0248879-3).

³² More information on the Avastin and Lucentis case is available from: <https://curia.europa.eu/jcms/upload/docs/application/pdf/2018-01/cp180006en.pdf>. Accessed 15 July 2021.

³³ Lara C. Pereira, et al., "Challenges in the regulation of high-cost treatments: An overview from Brazil", *Value in health regional issues*, vol. 20 (2019), pp. 191–195.

³⁴ Nathália Molleis Miziara and Diogo Rosenthal Coutinho, "Problemas na política regulatória do mercado de medicamentos", *Revista de saúde pública*, vol. 49 (2015).

Lessons from this case point out how important it is to connect drug pricing regulation with competition law and how an important policy, such as the one developed by CMED, might be used as a point to legitimate excessive pricing. When it comes to evaluating the conflict between competition's defense and regulation, the state act doctrine³⁵ might be useful as a framework to dismiss the apparent contradiction and indicate when competition authorities or competition law-based court decisions may come into effect.

The doctrine pictures the suspension of competition law enforcement when in conflict with regulation when the latter complies with two requirements: to expressly displace competition from the regulation policy and to guarantee effective supervision on regulation enforcement. The CMED case would not comply with either of these requirements, thus allowing the use of competition law.

Finally, more broadly, the transparency on the pharmaceutical market point could be useful to the present case. Transparency has been a global debate that is also a matter of concern at the national level in Brazil, as the company charges different prices for the same drug with different purchasers in the same country. The WHO resolution on market transparency approved by the World Health Assembly in 2019 addressed the issue of transparency on pricing.³⁶ Addressing this matter under competition law may be a potential path to promote access to medicines and solve the gap pointed out in the 2018 OECD report concerning patented medicines and excessive pricing. Although the point regarding logistics and scale consumption in the Trastuzumab case might indeed be applicable, the significant difference in prices and the lack of transparency regarding costs on the pharmaceutical market leave an open question about the fairness of the amounts charged by companies, like Roche, in this case and how justified (or not) such differences are.

³⁵ For further knowledge, see: https://www.law.cornell.edu/wex/state_action_requirement.

³⁶ World Health Organization. Improving the transparency of markets for medicines, vaccines, and other health products. *Seventy-second World Health Assembly* 28 May, 2019. Available from: https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-en.pdf. Accessed 11 July 2021.

4. GILEAD SCIENCES CASE: ALLEGED BUY-AND-RAISE AND EXCLUSIONARY PRACTICE

In 2019, nine civil society organizations³⁷ filed a complaint at CADE against the pharmaceutical company Gilead for abuse of a dominant position in relation to the drug Sofosbuvir in Brazil. The action is unprecedented in CADE for being the first on excessive prices of pharmaceuticals and the first proposed by patient and consumer groups.

Sofosbuvir, an antiviral drug for treatment of Hepatitis C, was developed by a start-up called Pharmasset through a partnership with a university and with significant public funding. After Phase III clinical trials, the company was purchased by Gilead, which released the drug in the US market and abroad under the brand name Sovaldi.³⁸ When released in 2013 in the US, it was sold at the extremely high price of US\$ 84,000. A US Senate investigative committee reported in 2015 that it did not find any justifiable relationship between investments in research and development and the launch price of Sofosbuvir.³⁹

The complaint in Brazil was based on research led by the Law and Poverty Group of the University of São Paulo, according to which between 2015 and 2018, a *de facto* monopoly period, Gilead supplied 99.96 per cent of the Sofosbuvir sold in the country. During this period, the average price charged ranged from R\$ 179.41 to R\$ 639.29 per pill of Sofosbuvir, resulting in revenue of R\$ 1.4 billion for purchases made by the Brazilian state alone. Due to high prices, the treatment had to be rationed, preventing a huge contingent of people from being treated and cured.

Between July 2018 and January 2019, University of São Paulo researchers point to a brief period of competition in which the amount charged by Gilead fell 89.9 per cent. After the patent was granted and until June 22 of this year (end of the period analyzed by the study), the average price per pill of Sofosbuvir rose 1,421.5 per cent in comparison with the original price. This is considered a period of formal monopoly, in which “arbitrary price increases” were observed.

The organizations requested the Brazilian competition body to fine Gilead and to impose, on an interim basis, the compulsory licensing of Sofosbuvir. As discussed earlier, in Brazil, the competition defense system law expressly provides for compulsory licensing as a measure to be adopted with both a function of mitigating effects and a punitive function. Thus, the flexibility of the TRIPS Agreement to address anti-competitiveness in the exercise of IPRs is integrated into the domestic legal framework. This measure would suspend the enforcement of Gilead patent rights and allow Sofosbuvir to be produced or imported and marketed in Brazil by other companies.

As alleged in the complaint, there was abuse of a dominant position in the marketing of Sofosbuvir in two dimensions: excessive pricing—adopted after obtaining the drug patent, and exclusionary practice—predatory conduct aimed at eliminating a competitor in the period prior to obtaining the patent.

³⁷ Public Defender's Office (DPU), Doctors without Borders, Idec, Human Rights Collective (CADHu), Brazilian Interdisciplinary AIDS Association (Abia), Grupo de Incentivo à Vida (GIV), São Paulo State AIDS NGO Forum (Foaesp), Rio Grande do Sul AIDS NGO Forum, AIDS Prevention Support Group (Gapa/BA), Grupo Solidariedade à Vida and Universities Allied for Essential Medicines (UAEM – Brazil).

³⁸ Michael McCarthy, “Hepatitis C drug maker puts profit ahead of patients, US Senate report charges”, *BMJ* (2015).

³⁹ <https://www.finance.senate.gov/imo/media/doc/11%20SFC%20Sovaldi%20Report%20Executive%20Summary.pdf>.

In fact, Gilead priced its medicine according to changes in the conditions of competition in three different periods in the timeline: first with *de facto* monopoly, then in a competition phase in which there was a competitor, and finally the *de jure* monopoly phase (after the patent was granted).

In the absence of other factors, exogenous or endogenous, that could explain such a drop in prices, only the presence of a competitor can explain this change in behavior in the pricing of the drug. The competition pattern was the only factor modified in the three events, exposing the causal link between obtaining a patent and overpricing.⁴⁰ When the competitor left the market, Gilead raised its price by 1.421 per cent, the average price for the public procurement scheme. As seen in other cases, such as the Aspen case in Italy,⁴¹ an unpredictable and big increase in price without an external shift in economic conditions is a good parameter to start evaluating excessive pricing.

After the complaint, CADE opened a preliminary investigation and is collecting data to decide if the complaint will become an inquiry. After two years of preliminary investigation, the General Superintendence still has not opened a formal inquiry. The relation between competition law and IP is a recent subject in Brazil and CADE can learn from the more active and progressive actions taken more recently by certain competition law authorities.⁴²

From the companies' side, it is worth discussing two important points directly related to the Brazilian context but also coherent with the global discussion: the legitimacy of the price according to the CMED regulation system and that the high prices were also a result of the other companies' actions on the supply chain, responsible for distribution and direct sell. The former falls on the same issues pointed at the Trastuzumab case, especially how new drugs in Brazil have an extremely high price cap. The latter deserves further attention.

Mark-ups on the supply chain in the pharmaceutical market are one of the transparency requirements usually raised by international organizations and civil society in order to fully understand price formation. There is very little information on that matter.

It is worth noting that in 2020, in the pandemic context, CADE's General Secretariat opened an inquiry to oversee the health technologies market and look for possible overpricing infractions. This action, initiated as an *ex officio*, included the requisition of price notes before and after the pandemic's onset from different companies, including in the pharmaceutical sector. This case acknowledges a key CADE competence, shared with other competition authorities and oversight bodies across the globe, i.e., the prerogative to demand information, including on innovation. As noted above, the lack of transparency is one of the main issues in the pharmaceutical sector,⁴³ allowing companies to overcharge and making it harder to fully understand the innovation, production and procurement processes.

⁴⁰ Lucia Helena Salgado, "The case of Sofosbuvir in Brazil: a natural experiment of abusive control of markets. 2021", Opinion offered to CADE to present arguments to overcome the controversy involving competition law and abusive prices in medicines. This document is public and can be found in case file no. 08700.005149/2019-18.

⁴¹ See summary of the Italian cases here: Italy, Excessive Pricing in Pharmaceutical Markets, 28 November 2018. Available from: [https://one.oecd.org/document/DAF/COMP/WD\(2018\)106/en/pdf](https://one.oecd.org/document/DAF/COMP/WD(2018)106/en/pdf).

⁴² Thus, it is important that the unconstitutionality recently declared by the Brazilian Supreme Court, contrary to the positions of ministers Roberto Barroso and Luiz Fux, is not once again used as a "wild card" in an attempt to revisit the competition law objectives. As Richard Epstein himself asserted, "The entire structure will be transformed for the worse if populist versions of competition law are allowed to dominate the area. It is a general proposition that bodies of law are good at doing one, and only one, task. The moment they are given two jobs—to promote efficiency and to create income equality, say—goals conflict and the doctrine muddles". JOTA, "Antitrust and intellectual property". Available from <https://www.jota.info/opiniao-e-analise/colunas/concorrenca-e-mercados/antitruste-e-propriedade-intelectual-20052021>. Accessed 15 July 2021.

⁴³ Vitor Henrique Pinto Ido, "Transparência no setor farmacêutico: uma nova dimensão do debate internacional sobre acesso a medicamentos?" *Trabalho, Educação e Saúde*. 2019, vol. 17, no. 3 Available from <https://doi.org/10.1590/1981-7746-sol00226>.

5. CONCLUSION AND RECOMMENDATIONS

The cases discussed here reveal the important role competition law can potentially play in post-grant flexibilities⁴⁴ in regulating the exercise of IPRs and advancing access to medicines, as well as the challenges in advancing these discussions in Brazil.

As noted by Carlos Correa, an adequate legal framework is a key component for using competition law-related TRIPS flexibilities.⁴⁵ The Brazilian competition legal framework provides instruments to reduce drug prices and restrain abusive and harmful practices in the pharmaceutical sector. It does allow a pharmaceutical company to be sanctioned regarding a specific drug-related intellectual property right because of an abusive economic practice.

CADE also has its own administrative process, regulated by its creation law and the Federal Administrative Procedure Law. These procedures may be faster and, even as a matter of principle, have less formality than court proceedings. In addition, the nature of the judges is substantially different, as the Administrative Tribunal admits counselors with in-depth knowledge of economics.

However, there are equally mishaps to consider. Orthodox economic theory does not acknowledge the concept of excessive pricing as part of competition law theory and practice in Brazil and the Americas in general. It is avoided as much as possible in orthodox theory because it goes beyond economic efficiency as an end in itself and encompasses the idea of fairness. This largely explains the reticence of CADE – and perhaps other jurisdictions in Latin America – to evoke the idea of an economic infraction *per se*.

Therefore, from both the theoretical and practical points of view, it is necessary to change the traditional view of competition law by expanding its concept to include elements like fairness, transparency and even access to essential goods. This has already been implemented in various ways: the broader view has been reflected in the abovementioned European Commission and South African decisions on excessive pricing, by the OECD Commission report and by novel theories that address competition law, for instance, the Neo-Brandeisian school,⁴⁶ which has now been explicitly integrated in the US Federal Trade Commission's current practices.

All that said, the Brazilian cases present potential lessons to other developing countries, and in that sense competition law authorities and civil society organizations willing to pursue this agenda should:

1. Consider moving beyond traditional views of competition law and integrating fairness as a parameter of evaluation;
2. Consider the big impact of monopolies on economics and that IP-based protection can cause harm to access to life-saving treatments and national economic development, thus requiring them to be addressed carefully, especially in the Global South;
3. Explore other, often overlooked, factors that influence pricing such as brand/trademarks, production capacity, industrial and trade secrets, marketing

⁴⁴ Post-grant flexibilities are the flexibilities within the framework of the TRIPS Agreement that apply after patent grant; in other words, they are hypotheses in which member states are not bound to protect IP rights after a patent is granted.

⁴⁵ Carlos M. Correa, "Intellectual property and competition – room to legislate under international law", in *UNDP, Using Competition Law to Promote Access to Health Technologies: A Guidebook for Low- and Middle-Income Countries*, F. M. Abbott (ed.). United Nations Development Program (2014) Available from SSRN: <https://ssrn.com/abstract=2439416>.

⁴⁶ Lina M. Khan, "Amazon's antitrust paradox", *Yale Law Journal*, vol. 126 (2016), p. 710.

practices and royalties. All of this is part of the analysis of the IP ecosystem and needs to be part of the competition law analysis portfolio;

4. Consider using competition authorities' prerogative to demand information on costs, including for research and development (R&D). CADE's powers to request documents and information, for instance, are broad and allow greater transparency on production, marketing, mark-ups and innovation costs, key factors indicated by the companies for pricing;
5. Do not assume, without further discussion, simplistic claims that any form of intervention against IP rights will be undermining innovation, especially in the Global South. There is empirical evidence to the contrary and without greater evidence it is not possible to automatically link monopoly-driven incentives to innovation;
6. Consider de-linking innovation costs from high prices, as many drugs are developed with public funding and the lack of transparency makes it harder to assume a direct link between costs and prices;
7. Address concrete economic issues in depth, in particular, information on prices (in domestic and foreign markets) and manufacturing costs. International jurisprudence can also be important to point out paths already traced by other competition authorities;
8. Consider the complementarity between regulation and competition law and that the latter can step in, especially on weak regulation or not well-enforced regulation;
9. Consider requesting information from other authorities, including foreign ones, and especially competition bodies that have already dealt with concrete related cases – for instance, a complaint about the same drug;
10. Consider the competition law system as one element within a broader ecosystem of economic regulation, which includes further institutions like drug pricing regulation authorities, market-approval agencies, courts and IP offices and value-based systems, including right to health and access expansion.

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ISSN 1819-6926