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Competition Law and Intellectual Property: A Study Drawing from The Eli Lilly Case on 'Sham Litigation' in Brazil

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Competition authorities may be the best equipped institutions to penalize certain illicit practices that involve intellectual property rights. This article analyzes the decision by the Brazilian Administrative Council for Economic Defense (Conselho Administrativo de Defesa Econômica – CADE) in the Eli Lilly case, in which the company was convicted for abusive use of the right to petition (sham litigation) with anti-competitive effects. It examines general aspects of technological dependence in the Brazilian pharmaceutical industry, presents the legal premises necessary for the understanding of the decision made by the competition authority, and analyzes the legal grounds for the sanction imposed on Eli Lilly.

Les autorités de la concurrence sont sans doute les plus à même de sanctionner certaines pratiques illicites touchant aux droits de propriété intellectuelle. Cet article analyse la décision du Conseil administratif de défense économique du Brésil (Conselho Administrativo de Defesa Econômica - CADE) dans l'affaire Eli Lilly, dans laquelle la société a été condamnée pour recours abusif à des fins anticoncurrentielles. Il examine les aspects généraux de la dépendance technologique envers l'industrie pharmaceutique au Brésil, présente les prémisses juridiques nécessaires à la compréhension de la décision prise par l'autorité de concurrence et analyse les fondements juridiques de la sanction infligée à Eli Lilly.

Puede que los organismos reguladores de la competencia sean las instituciones en mejor disposición para sancionar determinadas prácticas ilícitas relacionadas con los derechos de propiedad intelectual. En este artículo se analiza la decisión del Consejo Administrativo de Defensa Económica (Conselho Administrativo de Defesa Econômica, CADE) del Brasil en el caso de Eli Lilly, en el que se condenó a la compañía por un uso abusivo del derecho de petición (falso litigio) con efectos anticompetitivos. En el documento se examinan aspectos generales de la dependencia tecnológica en el sector farmacéutico brasileño, se presentan las premisas jurídicas necesarias para entender la decisión adoptada por el organismo regulador de la competencia y se analizan los fundamentos jurídicos de la sanción impuesta a Eli Lilly.

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1. Introduction

The relationship between Competition Law and Intellectual Property (IP) Law is frequently studied from two general perspectives, i.e., either complementarity or opposition. However, this simple dichotomic approach is not sufficient for the full comprehension of the actual legal, political, and economic challenges that arise from the topic. Considering thematic, geographic, or sectoral differences would allow to reveal the details of the interfaces between these legal norms.

Taking this observation into account, this paper aims at analyzing the topic by looking into the decision made by the Administrative Council for Economic Defense (Conselho Administrativo de Defesa Econômica - CADE), the Brazilian authority for competition defense, in the 2016 Eli Lilly case. On that occasion, CADE convicted the company for abusive use of the right to petition (sham litigation) with anti-competitive effects.

It is important to note that this text will deal with only one aspect of the interface between the two sets of legal norms, namely the one derived from the violation committed by Eli Lilly. The article is based on the premise that competition law *can* be applied to promote economic structures that are more conducive to the continuous process of innovation. One example is how the European Union has applied competition law to punish violations by companies in dominant positions.[1] Such a premise is more relevant in countries such as Brazil, given its economic and technological dependence in many areas, including the production of active pharmaceutical ingredients (APIs).

Competition law interventions that promote innovation can occur in at least three ways, whether intellectual property rights are involved or not: promotion of interoperability; prohibition of competitors' denigration; and sanction for misuse of the patent system[2], which will be discussed here.

The paper is divided into three sections. First, it will present general aspects of the Brazilian pharmaceutical industry, briefly touching on the peculiarities of the technological dependence in this sector. Second, legal issues regarding intellectual property rights in Brazil, essential to the understanding of the Eli Lilly case, will be considered. In the last section, the decision by CADE will be analyzed to demonstrate how the competition authority can contribute to prevent or sanction illicit practices involving intellectual property rights.

2. General aspects of the Brazilian pharmaceutical industry

The beginning of the Brazilian pharmaceutical industry traces back to the 1930s. Multinational companies established themselves in the country only since the 1950s, when a first wave of mergers and acquisitions of local firms by foreign companies took place. According to Júlia Paranhos, the multinationals continued to develop activities in the country and, by the 1970s, they accounted for 75% of the domestic market.[3] It is worth mentioning that multinationals established in Brazil some phases of manufacturing and marketing, but research and development (R&D) activities continued to be restricted to the global North countries.

The participation of these companies grew to 85% in the 1980s and further expanded during the 1990s. The advent of neoliberal governments to power promoted the abrupt opening of the market, the reduction of tariff barriers, and the process of currency appreciation against the dollar. This frustrated efforts to develop the local industry, including through the Drug Center (Central de Medicamentos - Ceme) and the Technological Development Company (Companhia de Desenvolvimento Tecnológico - Codetec). Also, this national economic policy caused a significant increase in imports. In this period, not even the manufacturing and marketing activities were done in the country, as the finished products were imported.[4]

[1] Pablo LEURQUIN, "Proteção da inovação do Direito da Concorrência da União Europeia: análise da indústria farmacêutica", *Revista de Direito Internacional*, v.18, n.2 (2021).
[2] Pablo LEURQUIN, *Proteção da inovação pelo Direito da Concorrência* (Belo Horizonte, Editora Expert, 2021).
[3] Júlia PARANHOS,, "Interação entre empresas e instituições de ciência e tecnologia no sistema farmacêutico de inovação brasileiro: estrutura, conteúdo e dinâmica, 327 f. Tese (Doutorado em Economia) – Instituto de Economia da Universidade Federal do Rio de Janeiro, Rio de Janeiro, 2010, p. 58 e s.
[4] Ibid.

The denationalization of the pharmaceutical industry continued until the publication of Law n. 9.782/1999, which established the National System for Health Surveillance and created the National Agency for Health Surveillance (Agência Nacional de Vigilância Sanitária - ANVISA). This legislation - known as the 'Generics Law' - allowed for the development of a generic industry in Brazil. It also promoted the growth of local companies by stimulating the relations between them and science and technology institutes (Institutos de Ciência e Tecnologia - ICTs), as well as making it possible to obtain funding for R&D.

The new innovation policy was an addition to other forms of state financing, as well as to the development of the Brazilian ICTs, which are for the most part publicly owned. The result of this new perspective on the relationship between the State, the industry and ICTs, was a progressive increase in the participation of generics in the Brazilian market. They went from 5.29% of the total pharmaceutical market in 2004, to 31.86% in 2017, similar to what was found in Spain (31%), although still far from France (42%), Germany (66%), and the United Kingdom (60%), countries that are more advanced in terms of their generics industry.[5]

In spite of the growth in this sector, there has been little progress in terms of local innovations. Júlia Paranhos and Lia Hasenclever argue that this is linked to the limited investment in R&D. According to the authors:

> What is done today in terms of modernization is only the dissemination of foreign innovation, and not the generation of innovation inside the country that may contribute to the development and growth of companies and a better competitive position in the national market. The focus of this sector in the production of generic drugs, the small size of most companies, the limited resources, and the lack of interest of multinational companies to invest in R&D activities in Brazil, greatly contribute to explain the low level of innovation in the pharmaceutical sector in the country. (Our translation. Original in footnote[6].)

It is not the aim here to advance any reflections on what industrial policies Brazil should implement to develop the pharmaceutical sector[7]; however, it is important to note that countries such as India and China provide examples of internationalization of R&D, unlike Brazil.[8] This brief overview confirms the continuity of a profound technological dependence of the country in this sector[9]. Also, it helps to contextualize the legal issues involving intellectual property rights on pharmaceuticals.

3. Legal issues involving intellectual property rights that impact competition in the Eli Lilly Case

Law n. 9.279, published on May 14, 1996, revoked the Code of Industrial Property, Law n. 5.772, published on December 21, 1971. Brazil quickly adopted legislation aligned with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the expansionist tendency that characterized the post-TRIPS period. Brazil did not utilize the transition period given to developing countries to implement specific TRIPS-compliant legislation.[10]

Instead, some provisions of the law actually give more protection than the minimum standards required by TRIPS, notably the '*pipeline protection*' which allowed for the revalidation in Brazil of certain patents granted abroad (see section below). Another relevant development under Brazilian domestic law was the interpretation that the TRIPS provisions are directly applicable, which led to a debate with respect to the so-called Exclusive Marketing Rights (EMRs) (also see below). Both issues were subsequently relevant to the Eli Lilly sham litigation case herein discussed.

[5] PROGENÉRICOS, Associação brasileira das indústrias de medicamentos genéricos, "Dados do mercado", 2017.
[6] O que se faz hoje em termos de inovação é apenas a difusão de inovação estrangeira, e não a geração de inovação dentro do país, em que pese sua contribuição para o desenvolvimento e crescimento das empresas e um melhor posicionamento competitivo no mercado nacional. O foco do setor na produção de medicamentos genéricos, o pequeno tamanho da maioria das empresas, as limitações de recursos e o desinteresse das empresas multinacionais em investir em atividades de P&D no Brasil contribuem fortemente para explicar o baixo nível de inovações no setor farmacêutico do país. Julia PARANHOS and Lia HASENCLEVER, "A proteção patentária e a interação empresa-ICT no sistema farmacêutico de inovação brasileiro", *Radar IPEA*, n. 29 (2013), pp. 39-48.
[7] On development opportunities in herbal and biosimilar industries, see: Lia HASENCLEVER, Júlia PARANHOS, Cíntia Reis COSTA, Gabriel CUNHA, Diego VIEIRA, "A indústria de fitoterápicos brasileira: desafios e oportunidades", *Ciência & Saúde Coletiva*, n. 22(8), 2017, pp. 2559-2569. See also: Eduardo Braz Pereira GOMES, Renato ROSSETO, Lucimar PINHEIRO, Lia HASENCLEVER, Júlia PARANHOS,"Desenvolvimento de biossimilares no Brasil" *Fronteiras*: Journal of Social, Technological and Environmental Science, v. 5, n. 1 (jan.-jun. 2016), pp. 31-42.
[8] Júlia PARANHOS,, "Interação entre empresas e instituições de ciência e tecnologia no sistema farmacêutico de inovação brasileiro: estrutura, conteúdo e dinâmica, 327 f. Tese (Doutorado em Economia) – Instituto de Economia da Universidade Federal do Rio de Janeiro, Rio de Janeiro, 2010, p. 69.
[9] Padmashree Gehl SAMPATH, "Technology and inequality: can we decolonise the digital world?", *South Views* n. 215 (Geneva, South Centre, 6 April 2021). Available from https://www.southcentre.int/wp-content/uploads/2021/04/SouthViews-Sampath.pdf.
[10] Carlos CORREA, "TRIPS agreement and access to drugs in developing countries", *Emory International Law Review*, v. 17, n. 2 (2003).

a) Pipeline Patents under Law n. 9.279/96

The revalidation of patents allowed for the recognition of patents obtained outside Brazil under certain conditions, if the request was made within one year of the publication of the 1996 Law.[11] In accordance with the law:

> Art. 230. A patent relating to substances, materials, or products obtained through chemical processes, and the substances, materials, mixtures or food products, chemical-pharmaceutical, and drugs of any kind, as well as the respective processes for acquisition or modification, can be requested by whoever has guaranteed protection in a treaty or convention in force in Brazil, *with the guarantee of the date of the first deposit abroad*, as long as its object has not been released in any market by the direct action of the holder or by a third party with the holder's consent, nor have been made by third parties, in the country, serious and effective preparations for exploring the object of the request or patent. ((Emphasis added; our translation. Original in footnote[12].)

This provision allowed therefore to rely on the examination made by a foreign patent office, with no respect for the novelty criterion applied in Brazil. In practical terms, the revalidation of patents allowed for the granting of patent protection to products that were already in the public domain in Brazil, since the former Brazilian legislation did not consider them patentable. [13]

One of the consequences of this system was the weakening of the generic drug industry and the subsequent rise in prices of medicines. Research has shown that Brazil pays up to sixty times the value of generics as compared to India, for example.[14] According to the Brazilian Interdisciplinary AIDS Association (Associação Brasileira Interdisciplinar de AIDS - ABIA), 1,182 pipeline patent applications were filed, of which, 45% were from the United States of America, 13% from the United Kingdom, 10% from Germany, 9.6% from Japan, and 7.7% from France. At least 340 drugs, which would not have been protected without the *pipeline* mechanism, received protection in Brazil.

One example is *Efavirenz*, used in the treatment of HIV/AIDS, which was protected by a *pipeline* patent. It cost US $580.00 per patient/year, until in April 2007 when the patent was declared of public interest and a compulsory license was issued. This license allowed the Brazilian government to buy the generic Indian version for US $190.00 (one hundred ninety dollars) per patient/year, until local production ensued in February 2009.[15]

Denis Barbosa states that revalidation patents do not derive from the negotiation of TRIPS, which is silent on such matter. The author further recalls that the negotiating parties rejected the incorporation of the "*pipelines protection*" in the final text of what would become the TRIPS Agreement. Moreover, Barbosa highlights that, since 1987, there has been pressure from the USA for Brazil to grant pharmaceutical patents. In January 1987, after negotiations between the Brazilian government and the USA commercial representatives, the removal of unilateral sanctions was agreed upon in exchange for a package of measures in favor of foreign patent holders. These pressures remained until the publication of the law, in 1996, even in spite of presidential changes in the period.[16]

b) Exclusive Marketing Rights (EMRs) in Brazil

The exclusive marketing rights (EMRs) during the transition period for developing countries was another

[11] The revalidation patents should not be confused with the *"mail box"* of art. 70.8 of TRIPS, according to which the Member-States had to receive patent filings to be examined after the end of the transition period. Contrary to the pipeline, the *"mail box"* allowed for the analysis of the patent application under the criteria of the new legislation.

[12] Art. 230. Poderá ser depositado pedido de patente relativo às substâncias, matérias ou produtos obtidos por meios ou processos químicos e as substâncias, matérias, misturas ou produtos alimentícios, químico-farmacêuticos e medicamentos de qualquer espécie, bem como os respectivos processos de obtenção ou modificação, por quem tenha proteção garantida em tratado ou convenção em vigor no Brasil, *ficando assegurada a data do primeiro depósito no exterior*, desde que seu objeto não tenha sido colocado em qualquer mercado, por iniciativa direta do titular ou por terceiro com seu consentimento, nem tenham sido realizados, por terceiros, no País, sérios e efetivos preparativos para a exploração do objeto do pedido ou da patente.

[13] Since 2009, the Direct Unconstitutionality Action n. 4234 is being processed at the Federal Court of Justice, questioning articles 230 and 231 of Law n. 9.279, published on May 4, 1996, under the rapporteur of Minister Carmen Lúcia. The two main arguments questioned by the Attorney General's Office are the disrespect for the novelty in concession of patents and the public domain irreversibility. However, there is yet no decision on the merit of the issue.

[14] Pedro Henrique VILLARDI MIRANDA, Francisco Viegas Neves da SILVA, Amanda Mey Carmo PEREIRA, *Perguntas e respostas sobre patentes Pipeline: como afetam a sua saúde?* (Rio de Janeiro, ABIA, 2009), pp. 7-9.

[15] For the list of drugs protected by revalidation patents, see the table prepared by the Interdisciplinary Brazilian AIDS Association (Associação Brasileira Interdisciplinar de AIDS (ABIA)): ABIA, "Identificação de produtos de patente pipeline". Available from http://www.abiaids.org.br/_img/media/ID_pipeline.xls.

[16] Denis Borges BARBOSA, "Sempre a inconstitucionalidade das patentes pipelines: uma visão renovada" (Jul. 2013).

element in TRIPS that impacted the pharmaceutical policy. In Brazil, there has been a discussion with practical implications about the recognition of such rights in the domestic legal system. As will be further shown, the alleged existence of EMRs was one of the arguments presented by Eli Lilly in the case commented below.

Article 70.9 of TRIPS created an obligation to grant exclusive marketing rights for pharmaceutical and chemical products for agriculture, without defining its precise legal form. It states:

> 70.9. 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.

Two aspects must be analyzed with regard to the debate on the incorporation of the EMRs into the Brazilian law: (i) to determine whether there is direct application of the TRIPS Agreement under Brazilian law; and (ii) to define the content and scope of EMRs.

The TRIPS agreement creates international obligations for the World Trade Organization (WTO) Members, but not direct obligations in the internal order. This interpretation derives from article 1.1 of TRIPS, which recognizes the freedom of Members in determining the appropriate way to implement the provisions of the Agreement in their respective legal systems and practices.

Denis Barbosa reaffirms this argument inasmuch as he does not characterize the TRIPS Agreement as a uniform law, for it does not build up a legal framework that directly confers rights to individuals. Thus, the recognition of EMRs depends on regulation through Brazilian legislation, which has never been enacted.

In addition, Barbosa emphasizes that the EMR, if its existence was to be accepted, faces another obstacle under the Brazilian legal system. The EMRs only apply to the patent applications that are in accordance with art. 70.9, i.e., those that utilized the mailbox. The possibility of applying for *mailbox* patents lasted only until January 1, 1995, according to the Provisional Measure n. 2.105-15, 2001, which was converted into the Law n. 10.196, published on February 14, 2001.[17]

In view of these arguments, it can be concluded that EMRs as such were not contemplated in the Brazilian legal system. However, as shown in the Eli Lilly case presented here, this argument was used in an attempt to legally extend patent protection.

4. The Eli Lilly Case

Eli Lilly do Brasil Ltda. and Eli Lilly and Company filed several lawsuits against the National Industrial Property Institute (Instituto Nacional de Propriedade Industrial - INPI) and the National Institute of Health Surveillance (Agência Nacional de Vigilancia Sanitária - ANVISA), in different judicial districts (Rio de Janeiro and Distrito Federal). The different lawsuits, as discussed below, led to the improper obtaining of marketing exclusivity for the high-cost cancer drug gemcitabine hydrochloride. In view of these facts, an administrative proceeding against Eli Lilly was launched by CADE's Secretary of Economic Law (Secretaria de Direito Econômico - SDE) on 12 January 2011. In June 2016, Eli Lilly do Brasil Ltda. and Eli Lilly and Company were sentenced by CADE[18] to pay a fine of R$ 36.600.000,00 (thirty-six million six-hundred thousand Brazilian reais) for abusive use of the right to petition (sham litigation), due to its harmful effects on competition. [19] The subsections below provide a deeper analysis of the case, based on three topics that were clarified by CADE's administrative court regarding which conducts were anti-competitive. The analysis is based on the vote by Councilor Ana Frazão. The topics are: a discussion on the applicability of the TRIPS Agreement right after its enactment (not anti-competitive), the illicit changes to the scope of patent applications filed by the companies (anti-competitive), and the effect of the 'fictitious' patent protection which was sought after via courts (anti-competitive).

[17] Denis Borges BARBOSA, "Direitos exclusivos de comercialização: um instituto inexistente no direito brasileiro" (2010), p. 20 e s.
[18] The CADE is composed of five councilors. In each case a rapporteur is nominated. When his/her vote is submitted to the plenary, the other councilors present their respective votes. The decision is made by the simple majority of councilors.
[19] It should be noted that not all lawsuits filed by the companies denoted an abusive practice, i.e., the filing of lawsuits is not per se illegal. It is therefore necessary to determine which behaviors by the companies are unlawful from a competition point of view. See CADE counselor Ana Frazão's vote: BRASIL, CADE, Voto da conselheira relatora Ana Frazão no processo n. 08012.011508/200791, *Associação Brasileira das Indústrias de Medicamentos Genéricos Pró-Genéricos x Eli Lilly*, 24 jun. 2016.

a) The discussion on the applicability of the TRIPS Agreement in 1996-2011: how the early behaviors by Eli Lilly were not deemed to be anti-competitive

On 21 June 1993, Eli Lilly filed a patent application for the "process to prepare a nucleoside enriched with beta-anomer" at INPI (PI 9302434-7). On 6 February 1996, after the TRIPS Agreement was enacted and ratified by Brazil, the company made a new administrative request to INPI for the examination of its previously filed application. However, INPI denied such request on the basis of Law n. 5.772 of 1971, which did not grant protection to pharmaceutical patents. INPI also argued that the TRIPS Agreement did not apply unrestrictedly and automatically, clarifying that it would only be applicable after one year and that, in addition to that, Brazil had the right to wait four years to apply the provisions of said agreement, that is, until January 1, 2000 (in accordance with art. 65.2 on the transition period for developing countries).

The new Industrial Property Law (Law n. 9.279) was published on 14 May 1996. It included the controversial revalidation patents procedure known as "pipeline patents' discussed above. Eli Lilly did not file a specific request at INPI within a year to benefit from such mechanism.

Eli Lilly did not accept the administrative decision referred to above and filed a lawsuit at the Rio de Janeiro Federal Court, requesting its annulment. The first instance decision dismissed the claim. However, the Regional Federal Court (Tribunal Regional Federal - TRF) of the 2nd Region (i.e., the Federal Appeal's Court) [20] nullified the administrative act that had refused patent application PI 9302434-7. In other words, it resubmitted the application to INPI for a new patentability criteria analysis to be undertaken.[21]

A subsequent lawsuit aiming at nullifying said decision ("ação rescisória") was submitted to INPI. On 30 June 2011, the Appellate Court of the 2nd region (TRF-2) ruled against Eli Lilly and in favor of INPI, i.e., it confirmed that no patents should be granted for pharmaceuticals in this case, given the applicable timeline of the TRIPS Agreement.[22]

The CADE decision considered that the demands by Eli Lilly in 1996 to have patent protection in 1996 were not anti-competitive. In other words, in none of the lawsuits mentioned in this subsection it could identify the use of abusive petition right with anti-competitive effects. Thus, bringing to courts a discussion surrounding the application of the TRIPS Agreement in 1996 (prior to the new legislation) was deemed legitimate.

b) Illicit changes to the scope of patent applications

Despite the legality of the first cases, others followed a different path: in 2004, a court ruling nullified INPI's decision to not grant Eli Lilly a patent for the "process to prepare a nucleoside enriched with beta-anomer". INPI then re-analyzed the patent application submitted by Eli Lilly on 17 February 2005. The patent was again rejected, this time based on the lack of inventive activity. In response to the negative, Eli Lilly presented on 6 July 2006 a new set of claims in the patent application. However, INPI denied, for the third time, the request made by the company.

At this point, the company presented two new set of claims in the patent application, changing its scope and content: it started to refer to it as a patent application to the "proceeding to prepare a nucleoside enriched with beta-anomer", and began referring to the claim as "preparation of a nucleoside enriched with beta-anomer *and compound*" (process and product patent) [23].

[20] The Brazilian federal justice system is composed, in the first instance, by federal judges and is organized into five regions. Each region corresponds to a Federal Regional Court (Federal Appeal's Court). The decisions of federal judges of first instance may be reviewed by the upper courts of the region to which they belong.

[21] BRASIL, TRF 2ª região, 4ª turma, *Apelação,* Processo n. 0531698-61.2001.4.02.5101 (TRF 2 2001.51.01.531698-3), Rapporteur: Federal Judge Rogério Carvalho, 3 mar. 2004.

[22] Three arguments were accepted by the court: (i) the failure to meet the requirements presented in the articles 229, 230, and 231 of Law n. 9.279/96 (revalidation patents); (ii) enforcement of the 1971 law, as the term to be considered in the patent request is the deposit date; and (iii) the nonexistence of a norm in the legal order regulating the unrestricted application of the TRIPS Agreement. BRASIL, TRF 2ª região, *Ação rescisória*, Processo n. 0009600-09.2007.4.02.0000 (TRF 2 2007.02.01.009600-2), Rapporteur: Federal Judge Messoud Azulay Neto, 30 jun. 2011.

[23] Brazilian law does not allow for amendments of the patent application claims, unlike some other systems. BRASIL, CADE, Vote of the reporting counselor Ana Frazão in process n. 08012.011508/200791, *Associação Brasileira das Indústrias de Medicamentos Genéricos Pró-Genéricos x Eli Lilly*, 24 jun. 2016.

Before INPI took a decision regarding these new claims, the administrative proceeding was suspended by virtue of a lawsuit filed on 4 August 2005. In such lawsuit, Eli Lilly requested the second rejection decision by INPI be annulled. Similar to what had been done in the patent application process, the company also tried to amend its claims in the lawsuit to include the new set of claims, thus altering its scope as well. The intention was to extend the protection to the product resulting from the claim. Thus, the strategy used by the company was to use this stratagem to illegally exclude generic competition from the market. This part of the strategy created by the company was not successful, as the Rio de Janeiro courts did not accept the request to introduce a broader patent application scope, and did not even discuss the possibility of bestowing patent protection for the product.

In the CADE decision, Councilor Ana Frazão stated that **this sequence of submissions to INPI and the courts denoted that the company tried to illegally bypass the administrative jurisdiction, and that this behavior constituted the beginning of Eli Lilly's anti-competitive practice.**

c) The anti-competitive effects of 'fictitious' patent protection based on Eli Lilly's conducts with the judiciary and INPI

After the unsuccessful strategy mentioned in the previous subsection, yet another lawsuit was filed by Eli Lilly. Such legal action was taken against the national regulatory agency ANVISA, and filed at the Federal Justice in the Distrito Federal. The lawsuit referred to a request for the recognition of EMR of gemcitabine hydrochloride in the terms of art. 70.9 of TRIPS – which, as discussed above, was not incorporated into Brazilian law in the first place. According to the company, the request for patent protection would be for the *product,* and not the process. By so doing, Eli Lilly did not inform the judge that it had *itself* altered its patent application claims at INPI after multiple rejection decisions, nor that the request to analyze previous claims had been equally denied by the Rio de Janeiro courts.

Without sufficient information (and, in fact, due to these willful omissions), the Federal District Court of Law[24] determined on 19 June 2007 that ANVISA should abstain from authorizing products similar to Gemzar (owned by Eli Lilly), until the final and unappealable decision of the lawsuit. The effects of such ruling persisted until March 7, 2008, when it was suspended by the Superior Court of Justice (Superior Tribunal de Justiça - STJ). This decision was based on the recognition of the monopoly effects of the injunction, as it hindered consumer access to the generic versions of the drug. In the continued illegal pursuit of extending its monopoly, Eli Lilly released slanderous information about Sandoz generic drugs, stating that its GEMCIT registration of the drug had been canceled.

Eli Lilly legally requested that Sandoz stop marketing its product. The court decision stayed in effect from 28 September 2007 to 21 December 2007, when the São Paulo Court of Appeals (Tribunal de Justiça de São Paulo - TJSP) accepted the possibility that Sandoz sell the drug for other types of cancer other than breast cancer. During this three-month period, Sandoz was not able to sell its drug and was banned from complying with the biddings it had won.

As a result of this strategic litigation, Eli Lilly enjoyed an undue monopoly that distorted prices, bringing damage to the public purse. According to the study of ProGenéricos, this was evident at the on-site public bidding sessions promoted by the São Paulo State Secretary of Health, when it was verified that the gemcitabine (1 g injection) was offered at R$ 530,00 (five hundred thirty reais) per unit[25].

In this context, the reporting counselor at CADE concluded that in trials for abuse of the right to petition with anti-competitive effects, the following elements should be analyzed: **plausibility of the actions, truthfulness of given information, and proportionality of the means used.** As the counselor clarifies:

[24] The Federal District Court of Law is the second instance (court of appeals) of the state justice of the Federal District.
[25] In the two public sales held by the São Paulo Secretary of Health (Secretaria de Saúde de São Paulo) for the acquisition of gemcitabine, 6,000 boxes were purchased, and the seller in the second situation was Sandoz.

Thus, the inclusion of the requests 15 and 16, in fact, did not aim at defining more precisely the object of the patent, but was part of a strategic behavior by the plaintiff that, previewing the impossibility of obtaining the patent, intended to alter its scope as a means to, later, obtain the grant of exclusive marketing right through the EMR. In fact, as will be seen below, this alteration was essential for the plaintiff to make use of the afore mentioned institute, as TRIPS only admits the EMR grant for product patents and not processes (§ 280). (Our translation. Original in footnote [26].)

Therefore, **the unlawfulness of Eli Lilly's behavior began, as mentioned, with the attempt to change the scope of the patent application at INPI. The company persisted with its unlawful strategy when it maliciously concealed information about the dismissal of the administrative lawsuit, misleading the magistrate to error, leading him to believe that INPI would give a positive response to its claim (i.e., grant of a product patent). This was followed by the exercise of the unlawfully achieved monopoly by Eli Lilly.**[27]

The condemnation by CADE also considered the court case filed by Eli Lilly against INPI at the Federal District Federal Justice, which had the same content as the one that was at the parallel proceeding at the 2nd region TRF. In this latter judicial instance, the decision had already been against Eli Lilly's interests. Thus, the attempt to choose the most favorable court (*forum shopping*) was another dimension in the instrumentalization of the right to petition for anti-competition ends.

Lastly, there is one essential difference between the Brazilian perspective adopted by CADE and the US theory of sham litigation[28]. While CADE's approach, based on civil and antitrust legislations in Brazil, does not require subjective guilt (i.e., intent) for an antitrust offense to be verified, the 'sham litigation' doctrine tends to require such stricter criteria. Based on this difference, in practice, the company violated the duty of care and objective good faith when it failed to inform the exact situation of the object of its request, as a tactic to obtain a favorable ruling. Hence, the application of the *sham litigation* theory would not even be necessary for the antitrust penalty. The Brazilian legal tradition itself, notably when considering abuse of the right to petition, offers its own legal grounds to punish this type of behavior.

5. Conclusions

The decision in the Eli Lilly case demonstrates both the necessity and the possibility for competition authorities such as CADE to penalize IP-related abuses under competition law. In particular, it highlights that intellectual property rights holders may abuse their right to petition (sham litigation) with anti-competitive effects. Furthermore, the ruling enables a reflection on the fact that some abusive practices, such as the ones sanctioned by CADE, are hardly noticed by the judiciary or by IP offices, thereby stressing the importance of competition defense authorities to scrutinize such behaviors.

The case offers a useful lesson for other developing countries and suggests the need to enhance inter-agency cooperation, strengthen their investigative capacity and pay particular attention to the role of IP in anti-competitive conducts. Competition authorities can provide solutions for gaps and abuses which arise from the exercise of intellectual property rights, which IP offices cannot address on their own. Therefore, the role of competition authorities needs to be 'expansionist' in their attention to anti-competitiveness with respect to IP (in fact, the opposite from the existing trend of expansionist intellectual property rights). This is even more important in technologically dependent countries, where access to technologies is even more crucial.

As a final word, competition authorities such as CADE, particularly in light of the technological dependence that characterizes the global South (and even more so in the pharmaceutical sector), should enhance and amplify their analyses of the violations to the economic order involving intellectual property rights. This is also

[26] Assim, a inclusão das reivindicações 15 e 16, na verdade, não visava a definir, de forma mais precisa, o objeto da patente, mas fazia parte de um comportamento estratégico da representada que, antevendo a impossibilidade de obtenção da patente, pretendia alterar seu escopo para, posteriormente, obter a concessão do direito de comercialização exclusivo por meio do EMR. De fato, como se verá adiante, essa alteração era essencial para que a representada pudesse fazer uso do referido instituto, na medida em que o TRIPs só admite a concessão de EMR para patentes de produto e não de processo (§ 280).

[27] On the new claims presented by Eli Lilly, it should be noted that there was a decision by INPI indicating that they extrapolated the application, which does not comply with the legislation in the country (§ 339).

[28] Ioannis LIANOS and Pierre REGIBEAU, ""Vexatious"/ "Sham" litigation in EU and US Antitrust Law: a mechanism design approach", *Antitrust bulletin*, v. 62, n. 4 (2017). Available from https://awa2018.concurrences.com/IMG/pdf/cles-1-2017.pdf.

the case for CADE: a cross-sectoral analysis of its decisions involving IP reveals that, overall, the topic has only been seldom addressed by the competition authority. This gap calls for more action to be taken to protect the public interest in cases of misuse or abuse of IP.

References:

Associação Brasileira Interdisciplinar de AIDS (ABIA). Identificação de produtos de patente pipeline. Available from http://www.abiaids.org.br/_img/media/ID_pipeline.xls.

BARBOSA, Denis Borges (2010). Direitos exclusivos de comercialização: um instituto inexistente no direito brasileiro.

BARBOSA, Denis Borges (2013). Sempre a inconstitucionalidade das patentes pipelines: uma visão renovada, pp. 1-32.

BRASIL, Conselho Administrativo de Defesa Econômica (CADE). Voto da conselheira relatora Ana Frazão no processo n. 08012.011508/200791. *Associação Brasileira das Indústrias de Medicamentos Genéricos Pró-Genéricos x Eli Lilly*. 24 jun. 2016. Available from https://sei.cade.gov.br/sei/modulos/pesquisa/md_pesq_processo_exibir.php?KOXi3eEqJC73dCc3G_MH5w73G76ivtXYDDG65Jr7vK4fhNNdRnnFDgAfJTIfRn8_ywCudV1gCNGrQiNgXFAcnSTTvwj1qQmjdE7tb7qYNhwaL0Vf-YBkgi1bioFNDs9V.

BRASIL, Tribunal Regional Federal (TRF) 2ª região, 4ª turma. Processo n. 0531698-61.2001.4.02.5101 (TRF2 2001.51.01.531698-3) (Relator: Desembargador Federal Rogério Carvalho). 03 mar. 2004. Available from http://www10.trf2.jus.br/consultas/?movimento=cache&q=cache:hv3SBucPZzkJ:trf2nas.trf.net/iteor/TXT/RJ0106410/1/57/82270.rtf+&site=v2_jurisprudencia&client=v2_index&proxystylesheet=v2_index&lr=lang_pt&ie=UTF-8&output=xml_no_dtd&access=p&oe=UTF-8.

BRASIL, TRF 2ª região. *Ação rescisória*. Processo n. 0009600-09.2007.4.02.0000 (TRF2 2007.02.01.009600-2). 30 jun. 2011. Available from http://www10.trf2.jus.br/consultas/?movimento=cache&q=cache:yvhG85cQtRQJ:trf2nas.trf.net/iteor/TXT/RJ0101310/1/5/357334.rtf+&site=v2_jurisprudencia&client=v2_index&proxystylesheet=v2_index&lr=lang_pt&ie=UTF-8&output=xml_no_dtd&access=p&oe=UTF-8.

CORREA, Carlos (2003). TRIPS agreement and access to drugs in developing countries. *Emory International Law Review*, v. 17, n. 2.

GOMES, Eduardo Braz Pereira, Renato ROSSETO, Lucimar PINHEIRO, Lia HASENCLEVER, Júlia PARANHOS (2016). Desenvolvimento de biossimilares no Brasil. *Fronteiras*: Journal of Social, Technological and Environmental Science, v. 5, n. 1, pp. 31-42. Available from https://www.researchgate.net/publication/304608997.

HASENCLEVER, Lia, Júlia PARANHOS, Cíntia Reis COSTA, Gabriel CUNHA, Diego VIEIRA (2017). A indústria de fitoterápicos brasileira: desafios e oportunidades. *Ciência & Saúde Coletiva*, n. 22(8), pp. 2559-2569. Available from http://www.scielo.br/pdf/csc/v22n8/1413-8123-csc-22-08-2559.pdf.

LEURQUIN, Pablo (2021). Proteção da inovação pela aplicação do Direito da Concorrência da União Europeia: análise da indústria farmacêutica. *Revista de Direito Internacional*, v. 18, n.2. Available from https://www.publicacoesacademicas.uniceub.br/rdi/article/view/7663/pdf.

LEURQUIN, Pablo (2021). P*roteção da inovação pelo Direito da Concorrência*. Belo Horizonte: Editora Expert.

LIANOS, Ioannis and Pierre REGIBEAU (2017). "Vexatious"/ "Sham" litigation in EU and US Antitrust Law: a mechanism in design approach. *Antitrust bulletin*, v. 62, n. 4. Available from https://awa2018.concurrences.com/IMG/pdf/cles-1-2017.pdf.

MIRANDA, Pedro Henrique Villardi, Francisco Viegas Neves da SILVA, Amanda Mey Carmo PEREIRA (2009). *Perguntas e respostas sobre patentes Pipeline: como afetam sua saúde*? Rio de Janeiro: ABIA. Available from http://www.abiaids.org.br/_img/media/PergResp_PIPELINE_PT.pdf.

PARANHOS, Júlia (2010). Interação entre empresas e instituições de ciência e tecnologia no sistema farmacêutico de inovação brasileiro: estrutura, conteúdo e dinâmica. 327 f. Tese (Doutorado em Economia) – Instituto de Economia da Universidade Federal do Rio de Janeiro, Rio de Janeiro.

PARANHOS, Julia and Lia HASENCLEVER (2013). A proteção patentária e a interação empresa-ICT no sistema farmacêutico de inovação brasileiro. *Radar IPEA*, n. 29, pp. 39-48. Available from http://repositorio.ipea.gov.br/handle/11058/5430.

PROGENÉRICOS, Associação brasileira das indústrias de medicamentos genéricos. Dados do mercado.

SAMPATH, Padmashree Gehl (2021). Technology and inequality: can we decolonise the digital world? *South Views* n. 215. South Centre. Available from https://www.southcentre.int/wp-content/uploads/2021/04/SouthViews-Sampath.pdf.

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