143 Research Paper
11 January 2022

Brazilian Competition Law and Access to Health in Brazil: Exploitative Pricing in the Pharmaceutical Sector

Bruno Braz de Castro

SOUTH CENTRE

RESEARCH PAPER

143

BRAZILIAN COMPETITION LAW AND ACCESS TO HEALTH IN BRAZIL: EXPLOITATIVE PRICING IN THE PHARMACEUTICAL SECTOR*

Bruno Braz de Castro**

SOUTH CENTRE

11 JANUARY 2022

*This research paper was translated from Portuguese by Dr. Natanael F. França Rocha.

** Bruno Braz de Castro is a researcher, lawyer and consultant specializing in Brazilian Competition Law. He holds a PhD and a Master's degree in Economic Law from the Federal University of Minas Gerais, Belo Horizonte, Brazil.

SOUTH CENTRE

In August 1995, the South Centre was established as a permanent intergovernmental organization. It is composed of and accountable to developing country Member States. It conducts policy-oriented research on key policy development issues and supports developing countries to effectively participate in international negotiating processes that are relevant to the achievement of the Sustainable Development Goals (SDGs). The Centre also provides technical assistance and capacity building in areas covered by its work program. On the understanding that achieving the SDGs, particularly poverty eradication, requires national policies and an international regime that supports and does not undermine development efforts, the Centre promotes the unity of the South while recognizing the diversity of national interests and priorities.

NOTE

The views contained in this paper are attributable to the author/s and do not represent the institutional views of the South Centre or its Member States. Any mistake or omission in this study is the sole responsibility of the author/s.

Any comments on this paper or the content of this paper will be highly appreciated. Please contact:

South Centre
International Environment House 2
Chemin de Balexert 7–9
POB 228, 1211 Geneva 19
Switzerland
Tel. (41) 022 791 80 50
south@southcentre.int
www.southcentre.int

Follow the South Centre's Twitter: South_Centre

ABSTRACT

This paper aims to analyze the interfaces between Brazilian Competition Law and the issue of access to medicines, with a special focus on abuse of industrial property rights and related exclusionary and exploitative effects. The paper analyzes the case law of Brazilian Administrative Council for Economic Defense (CADE) in the pharmaceutical sector and discusses abusive practices such as illegitimately imposing non-existent or invalid intellectual property rights with anticompetitive purposes. It then addresses abusive strategies in the exercise of industrial property rights which are, in essence, valid: i.e., exclusionary practices, aimed at artificially raising barriers to entry; and exploitative practices, directly translated as the exercise of market power to the detriment of the consumer. The latter ultimately result in exploitative excessive prices; contractual, quality or privacy degradation; and restrictions on supply, such as by hoarding/preventing the exploitation of industrial property rights. The paper concludes that the prohibition of exploitative pricing under the current competition law is legally valid and effective, with certain methodological concerns towards reducing the risk of wrongful convictions (for instance, by applying screening tests to determine the markets that are candidates for intervention). In view of such guidelines, the pharmaceutical industry appears to be an important candidate for antitrust attention, given the magnitude of the harm potentially derived from non-intervention against the practice. Remedies in this area, importantly, should focus on identifying and solving the sector's structural competitive problems. In the case of medicines subject to price regulation by the Drug Market Regulation Chamber (CMED), the technical expertise of the competition authority may be of great value in terms of competition advocacy, a fact that is demonstrated in light of recent discussions on extraordinary price adjustments because of competitive problems in certain markets.

El objetivo de este trabajo es analizar las interfaces entre el Derecho de la Competencia brasileño y el tema del acceso a los medicamentos, con especial atención a los abusos de los derechos de propiedad industrial en sus efectos de exclusión y explotación. El trabajo analiza la jurisprudencia del Consejo Administrativo de Defensa Económica (CADE) en el sector de los medicamentos y discute los abusos que buscan la imposición ilegítima de derechos de propiedad intelectual inexistentes o inválidos con fines anticompetitivos. A continuación, aborda los abusos en el ejercicio de los derechos de propiedad industrial que son, en sí mismos, válidos: las prácticas excluyentes, destinadas a elevar artificialmente las barreras de entrada, y las prácticas de explotación, que se traducen directamente en el ejercicio del poder de mercado en detrimento del consumidor. Estas últimas se traducen en precios excesivos explotadores, degradaciones contractuales, degradaciones de la calidad o de la intimidad, así como restricciones a la oferta como el acaparamiento/impedimento de la explotación de los derechos de propiedad industrial. El artículo concluye a favor de la validez y eficacia jurídica de la prohibición de los precios de explotación por parte de la actual Ley de la Competencia, con ciertas preocupaciones metodológicas para minimizar el riesgo de condenas erróneas (como la construcción de pruebas de "screening" de mercados-candidatos a la intervención). En atención a tales directrices, el sector de los medicamentos aparece como un importante candidato a la atención antimonopolio, dada la magnitud de los daños potencialmente derivados de la no intervención sobre la práctica. Las soluciones en este ámbito, sobre todo, deben centrarse en identificar y resolver los problemas estructurales de competitividad del sector. En el caso de los medicamentos sujetos a la regulación de precios por parte de la Cámara de Regulación del Mercado de Medicamentos (CMED), la experiencia técnica de la autoridad de la competencia puede ser de gran valor en la defensa de la competencia, lo que se demuestra a la luz de los recientes debates sobre los ajustes extraordinarios de precios debido a problemas de competencia en un mercado determinado.

O presente trabalho tem por objeto analisar interfaces entre o Direito da Concorrência brasileiro e o tema do acesso a medicamentos, com especial atenção aos abusos de direitos de propriedade industrial em seus efeitos exclusionários e exploratórios. O trabalho analisa a jurisprudência do Conselho Administrativo de Defesa Econômica (CADE) no setor de medicamentos e discute os abusos visando à imposição ilegítima de direitos de propriedade intelectual inexistentes ou inválidos com finalidade anticompetitiva. Em seguida, aborda os abusos no exercício de direitos de propriedade industrial que sejam, por si, válidos: práticas exclusionárias, voltadas à elevação artificial de barreiras à entrada, e práticas exploratórias, traduzidas diretamente no exercício de poder de mercado em detrimento ao consumidor. Estas últimas são manifestadas na forma de preços excessivos exploratórios, degradações contratuais, de qualidade ou de privacidade, bem como restrições na oferta como o açambarcamento/impedimento de exploração de direitos de propriedade industrial. O artigo conclui pela validade e eficácia jurídica da proibição a preços exploratórios pela Lei de Defesa da Concorrência vigente, com certas preocupações metodológicas a fim de minorar o risco de condenações errôneas (como a construção de testes "screening" de mercados-candidatos a intervenção). Em atenção a tais diretrizes, o setor de medicamentos comparece como candidato importante à atenção antitruste, haja vista a magnitude dos prejuízos potencialmente derivados da não-intervenção sobre a prática. Remédios nessa seara, de modo importante, devem focar na identificação e solução dos problemas competitivos estruturais do setor. Em caso de medicamentos sujeitos à regulação de preços pela Câmara de Regulação do Mercado de Medicamentos (CMED), a expertise técnica da autoridade concorrencial poderá ser de grande valia em sede de advocacia da concorrência, o que é demonstrado à luz das discussões recentes acerca do reajuste extraordinário de preços em virtude de problemas concorrenciais de determinado mercado.

L'objectif de cet article est d'analyser les interfaces entre le droit de la concurrence brésilien et le thème de l'accès aux médicaments, en accordant une attention particulière aux abus des droits de propriété industrielle dans leurs effets d'exclusion et d'exploitation. L'ouvrage analyse la jurisprudence du Conseil administratif de défense économique brésilien (CADE) dans le secteur des médicaments et discute des abus visant à imposer de manière illégitime des droits de propriété intellectuelle inexistants ou invalides à des fins anticoncurrentielles. Elle aborde ensuite les abus dans l'exercice des droits de propriété industrielle qui sont, en eux-mêmes, valables : les pratiques d'exclusion, visant à élever artificiellement les barrières à l'entrée, et les pratiques d'exploitation, directement traduites en l'exercice d'un pouvoir de marché au détriment du consommateur. Ces dernières sont manifestées par des prix excessifs, des dégradations contractuelles, des dégradations de la qualité ou de la vie privée, ainsi que des restrictions à l'offre telles que la thésaurisation ou l'entrave à l'exploitation des droits de propriété industrielle. L'article conclut à la validité juridique et à l'efficacité de l'interdiction des prix d'exploitation par la loi actuelle sur la concurrence, avec certaines préoccupations méthodologiques afin de minimiser le risque de condamnations injustifiées (telles que la construction de tests de "dépistage" des marchés candidats à l'intervention). En tenant compte de ces lignes directrices, le secteur des médicaments apparaît comme un candidat important pour l'attention antitrust, étant donné l'ampleur des dommages potentiellement dérivés de la non-intervention sur la pratique. Il est important que les mesures correctives dans ce domaine se concentrent sur l'identification et la résolution des problèmes structurels de concurrence du secteur. Dans le cas des médicaments soumis à la réglementation des prix par la Chambre de régulation du marché des médicaments (CMED), l'expertise technique de l'autorité de la concurrence peut être d'une grande valeur dans la défense de la concurrence, ce qui est démontré par les récentes discussions sur les ajustements extraordinaires des prix en raison de problèmes de concurrence sur un marché donné.

TABLE OF CONTENTS

1. INTRODUCTION

This paper aims to analyze the interfaces between Brazilian Competition Law and the issue of access to medicines, with a special focus on abuse of industrial property rights and related exclusionary and exploitative effects.

After this introductory section, the paper will focus on discussing the interface between Competition Law and Industrial Property with reference to the case law supporting the Brazilian Administrative Council for Economic Defense (CADE) especially in decisions regarding the pharmaceutical sector. It then addresses abusive uses of industrial property rights within the Brazilian legal framework for industrial property protection (at the administrative and/or judicial levels), regarding the illegitimate imposition of non-existent or invalid intellectual property rights with anticompetitive purposes.

Subsequently, the paper discusses abusive strategies in the exercise of industrial property rights which are, in essence, valid: i.e., exclusionary practices aimed at artificially raising barriers to entry, and exploitative practices, specifically the exercise of market power to the detriment of the consumer; which ultimately result in excessive prices; contractual, quality or privacy degradation; and restrictions on supply, such as by hoarding/preventing the exploitation of industrial property rights.

Thereafter, the paper goes on to analyze in greater detail the arguments held under CADE case law on exploitative pricing. It concludes that the prohibition of exploitative pricing under the current competition law is legally valid and effective, with certain methodological concerns towards reducing the risk of wrongful convictions (for instance, by applying screening tests to determine the markets that are candidates for intervention). In the scope of such guidelines, the pharmaceutical industry appears to be an important candidate for antitrust attention, given the magnitude of the harm potentially derived from the non-intervention against the practice. Remedies in this area, importantly, should focus on identifying and solving the sector's structural competitive problems. In the case of medicines subject to price regulation by the Drug Market Regulation Chamber (CMED), the technical expertise of the competition authority may be of great value as regards competition advocacy, a fact that is demonstrated in the light of recent discussions on extraordinary price adjustments because of competitive problems in certain markets.

2. COMPETITION AND INDUSTRIAL PROPERTY IN BRAZIL'S COMPETITION LAW

The protection of industrial property in Brazil, whose beginnings date back to the times of the Empire,[1] has the status of a right and is a fundamental guarantee under the Constitution of the Federative Republic of Brazil of 1988, currently in force.[2] In addition to this, the TRIPS Agreement was incorporated into Brazilian legislation by Decree 1,355/1994.

As regards patents on medicines, the adoption of the TRIPS led to important changes. As a matter of fact, the legislation in force until then – the Brazilian Industrial Property Code (Law No. 5772/1971) – did not grant patentability to "*substances, matter, mixtures or food, chemical-pharmaceutical products and medicines, as well as the respective processes of obtaining or modifying them*" (Article 9, c).

This non-patentability regime for medicines ended with the enactment of the current Industrial Property Law (IPL), Law No. 9279/1996 (Cf. Art. 8 *et seq.*, c/c Arts. 229 to 232).

On the other hand, IPL provides for – in accordance with the provisions of the TRIPS Agreement – compulsory licensing in cases of abusive exercise of rights, abuse of economic power (Art. 68, *caput*), non-exploitation/insufficient exploitation (Art. 68, §1), unsatisfactory exploitation based on the market needs (Art. 68, §1, II), patent interdependence (Art. 70), and national emergency/public interest (Art. 71). The enforcement of the LPI, in particular the registration and granting of industrial property rights – as well as the compulsory licensing of patents – is the responsibility of the Brazilian National Institute of Industrial Property (INPI).

Compulsory licensing in the context of abuse of economic power is an object of special importance as regards how competitiveness will be handled in specific sectors such as the pharmaceutical sector – marked by industrial property centralization as a strategic variable of competition[3].

In general, the pharmaceutical sector demands priority attention from the competition authority in view of economic characteristics such as high concentration and high barriers to entry, highlighting the need for large investments in research and development, and the strategic role of the architecture of industrial property rights (patents), in addition to demand-side issues such as low-price elasticity and information asymmetries (the "credential goods" nature of medicines).[4]

Anticompetitive practices that unduly extend the patent term – such as those discussed below – have a direct impact on access to medicines, as they cause artificial scarcity of the good.

---

[1] For a history of the evolution of industrial property protection in Brazil and compulsory licensing of medicines in Brazil, see AMARAL, Luciene Ferreira Gaspar; MALVEIRA, Sandra. *Acesso às Patentes de Medicamentos de Interesse da Saúde Pública em Tempo de Pandemia.* Revista Direito.UnB. 2020, V. 04, N. 02 (Tomo II), pp. 17–42. Available from https://bit.ly/2Vzhj1n, accessed on 8 August 2021.

[2] The Constitution of the Federative Republic of Brazil of 1988 establishes, as fundamental rights and guarantees (Art. 5, XXIX), that "the law shall ensure the authors of industrial inventions of a temporary privilege for their use, as well as protection of industrial creations, property of trademarks, names of companies and other distinctive signs, viewing the social interest and the technological and economic development of the country".

[3] Discussing the use of compulsory licensing for access to health in developing countries; See IDO, Vitor Henrique Pinto. Designing Pro-Health Competition Policies in Developing Countries. Research Paper No. 125. (Geneva, South Centre, December 2020). Available from https://bit.ly/3iuNaJI, pp. 27–28.

[4] "Credential goods" nature indicates that the quality of the good is not salient to the consumer, requiring an intermediary agent for such assessment (e.g., a physician). See FIUZA, Eduardo P. S. LISBOA, Marcos de B. *Bens Credenciais e Poder de Mercado: Um Estudo Econométrico da Indústria Farmacêutica Brasileira*. Texto para Discussão nº 846. Instituto de Pesquisa Econômica Aplicada (Ipea), 2001. Available from https://bit.ly/3fLUpek, p. 11.

A study by DEE—the CADE Department of Economic Studies—on "pharmaceutical patent awarding" in Brazil, based on the 2012 Medicines Market Monitoring System Database (Sammed), concluded that patents have a significant impact on supracompetitive pricing in the pharmaceutical sector:

> "In fact, the robust results obtained showed that without a patent, prices fell – on average – by around 66 per cent in the pharmaceutical market. **In this way, any artificial defenses of market power can guarantee a reasonable overprice, which is why surveillance and systematic analysis of the sector are justified**" (emphasis added).[5]

Like industrial property rights, free competition has constitutional status, appearing as a principle of the economic order (Art. 170, IV).[6] Going further, the Brazilian Constitution determines that "*The law shall repress the abuse of economic power that aims at the domination of markets, the elimination of competition and the arbitrary increase of profits*" (Art. 173, §4).

By the same token, the Antitrust Law in Brazil (Law No. 12529/2011) establishes the Brazilian Competition Defense System (SBDC), comprised of the Secretariat for Competition and Competitiveness Advocacy (as per Art. 19) or literally "Secretariat for Economic Monitoring" (SEAE); and the Administrative Council for Economic Defense (CADE) – a special autarchy with adjudicating power and with administrative jurisdiction over the entire Brazilian territory in cases of mergers (Art. 88) and violations against the economic order (Art. 36).

Art. 36 establishes a system of classification by effects, considering illegal any conduct, *in any way manifested* and regardless of fault, that can potentially produce the following effects: "*I – to limit, restrain or in any way injure free competition or free initiative; II – to control the relevant market of goods or services; III – to arbitrarily increase profits; and IV – to abusively exercise a dominant position*".

Additionally, the same provision presents an illustrative list of conduct that, once the aforementioned effects are produced, may constitute a violation against the economic order. The most prominent among them are:

> *XIX – to abusively exercise or exploit intellectual or industrial property rights, technology or trademark; and*
>
> *XIV – to monopolize or prevent the exploitation of industrial or intellectual property rights or technology*.

Still in terms of industrial property, the Antitrust Law, among the penalties provided for (Art. 38, IV), establishes a recommendation to the competent public agencies so that "*a compulsory license over the intellectual property rights held by the wrongdoer be granted, when the violation is related to the use of that right*", and establishes a determination of sale of assets (Art. 38, V). The approval of mergers may also be linked to the imposition of restrictions by the Tribunal of CADE, among which is included "*compulsory licensing of intellectual property rights*" (Art. 61, §2, I).

---

[5] The Study was published in Annex II to the Vote of Councilor-Rapporteur Ana Frazão in the Eli Lilly case. CADE. Administrative Proceeding No. 08012.011508/2007-91. Vote of Councilor Ana Frazão. 2015. Available from https://bit.ly/2VKigEk.

[6] Constitution of the Federative Republic of Brazil/1988, Art. 170. "*The economic order, founded on the appreciation of the value of human work and on free enterprise, is intended to ensure everyone a life with dignity, in accordance with the dictates of social justice, with due regard for the following principles: (...) IV – Free competition*".

The provisions listed above demonstrate that Brazilian legislation is grounded on the notion of complementarity between Antitrust and Industrial Property, which has been guiding CADE's case law on the matter,[7] as can be seen, for example, in the ANFAPE case, decided in 2018.[8]

Industrial property rights are conceived as instruments to guarantee the appropriability of investments in innovation,[9] allowing product differentiation and limiting the "free-riding" behavior of imitators.[10] On that account, even though the regular exercise of industrial property rights can lead to static inefficiencies, it is argued that incentives for innovation derived from them would act as an important competitive driver, from the perspective of dynamic efficiency and economic development.[11]

IP rights are therefore not conceived as cases of immunity to or exemption from competition law; they are, instead, analyzed as typical elements of competitive dynamics or strategic variables of competition, with peculiar effects in each specific case.[12] Accordingly, such rights – as well as any other business assets – can be exercised abusively when coupled with anticompetitive strategies, such as those aimed at eliminating competition, market domination, abusive exercise of a dominant position, or arbitrary increase of profits, under the terms of the competition legislation in force (Law No. 12529/2011, Art. 36, items I to IV).[13]

---

[7] See FILHO, Calixto Salomão. Teoria Crítico-Estruturalista do Direito Comercial. Marcial Pons: São Paulo, 2015, p. 152 (understanding industrial property as a special case for the enforcement of competition law).

[8] CADE. Administrative Proceeding No. 08012.002673/2007-51. Petitioner: Associação Nacional dos Fabricantes de Autopeças (ANFAPE). Respondents: Volkswagen do Brasil and others.

[9] Possas and Mello (2012, p. 133), on the importance of appropriability as a raison d'être of industrial property law, analyze: "*Intellectual property owes its economic significance to its constituting a property right, a socially acknowledged power of disposition and control over economic opportunities, which ensures the appropriability that its object is not physically and naturally provided with. Particularly relevant is its capacity to guarantee the possibility of appropriating the profits from the innovative effort to its owner, by hindering imitation and, thus, restricting competition to some degree".* POSSAS, Mario Luiz. MELLO, Maria Tereza Leopardi. *Antitrust and Intellectual Property: Conflicts and Convergences*. In: BURLAMAQUI, Leonardo. *et al.* (editors). "Knowledge Governance: Reasserting the Public Interest". New York: Anthem Press, 2012.

[10] In his vote for the ANFAPE case, Councilor Paulo Burnier da Silveira established "two purposes – (i) to encourage innovation and product differentiation and (ii) to prevent opportunistic behavior – which justify the exclusivity granted to the holder of the industrial property right, often to the detriment of competition. This, then, is the economic and social end of industrial property rights." CADE. Administrative Proceeding No. 08012.002673/2007-51. Vote of Councilor-Rapporteur Paulo Burnier. 2017. Available from https://bit.ly/2U4gwoJ.

[11] In the Vote of Councilor Carlos Ragazzo for the ANFAPE case, "Because it is aware of the vital role of differentiation and innovation in economic development and the well-being of society and consumers, antitrust law is receptive to accept this apparent and temporary restriction of competition from a static point of view, which in the short term may even cause decreases in supply, price increases and the exclusion of consumers, in favor of dynamic efficiency, which in the long term will increase competition for innovations and the introduction of new and better products and services, in favor of economic development and consumers". See CADE. Administrative Proceeding No. 08012.002673/2007-51. Vote of Councilor-Rapporteur Carlos Emmanuel Joppert Ragazzo. 2010. Available from https://bit.ly/3s1rY0Q, §33.

[12] In this regard, see Possas and Mello (2012, op. cit., p. 133) "*Intellectual property is not an antithesis of competition; it is rather a competition tool that, as others, may be used to obtain and/or maintain monopolistic positions. Its incentive-with-restraint effects are not dichotomous; on the contrary, the incentive and restraint dimensions are inherent and inseparable. Both are part of the same process – competition – and it is within this sphere, including companies' competitive strategies, that they must be dealt with*".

[13] See the Vote of Councilor Carlos Ragazzo for the Anfape case: "although it is certain that the exercise of industrial property rights does not constitute, in any way, an anticompetitive conduct *per se*, and that many times it does not even grant any market power to its holder, not infrequently these rights have anticompetitive effects which, effectively, imply an illegal anticompetitive conduct, subject to intervention by the antitrust authority *(...)*". CADE. Administrative Proceeding No. 08012.002673/2007-51. Vote of Councilor-Rapporteur Carlos Emmanuel Joppert Ragazzo. 2010. Available from https://bit.ly/3s1rY0Q, §34.

CADE's case law on the subject, although non-exhaustive,[14] has in fact been grounded in the notion of abuse of rights[15] to issue decisions of cases in which the exercise of an industrial property right proves incompatible with its economic and social purpose.

Finally, acknowledging as necessary the interface between antitrust and industrial property protection systems[16] also entails a discussion about the institutional design and governance between CADE and INPI. The position established in CADE's case law is that INPI is the relevant authority to examine and grant industrial property rights, and it is not the role of CADE to review INPI decisions or decide on patent term specifically.[17] Notwithstanding, as INPI does not examine abuse of industrial property rights granted under IPL, it is up to CADE to investigate any possible violation of the competition order in these contexts.[18]

In 2018, CADE and INPI signed a Technical Cooperation Agreement providing for joint action regarding the relationship between intellectual property and antitrust, with measures such as the exchange of information, data and documents; the provision of technical support in administrative proceedings; the conducting of joint studies and events; and other measures.[19]

2.1 Structural Control

Mergers in the pharmaceutical sector are especially worrisome when they enable the exercise of market power—with rising consumer prices or risks of shortages—, distort incentives for research and development of new treatments, or lead to problematic concentration of industrial property rights in the merged entity.[20]

Under Law 12529/2011, business contracts are subject to prior control by CADE (Art. 88, §§3 and 4) whenever such practices: constitute *acts of economic concentration*[21] (Art. 90); are

---

[14] For further details on case-law evolution in this context, see CUEVA, Ricardo Villas Bôas. A proteção da propriedade intelectual e a defesa da concorrência nas decisões do CADE. Revista do IBRAC, São Paulo, v. 15, n. 1, pp. 121–147, 2009. Available from https://bit.ly/3jJyZzY.

[15] In the case of Automotive Parts, the Councilor-Rapporteur Paulo Burnier da Silveira and other votes referred to the idea of abuse of rights which, according to Art. 187 of the Brazilian Civil Code of 2002, is characterized when the exercise of a right "manifestly exceeds the limits imposed by its economic or social order for the good faith or good morals". CADE. Administrative Proceeding No. 08012.002673/2007-51. Vote of Councilor-Rapporteur Paulo Burnier. 2017, cit., p. 26.

[16] On negative consequences of poorly designed intellectual property systems, see Stiglitz (2008): "a poorly designed intellectual property regime—one that creates excessively "strong" intellectual property rights—can actually impede innovation". STIGLITZ, Joseph E. *Economic Foundations of Intellectual Property Rights*. Duke Law Journal, vol. 57, p. 1696, 2008. Available from https://bit.ly/3Cp58VM.

[17] In the ANFAPE case, Councilor Paulo Burnier distinguished between the analysis of obtaining the IP right and the analysis of its abusive exercise: "In summary, CADE is not responsible for analyzing the validity of industrial design registrations on automotive parts granted by INPI to the Respondents, as it is a matter outside the competence of the antitrust authority. (...) What will be examined here, in accordance with the Antitrust Law, is the possible abuse in the exercise of rights in a way that it harms competition and may therefore constitute a violation of the economic order" (2017, op. cit., §129).

[18] Councilor Carlos Ragazzo, in the ANFAPE case, justified the competition control also in light of the fact that INPI does not investigate the competition impacts of registered rights: "It is the fact that no examination of abuse is part of INPI's analysis of economic power or harmful economic-competitive effects that may result from the industrial property rights granted. The agency, correctly, does not take these aspects into account, simply because they are not among the concession requirements that must be observed by it based on the Industrial Property Law. (...) **It is evident, however, that INPI does not carry out such analysis of abuse.** (...) the legal and legitimate granting of industrial property registration, even with the seal of INPI and Industrial Property Law, does not prevent the right lawfully obtained from being exercised in an abusive way" (2010, op cit., § 195).

[19] For details of the Agreement, see https://bit.ly/3w0TOwF.

[20] See EUROPEAN UNION. European Commission. *Competition Enforcement in the Pharmaceutical Sector (2009-2017)*. Luxemburgo: Publications Office of the European Union, 2019. Available from https://bit.ly/3s1dZbs , p. 10.

[21] Under art. 90 of the Brazilian Antitrust Law, economic concentration acts are defined as mergers, acquisition of control or parts of one or other companies, incorporations, associative contracts, consortia and joint ventures. Details of the criteria for notification of corporate transactions (acquisition of unitary or shared control, minority

performed on the national territory or produce or may produce effects thereon (Art. 2); and meet the minimum transaction criteria of Art. 88. Importantly, CADE may condition the approval of mergers to the imposition of "*applicable restrictions in order to mitigate occasional negative effects of the act of economic concentration over the affected relevant markets*" (Art. 61, §2), including compulsory licensing of intellectual property rights. Such restrictions (or antitrust remedies) comprise, according to the list of Art. 61, §2: *"I – the sale of assets or a group of assets that constitutes a business activity; II – the spinoff of the company; III – transference of corporate control; IV – accounting or legal division of activities; V – compulsory licensing of intellectual property rights; and VI – any other act or measure necessary to eliminate the harmful effects to the economic order*".

An analysis published in 2012 concluded that, of 83 mergers in the pharmaceutical sector, 80 were approved without restrictions and only 3 had restrictions as a condition for their approval, and in two of them the restrictions were not specifically related to the pharmaceutical sector.[22]

In this regard, a case in point is CADE decision, in 2010, for the merger that consisted in the acquisition of 100 per cent of the capital stock of Medley Indústria Farmacêutica S.A.—leader in Brazil's generics market at the time—by Sanofi-Aventis Brasil Group, which, after the buyout, consolidated itself as the laboratory with the highest revenue in Brazil, in both generic and branded drug markets.[23] After considering the need for caution regarding the acquisition of generic companies by manufacturers of reference medicines, the Councilor-Rapporteur of the case undertook a detailed analysis of horizontal overlapping and conditions of rivalry in the affected sectors, and concluded that there were competition concerns in two therapeutic subclass markets, A03F0 and B01C2, belonging to the dimension of *products*, as defined by the ATC (Anatomical Therapeutic Chemical) classification system.[24] The approval of the merger was conditional upon the sale of the medicines Digedrat, Peridal and Loprigel to a company with a maximum market share of 15 per cent in the relevant markets in question.

Another example is the joint venture, in 2015, between GlaxoSmithKline PLC (GSK) and Novartis AG, comprising GSK healthcare products and Novartis' over-the-counter products.

---

acquisitions above 5 per cent or 20 per cent, depending on the competitive situation, etc.) are found in Arts. 9 to 11 of CADE Resolution No. 02/2012.

[22] In both cases, the intervention was related to contractual clauses, such as non-compete clauses (AC 08012.009079/2008-72) and a clause establishing that the eventual disapproval of the act by CADE would not affect the validity of the contract between the parties. See SAMPAIO, Patricia Regina Pinheiro. GUIMARÃES, Heitor Campos de. Competências da Autoridade Concorrencial em Setores Regulados: Considerações à luz da jurisprudência do Cade no setor de medicamentos. *Economic Analysis of Law Review*, vol. 3, No. 2, pp. 281–306, Jul-Dec 2012, p. 303. Available from https://bit.ly/2VE7X4D .

[23] Merger File (AC) No. 08012.003189/2009-10. Merging Parties: Sanofi-Aventis Farmacêutica Ltda and Medley S.A. Indústria Farmacêutica. Vote of Councilor-Rapporteur César Costa de Alves Mattos. 2010. Available from https://bit.ly/3CwA5aJ.

[24] Regarding the definition of relevant market in the pharmaceutical sector, CADE jurisprudence has mostly adopted the ATC methodology, prepared by the European Pharmaceutical Marketing Research Association (typically the ATC4 level), although, depending on the case, additional or alternative criteria are considered , such as the active pharmaceutical principle ("API"), therapeutic indication, distinction between ethical-non-ethical, and, in older cases, a study commissioned by the then Secretariat of Economic Law (SDE) in the early 2000s. See SAFATLE, Leandro Pinheiro. LEAL, João Carvalho. BARBOSA, Luiz Coimbra. Castro, Bruno Ribeiro de. Procedimentos para a definição e análise antitruste de mercados relevantes de medicamentos. Contrato SDE/MJ n. 1/2003. ANPEC-IPEA. Available from https://bit.ly/3xzCs8M. See also Technical Opinion of the General Superintendence in Merger File (AC) No. 08700.004123/2012-86 (Takeda Brasil and Multilab), with a definition of market combining the ATC methodology with additional criteria and citing precedents. Merger File (AC) No. 08700.004123/2012-86. Merging Parties: Takeda Farmacêutica do Brasil Ltda. and Multilab Indústria e Comércio de Produtos Farmacêuticos. CADE General Superintendence Technical Opinion No. 100. 2013. Available from https://bit.ly/3jBQ0Mm. The relevant geographic market is typically defined as national, in light of health regulations that significantly limit the entry of imported medicines. See, for example, for case law in the same vein, Opinion No. 6/2015/CGAA1/SGA1/SG: Merger File (AC) No. 08700.009834/2014-09. Merging Parties: União Química Farmacêutica Nacional S.A. and Novartis Biosciences S.A. Opinion No. 6/2015/CGAA1/SGA1/SG. 2015. Available from https://bit.ly/2VIrvVA.

The approval of the deal was conditional upon the sale of the assets of GSK's nicotine replacement therapy business ("Niquitin").[25]

Also in 2015, CADE General Superintendence contested the buyout of the company Genix Industria Farmacêutica by the company Capsugel Brasil, pointing to a high concentration in the national market of rigid capsules used as an input in the production of medicines, which eventually made the Parties quit the negotiations.[26]

In 2019, there took place the joint venture by which GlaxoSmithKline PLC acquired control over Pfizer Inc.'s consumer healthcare sector.[27] The analysis identified horizontal overlapping in five markets,[28] but concluded that there was a competitive risk only in the domestic market for simple antacids (A2A1) in view of the high combined market share (62.9 per cent). The approval of the merger was therefore conditional upon the sale of the assets of Pfizer CH's magnesium hydroxide business.

2.1.1 Licensing of intellectual property

Still in the scope of structural control, it is worth noting CADE's prior control of intellectual property licensing agreements when these fall within the definition of "associative contracts" (Art. 90, IV) by Law 12529/2011.[29] CADE has extensive case law precedence on defining associative contracts in the context of intellectual property, structured around the analysis of exclusivity and non-compete clauses, thereby no intervention is made in the absence of such clauses[30] In 2014, CADE signed an understanding in the sense that intellectual property licensing agreements must be notified even when, in the absence of an explicit exclusivity clause, they contain atypical clauses that restrict independent competition and/or represent a joint venture.[31] In 2016, CADE enacted Resolution No. 17, providing that associative contracts under mandatory notification are only those "*with a duration equal to or greater than 2 (two)*

---

[25] Merger File (AC) No. 08700.008607/2014-66. Merging Parties: GSK and Novartis. Opinion No. 13/2015/CGAA1/SGA1/SG. 2015. Available from https://bit.ly/3fEWiJV.

[26] See Merger File (AC) No. 08700.009711/2014-78. Merging Parties: Capsugel Brasil Importação and Distribuição de Insumos Farmacêuticos e Alimentos Ltda. and Genix Indústria Farmacêutica Ltda. Opinion No. 3/2015/CGAA2/SGA1/SG. Available from https://bit.ly/3BZiCGh.

[27] Merger File (AC) No. 08700.001206/2019-90. Merging Parties: GSK and Pfizer. Vote of Councilor-Rapporteur Paula Farani de Azevedo, 2019. Available from https://bit.ly/2X229SY.

[28] Although considering possible limitations and alternative methodologies, the relevant market here was also defined according to the ATC methodology – a position mostly adopted by the Council – plus a distinction, in some specific cases, between prescription and over-the-counter medicines. See Opinion No. 11/2019/CGAA1/SGA1/SG of CADE's General Superintendence on the subject, in the same process. Merger File (AC) No. 08700.001206/2019-90. Merging Parties: GSK and Pfizer. Opinion No. 11/2019/CGAA1/SGA1/SG, 2019. Available from https://bit.ly/3lLYqmR.

[29]. Law 12529/2011 - "*Art. 90. For the purposes of Article 88 of this Law, a concentration act shall be carried out when: (...) IV - two (2) or more companies enter into an associative contract, consortium or joint venture*". Authors such as Paula Forgioni also argue that general contracts involving intellectual property may also fall under the hypothesis of item II of Art. 90 ("*II - one (1) or more companies acquire, directly or indirectly, by purchase or exchange of stocks, shares, bonds or securities convertible into stocks or assets, whether tangible or intangible, by contract or by any other means or way, the control or parts of one or other companies*"). See FORGIONI, Paula A. Os fundamentos do antitruste. 9. Ed. São Paulo: Revista dos Tribunais, 2016, p. 417.

[30] For a summary of CADE's case law evolution, see BARRIOS, Lucas. O contrato internacional de transferência de tecnologia e o direito da concorrência no Brasil: Análise à luz da recente jurisprudência do CADE. Revista de Defesa da Concorrência, v.2 n.2., 2014. Available from https://bit.ly/3fLAkVM. Likewise, the vote of Councilor-Rapporteur Alessandro Octaviani for the Monsanto-Bayer merger has an extensive case-law survey on the subject. Merger File (AC) No. 08700.004957/2013-72. Merging Parties: Monsanto do Brasil and Bayer S.A. Vote of Councilor-Rapporteur Alessandro Octaviani Luis. 2014. Available from https://bit.ly/2VD7nE3.

[31] In the joint trial of some of Monsanto's licensing contracts in 2013, the winning vote of Councilor Eduardo Pontual Ribeiro established the knowledge regarding the "existence of contractual characteristics that involve exclusivity in the use of the licensed company's production capacity, or involve restrictions or disincentives in the licensee's choice of hiring other licensors, or involving restrictions on the development of competing products close to the good developed from the licensed input or event" (p. 184). Merger Files (CA) No. 08012.002870/2012-38; No. 08012.006706/2012-08; No. 08700.003898/2012-34; and No. 08700.003937/2012-01. Vote (post case reappraisal) of Board Member Eduardo Pontual Ribeiro. 2013. Available from https://bit.ly/2VynDqq.

years that establish a common enterprise for the exploration of economic activity", provided that (I) "*the contract establishes the sharing of risks and results of the economic activity that constitutes its object*"; and that (II) "*the contracting parties are competitors in the relevant market object of the contract*" (Art. 2).[32]

The wording of Resolution 17/2016 excluded the express mention of purely vertical agreements contained in previous wordings.[33] This, however, did not mean an interruption in the examination of associative contracts of a predominantly vertical nature, such as distribution and licensing.[34] Indeed, CADE General Superintendence has been establishing the understanding that "*the need for competition described in the object of an agreement does not correspond to a limitation by Resolution No. 17/2016 to only agreements that generate horizontal overlapping*".[35]

For CADE General Superintendence, this includes potential competition related to joint production and marketing of medicines.

In 2017, when dealing with the associative contract between Ares Trading S.A (from the Merck group) and Pfizer for the co-development and co-marketing of a product with the active ingredient "avelumab" (Bavencio, in the USA) for metastatic Merkel cell carcinoma and other indications,[36] CADE's General Superintendence decided to analyze the operation "conservatively" in light of the potential competition in the relevant market regarding therapeutic indication,[37] also considering Merck as a potential competitor for the reason that it holds the Bavencio patent in the United States.[38] The operation was approved without restrictions.

---

[32] For more details on the subject, see BINOTTO, Anna. Cooperação e Concentração: o empreendimento comum e a nova disciplina dos contratos associativos. In *Revista de Defesa da Concorrência – RDC*. vol. 6, No. 1, (2018) pp. 232–260.

[33] Resolution 10/2014, in its Art. 2, considers associative contracts as "*horizontal or vertical cooperation or risk sharing that entail a relationship of interdependence*", defining vertical relationships as relevant whenever one of the parties holds at least 30 per cent of the relevant markets affected, the contract establishes the sharing of revenue/losses, and an exclusivity relationship arises from it.

[34] With a Lay-Judge's Vote in Consultation No. 08700.008419/2016-08, Councilor Cristiane Alkmin Junqueira Schmidt established that: "item II of Art. 2 of the aforementioned Resolution is not limited only to horizontal mergers, but it also covers cases of vertical mergers". See Consultation No. 08700.008419/2016-08. Interested Parties: Warner Bros Home Entertainment Inc. and EA Swiss Sàrl. Lay-Judge's Vote of Councilor Cristiane Alkmin Junqueira Schmidt. Available from https://bit.ly/37ufrK3. An analysis by Julia Krein of CADE's most recent jurisprudence showed that "the CADE General Superintendence learned of eminently vertical contracts (distribution and licensing) only based on the existence of a competitive relationship in any of the markets affected by the contract". See KREIN, Julia. Contratos Associativos: na contramão da lei nº 12.529/11. Revista do IBRAC, n.1, 2021, p. 316. Available from https://bit.ly/2XdjCYP.

[35] Merger File (AC) No. 08700.002074/2019-13. Merging Parties: AMBEV S.A. and Red Bull do Brasil LTDA. CADE General Superintendence Opinion No. 19/2019/CGAA3/SGA1/SG/CADE. Available from https://bit.ly/3Avxpsb.

[36] Pursuant to CADE'S General Superintendence Opinion No. 180/2017, "for patients with metastatic Merkel cell carcinoma and for patients with previously treated locally advanced or metastatic urothelial carcinoma, or regarding other products containing monoclonal antibody (a) MSB0010718C, (b) PF-06801591, (c) any additional antibody that selectively combines with PD-L1 or PD-1, or (d) any product in which the formula contains one or more antibodies in which at least one selectively combines with PD-L1 or PD-1 for potential treatment of different types of cancer ("Products")", Merger File (AC) No. 08700.003575/2017-55. Merging Parties: Ares Trading S.A. and Pfizer, Inc. Opinion No. 180/2017/CGAA5/SGA1/SG. Available from https://bit.ly/2X0uRnd.

[37] CADE General Superintendence analyzes the Opinion: "*Although there is still no product on the market in Brazil specifically indicated for metastatic Merkel cell carcinoma, there are some medicines specifically indicated for previously treated locally advanced or metastatic urothelial carcinoma (none with the asset Avelumab)*" (...). "*since there is a possibility that the medicine object of the operation will compete directly with those of Pfizer already existing in the Brazilian market, considering the scenario of the relevant market regarding therapeutic indication*" (*Idem*, §15).

[38] CADE General Superintendence concluded: "*In summary, Merck will launch, together with Pfizer, a medicine that may compete, in Brazil, with Pfizer's products. Furthermore, Merck is the holder of the Bavencio patent in the United States. Even if there is no effective competition between them in the Brazilian market, the possibility of Merck being a potential competitor could be raised*". *Idem*, §15.

The same notion of potential competition was the rationale behind the analysis of the associative contract between AstraZeneca UK Limited and Merck Oncology GMBH for the joint development, manufacture and commercialization of olaparib (Lynparza) and selumetinib (pipeline).[39] The operation was approved without restrictions.

CADE General Superintendence, however, has adopted a different stance apropos of pipeline medicines or those in a very incipient stage of development. An example can be found in Merger File No. 08700.00831/2019-14, established in 2019, with an associative contract between GlaxoSmithKline PLC and Ares Trading S.A. for co-development and co-marketing of the pipelined asset M7824 (for immunotherapy with fusion proteins[40] possibly in biliary tract cancer and non-small cell lung cancer), granting GSK exclusive licensing to the intellectual property related to that asset. CADE General Superintendence considered that it was a first-in-class product, still in Phase II of clinical trials and still without ATC classification, having been declared by the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) as an orphan drug (ODD) for the treatment of biliary tract cancer, with no certainty whether the medicine would be finalized and made available on the market. For all the above, the decision was not to proceed with the operation because it was impossible to fulfill requirement II of Art. 2 of Resolution 17/2016 (which states that the parties to the associative contract must be competitors in the relevant market), therefore concluding that "*it is not even possible to know, today, in which relevant market it will be inserted (or even whether it will belong to a totally new relevant market*").[41]

2.2 Anticompetitive Practices

According to CADE case law, it is possible to divide anticompetitive practices related to intellectual property into two axes.[42]

The first axis includes practices related to *abusive uses of the Brazilian legal framework for industrial property protection (at the administrative and/or judicial levels)*, which are aimed at illegitimately imposing non-existent or invalid intellectual property rights with anticompetitive purposes.

The second axis is related to *abuse in the exercise of industrial property rights which are, in essence, valid*.

In addition to these, regarding the pharmaceutical sector, important case law can be found available about horizontal restrictions in the pharmaceutical sector – a topic of a less controversial nature in CADE's decisions.[43]

---

[39] See Merger File (AC) No. 08700.006640/2017-02. Merging Parties: AstraZeneca UK Limited and Merck Oncology GMBH. Opinion No. 297/2017/CGAA5/SGA1/SG. Available from https://bit.ly/3xBA4i1.

[40] CADE General Superintendence Opinion described the asset as a "bifunctional fusion protein immunotherapy that combines a TGF-β trap with a PD-L1 to simultaneously block immunosuppressive pathways that are normally used by cancer cells to evade the immune system": See Merger File (AC) No. 08700.000831/2019-14. Merging Parties: GlaxoSmithKline PLC. and Ares Trading S.A. Opinion No. 83/2019/CGAA5/SGA1/SG. 2019. Available from https://bit.ly/3jys6kK.

[41] Ibid.

[42] In CADE decision for the ANFAPE case, Councilor Carlos Ragazzo divides anticompetitive practices related to intellectual property into two large groups: *"(i) on the one hand, fraud or abuse in the industrial property right registration procedure; and (ii) on the other hand, anticompetitive conduct arising from the abuse of the industrial property right per se, that is, from the abuse by the holder during the exercise of said right*". See Administrative Proceeding No. 08012.002673/2007-51. Vote of Director Carlos Emmanuel Joppert Ragazzo 2010, cit., §35.

[43] See SAMPAIO; GUIMARÃES (2012, *op. cit*., p. 298).

2.2.1 Abuse of the legal framework for industrial property protection

At this point, the discussion will address strategies resorted to regarding abusive or fraudulent uses of the Brazilian legal framework for the protection of intellectual property rights, taking into account the related anticompetitive impact. This may take place both at the administrative level (e.g., in INPI patent registration procedures) and at the judicial level (through abuse of the right to petition with anticompetitive effects, or sham litigation).

The European Commission's Pharmaceutical Sector Inquiry[44] (2009) analyzes such practices, especially in terms of competition between pharmaceutical originators and generics manufacturers or rivals, given that abusive uses of the patent protection legal framework can prevent or delay the entry of generic products on the market.[45] This type of abuse may be part of a "tool-box"[46] of strategies adopted by patent holders with a view to extending the commercial life of their products.

In Brazil, generics are mainly regulated by the Generics Law (Federal Law No. 9787/99).[47] According to CMED Resolution No. 2/2004, the factory price authorized for generic medicines must not be higher than 65 per cent of the price of the corresponding reference medicine (Art. 12). Regarding the impact of the Generics Law on competition, CADE, in 2010, addressed this concern in a decision:

> The major milestone for competition in the sector was Law No. 9787/99 (Generics Law), which brought profound changes to the Brazilian market of human health medicines. Based on such law, there is a growing replacement of branded products by generics, followed by a change in the sector's competition pattern due to the growing importance of the price variable in the choice of products.[48]

Given such competitive relevance, practices that have the potential to prevent or delay the entry of generics should be subject to special scrutiny by the antitrust system.[49]

With regard to abusive patenting strategies, *evergreening* stands out. It consists of life cycle strategies for extending the term of patent protection beyond 20 years,[50] such as the filing of successive or secondary applications derived from an original patent.

---

[44] EUROPEAN UNION. European Commission. Pharmaceutical Sector Inquiry, 2009. Available from https://bit.ly/2VEMY1N.
[45] Ibid., §473 et seq., e §1556 et seq.
[46] Ibid., §24.
[47] Federal Law No. 9,787/99 (the Generics Law) classifies medicines into three types (Article 1): reference medicine is an innovative product, with proper health registration and with proven efficacy/safety/quality at the time of registration); similar medicine, with form already authorized since 1976, refers to the product that contains the same active ingredient/concentration/pharmaceutical form/administration route/dosage/therapeutic, preventive or diagnostic indication of the reference medicine with sanitary registration, identified by trade name or brand; generic medicine – a medicine similar to the innovative reference medicine, interchangeable with it, produced after patent expiration/waiver or in another form of exclusivity; with proven efficacy, safety and quality by means of bioequivalence and bioavailability tests.
[48] Merger File (AC) No. 08012.003189/2009-10, Vote of Rapporteur-Councilor César Costa Alves Mattos. Merging Parties: Sanofi-Aventis Farmacêutica and Medley S.A. Indústria Farmacêutica. 2010, cit.
[49] In this regard, see CADE's decision for the "Cartel dos Genéricos" [Generics Cartel], which dealt with smear campaigns and boycotts coordinated by the main Brazilian laboratories in the face of the entry of generics in Brazil. Administrative Proceeding No. 08012.009088/1999-48, Petitioner: Regional Pharmacy Council of the Federal District. Respondent: ABIFARMA and Associated Laboratories. Still on defamatory campaigns related to the entry of generics, Administrative Inquiry (IA) No. 08012.011615/2008-08 also dealt with the allegation that Abbott had undertaken smear campaigns with ANVISA and health professionals, in relation to the competitor of its reference medicine (Sevorane). See IA No. 08012.011615/2008-08. Petitioner: Cristália Produtos Químicos Farmacêuticos Ltda. Technical Note 1/2019/CGAA1/SGA1/SG/CADE. 2019. Available from https://bit.ly/3jGzLNN .
[50] See IDO (2020, *op cit.*, p. 12).

In a statement to CADE, INPI defended the point that incremental innovations in the pharmaceutical sector do not, by themselves, characterize the practice of evergreening, but in certain circumstances they could be understood as strategies to prevent or delay the entry of generics. Incremental innovations in medicines would then constitute three modalities:

> Inventions necessary to make available a product based on the new medicine developed, such as inventions that present solutions to problems of stability and/or solubility of the drug or that enable the production of the medicine on a large scale, for example, new pharmaceutical formulations, salts, prodrugs and polymorphs;
>
> Inventions that provide drugs that are structurally similar, but with specific and/or improved properties, such as selection inventions;
>
> Inventions arising from new uses of already known drugs, but which can bring new therapeutic benefits at a lower development cost, enabling, for example, the development of treatments for neglected or orphan diseases, new medical uses.[51]

Another example are patent clusters (or patent thickets) – situations in which patenting is stratified in layers, so that the same invention is protected by a large number of patents (and patent applications), with different overlapping scopes, in addition to the basic patent (production process, reformulation, different dosage forms, etc.).[52] Besides aggravating transaction costs in certain cases,[53] this legal situation may delay the entry of generics as it works as a "multilayer" defense because, even if the basic patent is invalidated/expired, the other patents continue to impede the entry of the rival product.[54]

Strategies related to divisional patents are also a case in point, in which the applicant or the *ex officio* authority (LPI, Art. 26), in the face of a main patent application, divides it into one or several secondary patent applications (with the same or a narrower scope).[55] The pending analysis of divisional patents, even if the main patent has already been rejected or invalidated, creates uncertainty for generic manufacturers.[56]

Another example is defensive patenting, that is, when a given company pursues patents on inventions that do not have a reasonable prospect for commercial exploitation, so that it prevents current or potential rivals from developing them.[57]

In this vein, competitive analyses of second-generation product launches, with incremental innovation of existing drugs (e.g., follow-on products) aim to identify whether such launches constitute a strategy to make it difficult for generics to enter the first-generation drug market

---

[51] See Administrative Inquiry (IA) No. 08012.011615/2008-08. Petitioner: Cristália Produtos Químicos Farmacêuticos Ltda. Technical Note 1/2019/CGAA1/SGA1/SG/CADE, 2019, § 470.
[52] See Pharmaceutical Sector Inquiry, 2009, cit., §476.
[53] Vitor Ido, 2020, cit. p. 12, analyzes that, as layered patents are not always held by the same owner, situations arise in which the dominant market agent needs to negotiate licensing with other patent holders, increasing transaction costs and even causing the tragedy of the anti-commons, where underutilization of a given technology is caused by its ownership regime.
[54] Pharmaceutical Sector Inquiry, 2009, cit., §476. In a contribution to the OECD roundtable on Competition, Patents and Innovation (2009), the Commission noted that "*In some cases, individual blockbuster medicines are protected by up to 90 patent families translating into 1300 national and EPO patents and pending patent applications in the EU. This creates a dense web of patents around the originator company's blockbuster product which can lead to uncertainty for generic companies as to which of these patents they will possibly have to face".* OCDE. Competition, Patents and Innovation II, 2009, p. 173. Available from https://bit.ly/3jwA1yQ, accessed on 8 August 2021.
[55] Definition taken from the Pharmaceutical Sector Inquiry, 2009, cit., §432.
[56] Ibid., §523.
[57] Ibid., §1118. See also: Calixto Salomão Filho (2015, op. cit., p. 150) observes that defensive patenting can occur through *blocking* (acquisition of all new patents, without use) and *fencing* (filling of patent applications of all variations likely to be used by rivals).

and to channel the market demand towards second-generation products (e.g., by product switching or product hopping).[58]

Resorting to the methodology used in the European Commission's Pharmaceutical Sector Inquiry (2009), the Institute for Applied Economic Research (Ipea) carried out the "Brazilian Pharmaceutical Sector Competition Inquiry"[59] (henceforth referred to as the Inquiry Report) in order to quantify life cycle strategies related to innovative medicines in Brazil.

The Inquiry Report with partial results, published in 2013, focused on quantifying the launch of follow-on products as a strategy for innovative pharmaceutical laboratories. Considering a sample of 94 active ingredients, in 51 per cent of them second-generation products launched. Regarding such follow-on products, the Inquiry Report also stated that in 88.2 per cent the innovation did not involve chemical modification, with the majority being pharmaceutical combinations or dose changes, besides, to a lesser extent, pharmaceutical forms or the composition of the drug (modified release). In only 11.8 per cent of the cases there was a chemical change in the active ingredient (structural analogues, salts or isomers).[60] In the same sample, patent applications filed by holders of the primary patent (8.7 patent applications per active ingredient) exceeded the average number of follow-on product launches by five times (1.7 product per active ingredient).[61]

As stated in the Inquiry Report, "*This surplus indicates innovation strategies based on the filing of a wide family of patent applications (patent clusters) to protect around the primary patent*" (p. 36). The Inquiry Report showed, however, that 46.1 per cent of incremental patent applications were from competing laboratories, hence denoting that "*a large part of the incremental R&D that generates patent filings in Brazil is pro-competitive*". The Inquiry Report concludes with a suggestion of regulatory reinforcement to curb product switching strategies, especially an additional amendment in health legislation to prevent the adverse effects caused by withdrawing the original medicine from the market.

CADE General Superintendence analyzed the topic of product switching in 2019 when investigating Representation with regard to the conduct of Genzyme do Brasil Ltda. and Genzyme Corporation in the sevelamer hydrochloride market after the grant of registration for the drugs Hemosev and Foslamer, similar to Renagel (produced by Genzyme). For the complaint, a series of practices (such as sham litigation, defamatory campaigns with public agencies and consumers, and predatory pricing in public procurement) were pointed as being conjugated towards a greater objective, namely, the switching to second-generation products (Renleva, also owned by Genzyme).

In recommending the shelving of the proceeding, CADE General Superintendence, referring to the European Inquiry,[62] on the subject, argued that switching should be analyzed in light of three factors: (a) the timing of the product launch (whether it precedes or coincides with the expiration of the patent of the original medicine, since the strategy becomes more difficult when generic products are already on the market);[63] (b) whether it is accompanied by bridging strategies (strategies for transition to the new medicine, channeling the demand of the original

[58] Pharmaceutical Sector Inquiry, 2009, cit., §988. See also MATTHEWS, Duncan. GURGULA, Olga. Patent Strategies and Competition Law in the Pharmaceutical Sector: Implications for Access to Medicines. Queen Mary University of London, School of Law Legal Studies Research Paper No. 233/2016. Available from https://bit.ly/3CvvJ3E.

[59] PEREIRA, Dárcio Gomes. FIUZA, Eduardo P. S. *Os Direitos de propriedade intelectual nas estratégias de ciclo de vida para medicamentos de segunda geração : resultados parciais do inquérito brasileiro sobre a concorrência do setor farmacêutico*. Radar : tecnologia, produção e comércio exterior, Brasília, n. 29, 70 p., out. 2013. Available from https://bit.ly/3yyOoJt.

[60] Ibid., p. 32.

[61] Ibid., p. 35.

[62] Pharmaceutical Sector Inquiry, 2009, cit., §§ 1007 et seq.

[63] On the timing of follow-on product launches in Brazil, see Pereira and Fiuza, 2013, cit., p. 33.

medicine, even with the help of physicians and pharmacists); and (c) whether the original medicine is still being marketed.[64]

In a general analysis of the competitive legality of strategic patenting practices, CADE General Superintendence has recently expressed an understanding that the illegality of such practices is linked to the proof of fraud, such as falsehoods or other types of abuse.

2.2.1.a) Strategic patenting in the Abbott case

In 2019, CADE's General Superintendence concluded a proceeding that had been initiated in 2008 against Abbvie and Abbott – producer of the drugs Sevorane (sevoflurane), Norvir (ritonavir), and Meltrex/Kaletra (associations of ritonavir and lopinavir) – to investigate Representation, with complaints that the company allegedly used a set of actions to exclude rivals in the sector, such as similar drugs Sevocris (sevoflurane) and Ritovir (ritonavir).

According to the complaint, the Company had requested a patent on formulation and preparation of Sevorane, knowing or having reason to know that the application did not meet the patentability requirements, as it did not have any inventive step. The patent was later invalidated in Brazil, and in other jurisdictions, for lack of novelty and inventive step – as the active ingredient (sevoflurane) was already in the public domain. Therefore, after similar drugs had entered the market (Sevocris), a series of lawsuits regarding infringement of Abbott's patent were proposed.

In 2019, in the inquiry's concluding Technical Note,[65] CADE General Superintendence stated that "*it should be noted that antitrust actions in this case would be considered, for example, in the case of alleged fraud or bad faith in obtaining the patent*",[66] but pointed out that it was not CADE's responsibility to analyze the merits of the technical analysis regarding the existence of patentability requirements:

> It is true that the existence of patents properly granted by relevant authorities, which in turn protect modifications not really representing actual innovations, negatively affects the competitive environment. However, it is not up to CADE to remedy any deficiencies in the process of analyzing a patent application. Action in this sense, in addition to evading the powers legally assigned to this autarchy, would be reckless given its lack of expertise to deal with essentially technical issues. Any action by CADE to question or review INPI's decisions, in addition to being illegal, would have the deleterious effect of increasing the degree of uncertainty in the market.

In this case, in the absence of evidence of fraud, regardless of the invalidation of the patent in question, CADE General Superintendence concluded that there was no competitive offense.

In the ritonavir and lopinavir market, the complaint under analysis refers to the artificial extension of patent protection through a patent cluster, with the filing of several patent applications related to the same active ingredients (lopinavir and ritonavir), without any innovation involved, and ignoring the fact that ritonavir is in the public domain. The responding company, in particular, would have allegedly engaged in defensive patenting by applying for a patent on Meltrex (with a formulation identical to the already patented drug, Kaletra).

The analysis by CADE General Superintendence established that patent clusters are not necessarily a competitive offense, since there are situations in which additional patents protect

---

[64] Administrative Proceeding No. 08012.007147/2009-40. Respondents: Genzyme do Brasil Ltda. and Genzyme Corporation. Technical Note No. 10/2019/CGAA1/SGA1/SG/CADE. 2019. Available from https://bit.ly/2VJri44.
[65] Technical Note No. 1/2019/CGAA1/SGA1/SG/CADE in Administrative Inquiry No. 08012.011615/2008-08. Respondents: AbbVie Farmacêutica Ltda. and Abbott Laboratories Inc., cit.
[66] Ibid., §215.

relevant incremental innovation: "*It is not too much to emphasize that the achievement of a set of patents for the same drug, although it hinders the entry of generic competitors, it does not necessarily have negative net effects in terms of social welfare*" (§490). It reiterated, as had previously stated, that it was not the responsibility of CADE to analyze the technical and complex merits of the discussion about the existence of patentability requirements or determine "*how many patents for the same drug should be considered adequate or sufficient*"[67] (§494).

CADE General Superintendence stated, however, that there is a possibility of an anticompetitive offense "*in the event that the submission of one or more patent application(s) is found to be part of a broader strategy for which there is no other plausible justification other than the anticompetitive intent*" (§495). As an example, it mentions bad faith applications based on falsehood, or even the "*submission of several applications with a low probability of a favorable outcome, with the sole purpose of generating uncertainty in the market throughout the analysis process*", although it recognizes that the levels of evidence in the latter case would be low.

In conclusion:

> 535. "In this context, it is not the responsibility of the antitrust authority to go into the merits of the discussion about the technical adequacy of a given pharmaceutical patent application. Such analysis is technical in nature and extremely complex, and must be carried out on a case-by-case basis by the legally competent authorities and according to strict criteria in order to allow desirable incentives for innovation without, at the same time, unduly granting monopoly rights. Assuming that the patent application was made in strict compliance with the principle of good faith, backed by complete and reliable information, it is not up to the antitrust authority to question the existence or not of patentability requirements". (...)

After analyzing that the specific situation was not a case of bad faith in the manner described above, CADE's General Superintendence shelved the inquiry.

2.2.1.b) Evergreening and the Supreme Federal Court of Brazil

The undue extension of patent protection has been at the center of public discussions about intellectual property and access to medicines in Brazil recently, since its harmful effects were supposedly aggravated by a peculiar provision under the sole paragraph of Art. 40 of the Industrial Property Law – IPL.[68] This provision allows for the extension of the patent protection term in case of delay in the analysis by INPI (by establishing that patent term shall not be less than 10 (ten) years, counted from the date of grant).

Protection for the patent applicant is obtained through Art. 44 of IPL, which provides that "*Art. 44. The right to obtain a compensation for the unauthorized exploration of the subject matter of a patent, including regarding the exploitation between the date of publication of the application and the granting of the patent, is guaranteed to the patent owner*".

---

[67] Still on evergreening, CADE General Superintendence stated "the mere patent application should not be seen as an antitrust offense, unless there are indications that the application is based on false information, with the clear intention of misleading the authority, or that it is unequivocally characterized that the set of applications was known to have a low probability of being granted favorably and that the applicant's sole intention would be to generate uncertainty in the market throughout the examination process" (Ibid., §528).

[68] Law 9279/1996 stipulates: "*Art. 40. A Patent of invention will have a term of 20 (twenty) years and a utility model patent a term of 15 (Fifteen) years, counted from the filing date. Sole Paragraph - The term will not be less than 10 (ten) years for patents of invention and 7 (seven) years for utility model patents, counted from grant, except when INPI is prevented from proceeding with the examination as to the merit of the application, due to a proven pendente lite or for reasons of "force majeure*".

Brazil's Federal Court of Accounts (TCU), in this regard, notes that

> "Third parties interested in exploiting the technique do not risk exploiting it until the applicant's application has been decided. As a result, the patent, even if not yet granted, has economic efficiency in the face of its competitors from the filing date".[69]

As CADE General Superintendence observed in a recent Technical Note:

> "As seen, in the case of the pharmaceutical sector, the existence of a pending application can result in a *de facto* monopoly because, even if there is no property right monopoly, there is a great risk for a generic company to enter the market prior to the patent examination completion".[70]

An analysis published in 2020 showed that delays are more often seen with regard to the INPI's examination process of patents on medicines (average of 13 years), and estimated that in the pharmaceutical sector "*92.2 per cent of the already granted patents that are extendable will be valid for more than 20 years*".[71] The same study concluded that, between 2014 and 2018, with respect to the nine medicines with the highest costs and entitled to patent extension under the sole paragraph of Art. 40 of IPL, the additional costs imposed on the Brazilian Unified Health System (SUS) were at least R$ 1.2 billion.[72] This amount, for the study, represents 1.1 per cent of the SUS budget in 2018, 5.4 per cent of medicine expenditure by Federal, State and Municipal Governments in 2016, and 57.7 per cent of R&D expenditure in Brazil by the pharmaceutical industry in 2014.[73]

Brazil's Federal Court of Accounts (TCU), in a recent Rendering of Account, identified that evergreening in the pharmaceutical sector is greatly aggravated by its combination with the patent extension provided for in the sole paragraph of Art. 40 of IPL.[74]

In May 2021, the Federal Supreme Court of Brazil (STF) ruled on ADI ("Direct Action of Unconstitutionality") 5529. On the subject, the constitutional court's pronouncement on anticompetitive abuse of industrial property rights emphasizes:

> Thus, the arbitrary extension of the privilege comes to the detriment of the market as a whole, causing precisely what the Constitution sought to repress, that is, the domination of markets, the elimination of competition, and the arbitrary increase in profits, deepening inequality between agents and transforming what was justifiable and reasonable into an unconstitutional situation. The industrial property right, to be exercised, must be considered necessary and adequate for the purpose for which it is intended, without incurring aggression or nullification of other applicable constitutional precepts, such as the principles that govern the economic order. It so happens that, in the present case, there is a contradiction to such principles, notably free competition

---

[69] BRAZIL. Federal Court of Accounts. TCU, Rendering of Account No. 015.369/2019-6, Audit Report, 2020, §227. Available from https://bit.ly/3AoH83m.

[70] Administrative Inquiry (IA) No. 08012.011615/2008-08. Petitioner: Cristália Produtos Químicos Farmacêuticos Ltda. Respondents: Abbvie Farmacêutica Ltda. and Abbott Laboratories Inc. Technical Note 1/2019/CGAA1/SGA1/SG/CADE. 2019, cit., §494.

[71] PARANHOS, Julia. MERCADANTE, Eduardo. HASENCLEVER, Lia. *O custo da extensão da vigência de patentes de medicamentos para o Sistema Único de Saúde*. Cadernos de Saúde Pública, 2020, p. 4. Available from https://bit.ly/3s3Aa0I.

[72] The analysis estimates, in another scenario, savings of up to BRL 3.9 billion in SUS expenditures. Ibid., p. 10.

[73] Ibid., p. 10.

[74] The Federal Court of Accounts - TCU analyzed the example of the active ingredient "etanercept" (second largest in federal government purchases since 2010, according to TCU). In research conducted in 2020, TCU identified 15 (fifteen) pending patent applications, the first from 1999 and the last 2015. Based on Art. 44, TCU analyzed that the term of patent protection could reach "*36 years (2015+20-1999), which could be even longer in the event of an extension of the term resulting from the sole paragraph of Art. 40 of IPL, in case the patent would be granted after 2025*". BRAZIL. Federal Court of Accounts. TCU, Rendering of Account No. 015.369/2019-6, 2020, cit., §232.

> and consumer protection, since the questioned article bars the action of economic agents in the industry for a period that extends in an uncertain and unpredictable way, allowing an unjustifiably long industrial property protection.[75]

The Federal Supreme Court of Brazil, then, ruled unconstitutional the sole paragraph of Art. 40 of IPL,[76] in view of, among other principles, the constitutional principles of free competition and consumer protection (CR/88, Art. 170, IV and V) and the right to health (CR/88, Art. 196).

2.2.1.c) Abuse of the right to petition with anticompetitive effects

In the context of abuse of the right to petition with anticompetitive effects (sham litigation), analyses often seek to identify situations in which a given economic agent makes use of fraudulent strategies or, in another way, out of step with the scope of the constitutional right to petition with administrative bodies or to the Judiciary (Art. 5, XXXV), for artificially raising barriers to entry – especially, raising rivals' costs, hindering or preventing their entry into the market (Law 12529/2011, Art. 36).[77]

In the AstraZeneca case (2005, confirmed by the Court of Justice of the European Union in 2012), the European Commission concluded that misleading practices and abuse of regulatory procedures by AstraZeneca (patent holder of the medicine Losec) were unlawful, meant to delay the entry of generic omeprazole on the market in order to promote switching to the second-generation product esomeprazole.

At this point, it is worth noting CADE's decision in the Eli Lilly case (2015),[78] in which the responding pharmaceutical companies had filed several lawsuits in different Brazilian states ("forum shopping"), in the face of various public institutions such as INPI and Anvisa, to obtain undue exclusivity on the commercialization of gemcitabine hydrochloride (indicated for the treatment of cancer).[79]

Following the case-law line drawn in previous decisions on the same topic,[80] CADE started by referring to tests established by the US Supreme Court case law – such as "PRE"[81] and "USS-

---

[75] BRAZIL. Federal Supreme Court of Brazil. ADI 5529 MC/DF. Rapporteur Minister Dias Toffoli. Trial 04/07/2021. Available from https://bit.ly/3CyWVi3.

[76] The decision has *ex nunc* effect, not affecting patents already granted and still in force. In light of the Covid-19 pandemic, however, the Federal Supreme Court of Brazil decided that the decision would have retroactive effect (*ex tunc*) in view of patents granted with an extension of term for pharmaceutical products and processes, equipment and health materials, so that the decision also applies "*on patents already granted with the extension provided for in the sole paragraph of art. 40 of the LPI*". See Ibid.

[77] See CASTRO, Bruno Braz de. *Sham Litigation: o abuso do direito de petição com efeitos concorrenciais*. Revista do IBRAC, v. jul-dec, pp. 58–74, 2010. Available from https://bit.ly/3yELW48 .

[78] Administrative Proceeding No. 08012.0011508/2007-91. Respondents: Eli Lilly do Brasil Ltda. and Eli Lilly and Company. Vote of Councilor-Rapporteur Ana Frazão. Available from https://bit.ly/2VKigEk.

[79] The lawsuits were allegedly carried out fraudulently, with changes in the scope of the patent application and omission of relevant information, having been relatively successful, including the temporary withdrawal of a rival from the relevant market (Sandoz).

[80] For an analysis of CADE's jurisprudence on the subject, see RENZETTI, Bruno Polonio. *Tratamento do Sham Litigation no Direito Concorrencial Brasileiro à Luz da Jurisprudência do CADE*. Revista de Defesa da Concorrência, vol. 5, No. 1, 2017. Available from https://bit.ly/2U5rkDd.

[81] The PRE test was established in the 1993 US Supreme Court decision in the case of Professional Real Estate Investors (PRE), Inc, et al v. Columbia Pictures Industries, Inc. The test is based on an objective prong (lawsuit is objectively baseless, without realistically expecting success on the merits) and a subjective prong (lawsuit interferes directly with the business relationships of a competitor, through the 'use of the governmental process).

POSCO",[82] followed by analysis of sham litigation and judicial agreements"[83] – for the characterization of sham litigation.[84] Based on this reference, the decision established that CADE should not be limited to the analysis of a certain isolated action: "It is up to CADE, then, to assess the existence of strategic behavior standards, from a macro view, as regards the conduct held by the responding party".[85]

The responding companies were convicted based on the conclusion that there was a "*fraudulent strategy*" with an "*unexpected and unreasonable*" pattern of behavior, translated into: (i) "*obtaining state support that is favorable to the petitioner, but achieved through falsehood*"; (ii) "*filing of legal actions without foundation, when there is a clear lack of legal conditions, or material omissions or contradictory positions, and filing of actions that are manifestly unfit*"; and with (iii) "*potential anticompetitive purpose and outcome, that is, the party expects to cause direct or collateral damage to competitors (fraud awareness)*".

Based on these same tests, CADE also decided to shelve recently other proceedings dealing with sham litigation regarding the entry of generics and similar products in the pharmaceutical sector,[86] including the protection of data packages of reference medicines.[87] It should be noted that, for cases of sham litigation, CADE's case law does not require proof of market percentage referring to presumption of dominance, as provided for in Law 12529/2011 (20 per cent, according to Art. 36, §2).[88]

---

[82] The USS-POSCO test was entered into by the United States Court of Appeals at the 9th Circuit in 1994 in the case of USS-POSCO Industries v. Contra Costa Building ("USS-POSCO"). Going beyond the PRE test, based on the analysis of a single lawsuit, it establishes the abusive nature of the right to petition in reference to cases of serial litigation or repetitive lawsuits, without concern for the reasonableness/merit of the causes, and with evidence of the anticompetitive purpose revealed by the *filing* of serial lawsuits *per se*, and not just in the final result of a single lawsuit.

[83] The analysis of cases of sham litigation involves lawsuits based on false or fraudulent information, and the analysis of agreements involves those adopted to promote the consensual exit of a competitor from the market and its compensation. See analysis of these conditions in Technical Note No. 16/2018/CGAA1/SGA1/SG/CADE for Administrative Proceeding No. 08700.010811/2014-47 (Respondents: Lundbeck Brasil Ltda and H. Lundbeck A/S). Available from https://bit.ly/3AqGlyL .

[84] In the US system, antitrust immunity to the right to petition falls within the scope of the Noer-Pennington Doctrine. The "*sham exception*" to such immunity was the subject of long case-law construction. On the subject, see CASTRO, Bruno Braz de. Sham Litigation... cit. 2010.

[85] See Administrative Proceeding No. 08012.011508/2007-91. Vote of Councilor Ana Frazão. 2015, cit, p. 192.

[86] See also: Technical Note No. 1/2019/CGAA1/SGA1/SG/CADE for the Administrative Inquiry (IA) No. 08012.011615/2008-08, Respondents: Abbvie Farmacêutica Ltda. and Abbott Laboratories Inc., cit. CADE's General Superintendence, with reference to American and European jurisprudence, stipulated that Abbott's actions to protect its patent against patent infringement (including using the controversial thesis of "patent infringement by equivalence") did not constitute sham litigation.

[87] In Administrative Proceeding No. 08012.006377/2010-25, which dealt with several legal and administrative actions adopted by the Respondents Lundbeck Brasil LTDA and H. Lundbeck A/S concerning the use, by Anvisa, of a data package of reference medicines for the registration of generic and similar medicines, Councilor-Rapporteur Polyana Vilanova decided for the absence of sham litigation in light of the controversial nature of the thesis under discussion in the Judiciary, ruling out the applicability of the mentioned tests because, among other reasons, "*the controversy over the protection of the data package is not trivial, not even specific to the medicine Lexapro. In fact, it includes divergent positions*". (Administrative Proceeding No. 08012.006377/2010-25. Respondents: Lundbeck Brasil LTDA. and H. Lundbeck A/S. Vote of Rapporteur-Councilor Polyana Ferreira Silva Vilanova. 2018. Available at https://bit.ly/3iAD5uR). The same justification was presented for the filing of Administrative Proceeding No. 08012.007147/2009-40 (Respondents: Genzyme do Brasil Ltda. and Genzume Corporation) which dealt, among other things, with the practice of "*a series of judicial and administrative measures in the sevelamer market, with the supposed objective of delaying the entry of competitors in the market and maintaining the monopolistic position that it enjoyed since the issuance of the registration of Renagel as a reference medicine in Brazil in 2002*". See Administrative Proceeding No. 08012.007147/2009-40. Respondents: Genzyme do Brasil Ltda. and Genzyme Corporation. Technical Note No. 10/2019/CGAA1/SGA1/SG/CADE. 2019. Available from https://bit.ly/2VJri44.

[88] In Administrative Proceeding No. 08012.010648/2009-11, the Councilor-Rapporteur Eduardo Pontual analyzed: "*In fact, the smaller the presence of the respondent in the market, the smaller its share, the greater the harm that sham litigation can cause*", it is only necessary to realize that "*the advocated change of the legal environment of competition creates market power with the ability to generate market dominance*". Administrative Proceeding No. 08012.010648/2009-11. Respondents: Abióptica and others. Vote of Councilor-Rapporteur Eduardo Pontual Ribeiro. Available from https://bit.ly/3xxrJfd.

2.2.2 Abuse in the exercise of industrial property rights

The above section addressed practices related to the system of illegitimate acquisition and imposition of insubstantial industrial property rights (without efficacy and/or validity), but there is another context in which there is abuse regarding *the exercise* of such rights. Regardless of whether the industrial property right is by itself valid, this business asset (like any other) may be used in anticompetitive strategies.

As presented above, CADE case law establishes that the illegality, or abuse, in the exercise of an industrial property right derives from its use in clearly non-compliance with the limits imposed by its "*economic or social order for the good faith or good morals*" (Art. 187, Brazilian Civil Code of 2002).

Some of these anticompetitive conducts can be implemented through licensing agreements, to be analyzed according to their restrictive vertical and horizontal effects.[89] Law 12529/2011, Art. 36, §3, establishes as potentially unlawful to:

> VIII – to regulate markets of goods or services by establishing agreements to limit or control the research and technological development, the production of goods or services, or to impair investments for the production of goods or services or their distribution.

Moreover, analyses of abuse in the exercise of industrial property rights typically fall within the legal status of abuse of dominance. In general, the issue of abuse of dominance is less representative in relevant authority's judgments. The OECD, in a recent peer review (2019), pointed out that CADE "*should give higher priority to abuse of dominance investigations*,[90] *and rely less on settlement negotiations to conclude cases in order to generate a body of case law in this area*".[91]

Competitive control in the practice of *refusing to license* can play an important role in ensuring access to medicines when a pharmaceutical company, holder of exclusivity rights considered *essential* for a relevant subject-matter, refuses its licensing, artificially raising barriers to entry, against both current and potential rivals in vertically related markets.[92] Law 12529/2011, on refusal to deal, establishes as illegal practices those that aim to:

> Art. 36 §3 III – to limit or prevent the access of new companies to the market;
>
> IV – to create difficulties for the establishment, operation or development of a competitor company or supplier, acquirer or financier of goods or services; and
>
> V – to prevent the access of competitors to sources of input, raw material, equipment or technology, and distribution channels.

---

[89] In the ANFAPE Case, Councilor Carlos Ragazzo commented on the anticompetitive effects derived from licensing agreements, such as horizontal restrictions, resale price fixing, tie-in sales, exclusivity, problems in cross-licensing agreements and pools, grantbacks. In the context of unilateral practices, see cit, §40. On the subject, see also Ido, 2020, cit., pp. 16-18.

[90] On the subject, see also CASTRO, Bruno Braz de. *Finalidades da Política Concorrencial e Promoção da Rivalidade em Países em Desenvolvimento: Argumentos em Prol de um Foco Renovado no Combate a Abusos de Posição Dominante*. REVISTA DO IBRAC, v. 24, p. 90-136, 2018. Available at https://bit.ly/2VC9us0.

[91] OECD. OECD Peer Reviews of Competition Law and Policy: Brazil 2019. Available at https://bit.ly/3vM9ftZ, p. 4.

[92] See: Ido (2020, cit., p. 17) argues that licensing agreements between large transnational pharmaceutical companies with national generic companies and laboratories may become an ever-increasing model to ensure production of and access to medicines, leading to simultaneous transfer of technology and reduction of prices. He notes, however, that the policy has also been criticized for excluding certain countries, which leads to negative impacts.

In this regard, CADE case law favors imposing the supply obligation in contexts where the supply is considered essential infrastructure,[93] even including the supply of products protected by industrial property.[94]

In 2015, CADE General Superintendence analyzed the issue of *refusal to license* essential patents in the context of the 3G technology standard (standard essential patents),[95] but did not elaborate on the matter, thus shelving the process due to lack of evidence of the alleged conduct.

2.2.2 a) Exploitative excessive pricing

In the antitrust discipline of corporate pricing policies,[96] theory makes a distinction between *exclusionary excessive pricing* – abusive practices aimed at delaying or preventing the entry of rivals into a given relevant market, whose analysis is equivalent to constructive refusals to deal, as mentioned earlier – and *exploitative excessive pricing*.

Exploitative excessive pricing manifests illegal economic effects caused when a competitor aims at "*the domination of markets, the elimination of competition and the arbitrary increase of profits*", as provided for in the Constitution (CR/88, Art. 173, §4), established by Law 12529/2011 as unlawful anticompetitive economic effects (Art. 36). This modality of abuse of dominance is directly related to the exercise of market power over consumers,[97] translated not only into the setting or readjustment of exploitative excessive prices, but also into the reduction of technological efforts for greater efficiency or the launch of new products,[98] or degradation of quality, privacy, or other contractual conditions.

In CADE case law, expressiveness in the discussions related to exploitative excessive pricing, especially during the 1990s and 2000s, is remarkable. A survey published in 2012 evaluated that, of 55 administrative proceedings involving the pharmaceutical sector, 46 referred to "*abusive pricing/unjustified price increase*".[99]

In fact, the current Brazilian Competition Defense System (SBDC) has its genesis related, in part, to the political concern with exploitative pricing in the pharmaceutical sector. Despite this, the practice of exploitative pricing has not yet found viability as a theory of damage capable of generating convictions under CADE case law, although there are important debates about its conceptualization, measurement and remedy.

---

[93] See Administrative Proceeding No. 08012.00172/1998-42, in which CADE adopted the "essential facilities doctrine" to determine the supply of spare parts related to telephone exchanges, many still protected by industrial property. Administrative Proceeding No. 08012.00172/1998-42. Respondent: Matec. Petitioner: Power-tech. Vote of Councilor-Rapporteur Ronaldo Porto Macedo Júnior. 2002. Available from https://bit.ly/3yuEWXv.

[94] Preliminary Inquiry No. 08012.005727/2006-50. Respondent: Alcoa Alumínio S.A. Vote of the Councilor-Rapporteur César Mattos. 2010. Available from https://bit.ly/37JR7UN.

[95] Preparatory Proceeding No. 08700.008409/2014-00. Petitioner: TCT Mobile Telefones Ltda; Respondent: Telefonaktiebolaget L M Ericsson. Technical Note No. 11/2015/CGAA1/SGA1/SG/CADE. Available from https://bit.ly/2U2usQ4.

[96] Said discipline also includes predatory, discriminatory and other pricing.

[97] See EVANS, David S.; PADILLA, A Jorge. Excessive prices: using economics to define administrable legal rules. CEPR Discussion Paper No. 4626, 2004. Available from https://bit.ly/3yzn9P3 , pp. 02-05.

[98] LYONS, Bruce. The paradox of the exclusion of exploitative abuse. In: SWEDISH COMPETITION AUTHORITY. The pros and cons of high prices. Kalmar: Lenanders Grafiska, 2007. p. 66. Available from https://bit.ly/2VKSQGE

[99] SAMPAIO; GUIMARÃES, 2012, *cit*., p. 290.

According to reports, one of the motivations for the enactment of Federal Law No. 8884/1994 was the opposition, expressed by the then President of the Republic, Itamar Franco, with regard to prices of medicines.[100,101]

Law No. 8884/1994 established in its Art. 21, XXIV and sole paragraph, quite detailed legislative provisions on the subject of exploitative pricing:

Art. 21. The acts spelled out below, among others, will be deemed a violation of the economic order, to the extent applicable under Article 20 and items thereof:

> (...)
> XXIV – to impose abusive prices, or unreasonably increase the price of a product or service.
>
> Sole Paragraph. For the purpose of characterizing an imposition of abusive prices or unreasonable increase of prices, the following items shall be considered, with due regard for other relevant economic or market circumstances:
>
> I – the price of a product or service, or any increase therein, vis-à-vis any changes in the cost of their respective input or with quality improvements;
>
> II – the price of a product previously manufactured, as compared to its market replacement without substantial changes;
>
> III – the price for a similar product or service, or any improvement thereof, on like competitive markets; and
>
> IV – the existence of agreements or arrangements in any way, which cause an increase in the prices of a product or service, or in their respective costs.

Likewise, the enactment of Law 8884/1994 and the consolidation of the Brazilian Competition Defense System (SBDC) in subsequent years took place in the midst of a series of administrative proceedings submitted to CADE to determine drug pricing practices.

Noteworthy is the establishment, in 1999, of a Parliamentary Commission of Inquiry (CPI) by the National Congress of Brazil to investigate allegations of abusive pricing and other practices related to the pharmaceutical sector (CPI on Medicines). The CPI Report, published in 2000, qualified access to medicines as an antitrust concern and, with CADE, proceeded with Representations against 42 (forty-two) laboratories due to the practice of abusive medicine price adjustments.[102] The Representations, judged by the then Secretariat of Economic Law of the Ministry of Justice of Brazil (SDE/MJ), culminated in the establishment of 53 (fifty-three) administrative proceedings, separately, for each of the laboratories.[103] After a long

---

[100] MAZZUCATO, Paolo Zupo. *Medicamentos e Livre Concorrência.* Revista de Informação Legislativa, a. 42, n. 167, jul/set/2005, p. 116.

[101] See Professor José Del Chiaro in an interviewed by the ConJur website: "ConJur — CADE gained more autonomy in 1994, when it was transformed into an autarchy by Law 8,884. In what context did this law arise? José Del Chiaro — It emerged during the Itamar Franco government. He was annoyed by the rise in medicine prices and wanted to find a way to stop it. Therefore, he hastened the passage of the antitrust law, but he was wrong about its purpose. For Itamar Franco, the legislation would be a price control instrument. At that time, there was no understanding that prices would be balanced by free competition and that this would be a long-term process". Read the interview at https://bit.ly/3fKJtgY.

[102] The rationale behind the claims, as stated in the CPI Report, was the rapid increase in medicine prices observed between 1993 and 1999, compared to the official inflation index, and the reviewing of laboratory cost spreadsheets by the CPI. See BRASIL. Câmara dos Deputados. *Relatório da CPI-Medicamentos.* Relator Deputado Ney Lopes. Available from https://bit.ly/3fMLuJK , accessed on 08 Aug. 2021, pp. 90–94.

[103] See Administrative Proceeding No. 08012.000581/2000-16. Petitioner: CPI dos Medicamentos. Respondent: Abbot Laboratórios e outros. Available from https://bit.ly/3xyz6mJ.

investigation regarding such proceedings, however, all were shelved without convicting the responding laboratories.[104]

Controversies over medicine pricing led to a series of initiatives, culminating in the creation of the Medicines Market Regulation Chamber (CMED) by Law No. 10742/2003, which establishes, in its Art. 1, that the purpose of regulating the pharmaceutical sector is "*to promote pharmaceutical assistance to the population, through mechanisms that stimulate the supply of medicines and the competitiveness of the sector*". CMED adopts a price cap regulation, using an index, a productivity factor, and a relative price adjustment factor within and between sectors (Article 4, §1). The prices set by CMED are divided into: *Factory Price*, price cap for commercialization between the laboratory or distributor and the Unified Health System (SUS) and private hospitals; *Maximum Consumer Price* for retail; *Maximum Price of Sale to the Government*: mandatory discount on the Factory Price for commercialization to entities of the direct and indirect public administration of the three Brazilian federative levels.

CMED has broad competence, under Art. 6, IV of Law 10742/2003, to decide for the exclusion and re-inclusion of groups, classes, subclasses of medicines and pharmaceutical products to undergo price adjustments. Some medicines, under CMED Resolutions, are therefore authorized to be commercialized, such as over-the-counter medicines, homeopathic/herbal medicines, expectorants, non-narcotic analgesics, some anti-flu medicines, multivitamins and others (CMED Resolution No. 05/2003 and Annex No. 03/2010, among others). Since the advent of CMED, the attempt to control excessive medicine pricing through competition has had less space.[105]

Furthermore, Law 12529/2011 did not repeat the specific provision on excessive pricing contained in Art. 21, XXIV and sole paragraph of Law 8884/1994. Notwithstanding, the constitutional repetition of "*to arbitrarily increase profits*" and "*to abusively exercise a dominant position*", with specific mention of "*to monopolize and prevent the exploitation of industrial or intellectual property rights or technology*" (Art. 36, XIV), among other references, is conceptually related to exploitative pricing, as will be discussed in a later section. Within the scope of CADE case law, important discussions on the subject, albeit occasional, are still conducted, as will be mentioned below.[106]

With the emergence of the COVID-19 pandemic, the issue of abusive pricing and access to healthcare takes on renewed importance.[107] CADE General Superintendence initiated the Preparatory Proceeding for Administrative Inquiry with the following justification:

> In view of the high demand for medical-pharmaceutical products due to the need for emergency care motivated by the increase in COVID-19-related cases, companies in the health sector may be arbitrarily and abusively increasing prices and profits, making it necessary, on the CADE's part, to ensure that such abusive practices, if effectively

[104] See Sampaio and Ferreira, 2012, *op cit*, p. 293.
[105] Ibid.
[106] An example is the claim related to exploitative prices for Sofosbuvir, based on a study by University of São Paulo (USP)researchers and civil society organizations such as the Brazilian Institute for Consumer Protection (IDEC). See https://bit.ly/2U5CW9h.
[107] Technical Note published in 2020 by DISET-IPEA (Institute for Applied Economic Research) analyzed that access to reasonable prices of items necessary to manage the COVID-19 pandemic is an obstacle to the industrial property rights structure of the sector. The agency has identified more than 330 patents in force or pending applications at INPI regarding pulmonary ventilators, in addition to dozens of patents related to diagnostic items, reagents, respiratory protection, masks, and other products, and concludes by pointing the need for, among other measures, an assessment of the feasibility of compulsory licensing. ZUCOLOTO, Graziela; MIRANDA, Pedro; PORTO, Patrícia. *A propriedade Industrial Pode Limitar o Combate à Pandemia?* Nota Técnica nº 61 – DISET – Instituto de Pesquisa Econômica Aplicada, 2020. Available from https://bit.ly/37sKiGX , accessed on 08 Aug. 2020.

verified, are punished based on Art. 36, I, III and IV, with the penalties stipulated in Arts. 37 and 38, all of Law No. 12259/2011.[108]

Within the scope of this proceeding, CADE General Superintendence issued dozens of official letters requesting information from drug and hospital supply companies—such as invoices showing prices between 2019 and 2020—about the pricing of products related to the treatment of COVID-19 (alcohol gel, surgical masks, tests, and medicines). To date, there has been no mention of specific medicines by CADE General Superintendence, only a request for information about prices of "*products that may have been used to combat COVID-19*". Responses by some pharmaceutical companies, however, contain mentions to medicines.[109]

In 2021, the Brazilian Institute for Consumer Protection (IDEC) requested official participation as an Interested Third Party within the scope of the aforementioned Preparatory Proceeding. The submitted petition requested that the scope of the proceeding was more specific when reporting the increase in medicine prices, including those used for intubation of patients in critical condition due to COVID-19 – in some cases, as the Institute denounces, they found a price increase of up to 900 per cent.[110] To date, CADE General Superintendence has not yet published an assessment of the responses to the official letters issued, or information on the possible course of the proceeding.

2.2.2 b) Arguments about exploitative pricing under CADE case law

With regard to exploitative pricing in medicines and in general[111], the merits of the conduct were discussed in some situations, without convictions. Based on CADE case law on the subject, some arguments can be highlighted, with special emphasis on the debates within the scope of the "CPI on Medicines" cases described above, and in the White Martins case (2010).[112]

Contrary to the recognition of and/or intervention in the practice of exploitative pricing as an autonomous competitive offense, some of the arguments presented were as follows:

- Intervention violates the constitutionally established free pricing system; the social function of monopoly profits, establishing that supracompetitive pricing would act as a reward for risky business investments;[113]

[108] Preparatory Proceeding No. 08700.001354/2020-48. Respondents: Companies in the markets of hospital, pharmaceutical, medical material distribution, medicines, and the like. Available from https://bit.ly/2VyVDmy.
[109] Among the defendants' responses to the official letters, in the context of medicines, for example, are those sent by pharmaceutical companies Pfizer (on medicines such as Zitromax, Zinforo, Torgena, Meropenem, Zyvox and Precedex); Sanofi-Medley (Allegra, Allenasal, Anador, Bisolvon, Desloratadine, Cetirizine, Dipyrone, Ibuprofen and others); Novartis-Sandoz (whose medicines list appears as restricted access); Ache (Dipyrone, Paracetamol, Loratadine, Polaramine, Fexofenadine, Compound Decongestants); Bayer and Jansen (reported that they do not provide medicines for this purpose).
[110] Specifically, the critical level of stocks of "propofol, cisatracurium, atracurium, rocuronium, midazolam, fentanyl" was mentioned; and the shortage of the medicines "rocuronium, midazolam, propofol, cisatricurium, fentanyl, atracurium, pancuronium, clexane, dormonid, methyl prednisone, nimbium, ketamine, dopamine, esmeron, noradrenaline, sedatives, tocilizumab, vecuronium, codeine, dextroketamine, diprivan, dormire, enoxaparin, mycophenolate, omeprazole, slow". See https://bit.ly/3At8QvK.
[111] For a more detailed analysis about exploitative pricing in general, see CASTRO, Bruno Braz de. Preços exploratórios: por uma nova teoria da decisão. Revista do IBRAC, v. 23, pp. 11–69, 2017. Available from https://bit.ly/3xujHUh.
[112] The White Martins case (2010) was about price increases in the oxygen market. The Respondent allegedly made an increase from BRL 2.50 to BRL 4.00/cubic meter in oxygen in January 1998. The case was shelved without conviction, but the debates between the Board Members at the time revolved around the characterization and feasibility, in theory, of discussions about exploitative pricing as an autonomous offense. Administrative Proceeding No. 08012.000295/1998-92. Petitioner: Sindicato da Indústria Mecânica, Metalúrgico e Material Elétrico de Ipatinga/SA. Respondent: White Martins S/A. Available from https://bit.ly/3ivX7qg.
[113] Preliminary Inquiry No. 08012.007514/2000-79. Petitioner: CPI dos Medicamentos. Respondent: Laboratório Teuto-Brasileiro Ltda. Lay-Judge's Vote of Councilor Elizabeth Farina. 2007. Available from https://bit.ly/3iA05Kw.

- Excessive prices tend to self-correct, as they attract the entry of new competitors and the return of the price level to the competitive level;[114]
- Exploitative pricing cannot be an autonomous offense, since, at most, it constitutes evidence of other anticompetitive practices (these, yes, within CADE competence) or of market failures that prevent the free formation of prices (to be managed by sectoral regulation);[115]
- Intervention in exploitative pricing would imply the need for imposition and inspection of prices, a task beyond the scope of CADE;[116]
- The legal provisions related to excessive prices would suffer from an *efficiency problem* due to: (a) measurement difficulties and arbitrariness in defining the price excessiveness; (b) high risk of type 1 errors (wrongful convictions) with a disincentive to innovation; (c) tendency to market self-correction of excessive prices;[117]

Due to such an *efficiency problem*, Councilor Carlos E. J. Ragazzo suggests, in his vote for the White Martins case (2010), that the proceedings dealing with complaints of excessive prices as an autonomous offense should not even be instituted, as they cause the waste of public resources in discussions that could never lead to convictions.[118]

In support of recognizing exploitative pricing as an autonomous anticompetitive practice, there are arguments based on the need to attribute maximum efficiency to the constitutional command to repress the arbitrary increase in profits (CR/88, Art. 173, §4) and legislative provisions related to the subject.[119]

In the context of such legislative provisions – and as an important attitude for the discussion on exploitative pricing and intellectual property – the vote of Councilor Vinícius Marques de Carvalho for the White Martins case (2010) pointed out that CADE's refusal to even acknowledge complaints dealing with exploitative pricing as autonomous offences could generate situations of "national catastrophe". To illustrate, he used as an example a complaint of abusive prices in intellectual property rights over cultivars (under Law No. 9.456/97, establishing the power and duty of CADE to rule on compulsory licensing of the industrial property right in question in the event of "unjustified restriction on competition", Art. 31).[120]

Also, in the White Martins case (2010), CADE Department of Economic Studies described the arguments of those who supported the antitrust control of exploitative pricing:

> "(i) there is a need for consistency with the objectives of antitrust policy, as the clear threat to consumers posed by abusive prices requires the use of antitrust policy to avoid them, or to penalize those who practice them; (ii) price regulation can occur in the scope of antitrust, consumer protection or market regulation; (iii) evaluation difficulties are exaggerated; (iv) the potential distortions caused by price regulation are overestimated;

"*Preventing the firm from making its monopoly profits, in this case, would have the effect of discouraging the entrepreneur from taking risks intrinsic to any investment, which is an undesirable outcome from any perspective. It is even more undesirable when taking as a parameter the objectives of defense of competition*".

[114] Administrative Proceeding No. 08012.000966/2000-01. Petitioner: CPI dos Medicamentos. Respondent: Laboratórios Pfizer Ltda. Vote of Board Member Luiz Carlos Delorme Prado. 2008. Available from https://bit.ly/3jIxbHr.

[115] Ibid.

[116] Ibid.

[117] White Martins case (2010, cit.). Vote of Councilor Carlos Emmanoel Joppert Ragazzo, p. 25.

[118] Ibid., p. 30.

[119] White Martins case (2010, *cit.*). Vote of Councilor Vinícius Marques de Carvalho, p. 15.

[120] Councilor Vinícius Marques de Carvalho argued: "*even in the absence of a normative parameter to know what an acceptable price and a prohibitive price is, CADE will have to stand a position on the matter, evaluating whether or not there is abusiveness in the policy of pricing. To think otherwise would be to admit a national catastrophe*." Ibid., p. 16.

> and (v) price regulation is not the only remedy, thus being possible to attack the causes of abusive prices and not only the effects (high prices)".[121]

There were also arguments supporting the creation of screening tests to determine the markets that are candidates for intervention, with a view to optimizing antitrust analysis and minimizing the risk of wrongful convictions.[122]

Even under the aegis of Law 12529/2011, recent statements made by CADE contain clear indications that exploitative prices continue to represent a competitive concern.

An important example is the Technical Note of CADE's General Superintendence regarding the administrative proceeding that discussed the collection of an abusive fee for the segregation and delivery of port containers (THC2 or SSE) at the port of Suape, in the state of Pernambuco, Brazil, published in April 2020. In the document, CADE General Superintendence corroborates arguments that the focus of the antitrust policy is the competitive process, so that the price level would represent a mere reflection of such a process.

CADE, however, exceptionally established the possibility that excessive pricing, in essence, constitutes an object of antitrust concern, when practiced by a company with "undeniable market power" (and gave an example of a monopoly company with a nonfungible good, without appropriate sector regulation).[123] Thus, with reference to the OECD literature on the subject, CADE stated that circumstances favorable to intervention would include the low potential for market self-correction ("permanently high" barriers to entry) and abusive prices themselves, regulatory absence/failure, and damages for consumer welfare.[124] From this, it concluded that "the conduct investigated meets the conditions indicated by the literature as favorable to the pursuit of abusive pricing by the antitrust authority".[125]

In the same case, Councilor Luiz A. A. Hoffman also expressed an understanding that excessive exploitative pricing continues to be an object of competitive concern under Law 12529/2011, applying said theory to the case in question.[126]

---

[121] See Summary of the arguments prepared by CADE Department of Economic Studies in a Technical Note for the White Martins case (2010, cit.).

[122] For an analysis in detail of CADE jurisprudence on the subject and the implementation of screening systems for complaints about abusive pricing, see MACHADO, Kenys Menezes. *Uma Análise Da Recomendação Da Jurisprudência Recente Do Cade Ao Uso De Triagem Em Casos Envolvendo Preço Abusivo*. Revista do Ibrac, vol. 19, No. 21, pp. 37–55, jan./jul., 2012.

[123] CADE General Superintendence stated: "*However, such an understanding does not exhaust the question of the imposition of abusive prices by a firm with undeniable market power, as occurs in very specific circumstances in markets where the firm is a monopolist of an infungible good or essential infrastructure, for example. In such cases, in the absence of sectoral regulation to regulate this issue and prevent the abuse of market power by the firm that practices the so-called abusive price, there should be applied the determination contained in art. 36, items III and IV, of Law No. 12529/2011, which defines as a violation of the economic order any acts that produce the effects of an arbitrary increase in profits and abusive exercise of a dominant position.*" (underlined in the original). See Administrative Proceeding No. 08700.005499/2015-5. Respondent: Tecon Suape S.A. Technical Note No. 7/2020/CGAA3/SGA1/SG/CADE, §182. Available from https://bit.ly/31UegnP.

[124] Ibid., § 187.

[125] Ibid., *§ 188.*

[126] The Councilor argued: "In fact, the reading of the aforementioned legal diplomas shows that there is no express provision of "abusive prices" as an unlawful conduct, in addition to the legislator's will not to typify the practice, by itself, as an anticompetitive infraction. However, an extensive interpretation makes it possible to frame such a practice in the conduct of "arbitrary increase in profits", so that "the price or excessive increase in itself cannot be considered a practice harmful to competition; it will be so only to the extent that it results from an infringement, or if it is capable of causing an anticompetitive effect". Furthermore, the Councilor recognizes "at least suspicions about the practice of abusive prices, especially in the exploitative modality, in the present case". See Administrative Proceeding No. 08700.005499/2015-5. Respondent: Tecon Suape. Vote of Councilor Luiz Augusto A. Hoffman, §353. Available from https://bit.ly/3oe1V5j .

From this point, in light of the literature on the subject, the discussion will further the aforementioned arguments and their possible repercussion in debates on exploitative medicine prices in Brazil.

3. ANALYSIS: THE EFFICIENCY OF INSTITUTING EXPLOITATIVE PRICING IN BRAZILIAN LAW

It would be incoherent to argue that abusively exercising an exploitative dominant position – whether through excessive prices or through degradation of quality, in aspects such as privacy – would not be included in the legislative definition of "*to arbitrarily increase profits*" or yet in the provisions with regard "*to control the relevant market of goods or services*" and "*to abusively exercise a dominant position*" (Law 12529/2011, Art. 36).[127]

Even if this issue is considered from a point of view strictly guided by economic welfare theory, there would still be an inconsistency because an analysis by effects, under the rule of reason, determines the illegality of any behavior that restricts competition (from cartel to resale price fixing), precisely, in light of its ability to allow the exercise of market power, with effects such as supracompetitive pricing, reduction of consumer surplus, and reduction of total welfare due to deadweight loss.[128]

Such indivisibility is especially evident in the case of goods protected by intellectual property. When the Antitrust Law, in its Art. 36, §3, XIV, establishes that it is unlawful to, here resorting to the original verb in Portuguese, "*açambarcar*" (which means to "*hoard*", that is, to accumulate, to monopolize) and "*prevent the exploitation of industrial or intellectual property rights or technology*", it refers of course to a practice of "*monopoly by hoarding*", generating *deadweight loss*, which is conceptually indivisible from the excessive exploitative price.

By the same token, there are legislative provisions on the potential illegality of these practices:

> Art. 36 – [...]
>
> XIII – to destroy, render useless or monopolize the raw materials, intermediate or finished products, as well as to destroy, disable or impair the operation of equipment to produce, distribute or transport them; [...]
>
> XVI – to retain production or consumption goods, except for ensuring recovery of production costs;
>
> XVII – to partially or totally cease the activities of the company without proven just cause.

Given the teleology of Brazilian competition law and the comprehensive nature of the provisions of Art. 36 of Law 12529/2011, it would be inconsistent to disqualify exploitative pricing as a competitive concern. In the words expressed in the vote of Councilor Vinícius Marques de Carvalho for the White Martins case (2010):

> "If the matter of abusive pricing is banned from the competence of the Antitrust Authority, there will be great difficulty in understanding the legal system as a cohesive whole that has logic and that can serve social interests. Note that the hypothesis defended here is that abusive pricing can be a practice, analyzed by CADE, not only against competitors (such as the refusal of disguised sales) **but also addressed**

[127] The Brazilian Consumer Protection Code also establishes, in its Art. 39, V, that an abusive practice consists of "*demanding a manifestly excessive advantage from the consumer*".

[128] On the methodological role of welfare theory concepts in Brazilian competition law, see CASTRO, Bruno Braz de. *Eficiência e ideologia: inovação, desigualdade e o custo dos erros na tecnocracia antitrus*te. Revista de Defesa da Concorrência, v. 6, pp. 58–94, 2018. Available from https://bit.ly/2XbfKHQ.

> **exclusively against consumers, both by association of this behavior with others (such as hoarding of intellectual property rights; price discrimination; or tie-in sales) or as exclusive conducts for various structural/behavioral reasons**. These points will be explored below" (pp. 15–16, emphasis added).

It is also worth considering the normative contours around the concept of exploitative pricing by competition law.[129] It is not about trying to assign an intrinsic value to a certain good or setting an "X" fair price.[130] operationalizing the concept of exploitative pricing is about identifying the *arbitrary* increase of profits (CR/88, Art. 173, §4) or, in other words, deadweight loss derived from the exercise of market power.[131] This excess is measured against what would be identifiable in an environment with effective competitive pressure.[132]

This perception of excessiveness, in this regard, does not lessen the methodological difficulties around the theme, as there are still inaccuracies about its concrete definition, measurement and remedy.[133]

Regarding measurement methodologies, considerable theoretical and case-law evolution is evident on the subject, with relative improvement of techniques.[134] The OECD 2011 Report on the topic stresses that convergence of methodologies may be ideal: "*no single test can be considered sufficiently reliable and that increased reliability can emerge from aggregating results from different benchmarking tests*".[135] Fletcher and Jardine (2007) argue that such difficulties cannot be overestimated, as there will be "*cases where the excessive pricing is sufficiently extreme that it is relatively easy to demonstrate*".[136]

In addition to such methodological complexity, there are several arguments in the sense that a non-interventionist approach to exploitative pricing, as a general rule, would be more desirable in view of the negative impacts of wrongful convictions (type I errors), such as

---

[129] See CASTRO, 2017, *cit.,* p. 19.
[130] Likewise, in order to establish the undesirability of a cartel, it would not be necessary for the competition authority to unequivocally stipulate the competitive price "x" that would apply in the absence of the combination.
[131] "In general, economic analysis seeks to identify what price level arises from an industrial or market structure. There is no abusive price level, but a price level theoretically related to the characteristics of an industrial structure. To reach this conclusion, the analyst 'designs' market structures - for example, one with a greater number of producers and another with a smaller number of producers - and establishes a comparison between them: case A versus case B. So, prices are high or low only when compared to other industrial structures. Note, therefore, that these prices are not low or high in themselves, but vary depending on a relationship between alternative scenarios, which are certainly discretionary. Also note that the highest price is not considered abusive" (RUIZ, 2011, p. 285).
[132] In this sense, the decision of the European Court of Justice for the United Brands case (1978), the essential thing regarding excessive prices is to identify whether "the dominant firm used the opportunities provided by its dominant position in order to reap commercial benefits that it would not have reaped had there been normal and sufficiently effective competition". In this vein, "to charge a price that is excessive because it bears no reasonable relation to the economic value of the product supplied would be an abuse of a dominant position" (§9). EUROPEAN UNION. European Court of Justice. C-27/76 United Brands. 1978. Available from https://bit.ly/3xySdwX.
[133] See OECD. *Excessive prices. DAF/COMP(2011)18*. 07 Feb. 2011, p. 43. Available from https://bit.ly/3lUI23o. p. 32.
[134] For a summary of the various possible techniques and their limitations and advantages, see OECD 2011, p. 62 *set seq*. On convergence of methodologies, see CASTRO, 2017, *cit.*, p. 53.
[135] OECD, 2011, *cit.*
[136] FLETCHER, Amelia. Jardine, Amelia. Towards an Appropriate Policy for Excessive Pricing. 12th Annual Competition Law and Policy Workshop, 2007, p. 9. https://bit.ly/3AoeO15 .

damage to incentives for business innovation.[137] Excessive prices, on the other hand, would tend to self-correct, generating only temporary allocative inefficiency.[138]

Devlin and Jacobs (2010, p. 97) note, however, that these premises about impacts on incentives to innovate and on market self-correction may be mistaken because neither has been subject to empirical testing.[139] If these premises are false (for example, if market self-correction does not take place within a reasonable time frame), the social harm resulting from type II errors (erroneous acquittals) may assume a much greater magnitude than erroneous convictions. According to the OECD 2012 Report, the main arguments in favor of intervention are structured on the basis of the lack of market self-correction.

"One of the key reasons in favour of intervention in excessive price cases is when markets lack self-correction or at least lack self-correction within a reasonable time frame. Modern economics recognizes many market failures causing this problem. Competition authorities, as the guardians of functioning markets, are well aware of the conditions required for markets to generate socially desirable outcomes. Market power may be based on other factors than superior efficiency or performance, such as first mover advantages in a network industry." (OECD, 2011, cit., p. 35).

Indeed, the last few years have been marked by important empirical publications questioning the tendency towards self-correction of supracompetitive prices as a general rule.[140]

Furthermore, Ezrachi and Gilo (2009, *cit.,* p. 6) observe that "*High prices, in and of themselves, do not attract new entry: It is the post-entry price, and not the pre-entry price, that potential entrants consider when deciding whether to enter*."[141]

In this way, markets with the presence of "*high and non-transitory barriers to entry*" (Motta and Streel, 2007, cit, p. 23), such as markets marked by entrenched dominant positions and protected by a deficient patent structure under the conditions described in the previous sections, may present post-entry pricing prospects that are not very attractive to entrants.

As for the impacts of competitive control upon incentives for innovation,[142] it is important to take into account the structure of such incentives in the specific case and determine the origin of the dominant position.[143] Motta and Streel (2007, cit., p. 24) argue that the origin of the

---

[137] Evans and Padilla (2004, cit, p. 23) explain in detail that the cost of erroneous convictions in cases of exploitative prices would be the reduction of incentives to invest and innovate, by creating a vertical limit for profits (in case the designed rule was "a price is excessive when it is above X percent of the cost"). This is not necessarily the case when, as stated above, the definition of abusiveness in the pricing practice will always be made in concrete, in reference to the competitive conditions of the sector, and not in terms of the stipulation of a general price cap. See CASTRO, *cit.,* 2017, p. 49.

[138] See OECD (2011, *cit.,* p. 7): "*In fact the costs of a type I error, i.e., a false condemnation, is likely to outweigh the costs of a type II error, i.e., a false acquittal. The reason for this is that a non-intervention bears the hope of the market self-correcting through entry, resulting in competition and the usual benefits associated with it such as lower prices, higher quality and more variety, while in the meantime "only" distorting allocative efficiency through its effect on prices*".

[139] DEVLIN, Alan; JACOBS, Michael. Antitrust Error. *William & Mary Law Review*, Williamsburg, v. 52, p. 97, 2010. Available from https://bit.ly/3fPEhse.

[140] GRULLON, Gustavo; LARKIN, Yelena; MICHAELY, Roni. Are U.S. Industries Becoming More Concentrated? Social Science Research Network, No. October, pp. 1–80, 2018. Available from https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2612047.

[141] EZRACHI, Ariel; GILO, David. Are excessive prices really self-correcting? *Journal of Competition Law and Economics*, [s.l.], vol. 5, No. 2, pp. 249–268, 2009. Available from https://bit.ly/3lMGU1P.

[142] Fletcher and Jardine (2008, cit, p. 49) for example, argue against intervention in the context of the presence of patents. Brennan (2007) argues that antitrust intervention is not always harmful to incentives for innovation.

[143] Importantly, this is evident, for example, in the European "Commission's Guidance Paper on Abusive Exclusionary Conduct (2009), which states that the imposition of supply obligations in cases of refusal to deal may not be detrimental to incentives to innovate: "*In some specific cases, it may be evident that the imposition of the supply obligation will manifestly not have negative effects on the incentives of the product owner and/or other*

dominant position may even be traced back to "*un-condemned past exclusionary anticompetitive practices*".

It is also worth considering the importance of competitive pressure and rivalry in maintaining incentives for innovation,[144] as well as the importance of distinct centers of trial-and-error experimentation for a healthy innovation ecosystem.[145]

Thus, it is justifiable to establish criteria to select markets that are candidates for a price screening, in which the risks of erroneous decisions are minimized.[146] Still in the White Martins case (2010), Councilor Ricardo Machado Ruiz even proposed a test to select cases subject to conviction by the SBDC, with special attention to situations in which the dominant company holds exclusivity on production processes or on the offer of the good/service:

> "(a) The price-setting firm must have a dominant position in the relevant market;
>
> (b) The products and services considered must be comparable in terms of technology. Comparisons should therefore be avoided between prices of products that have undergone significant technological changes or that incorporate some elaboration or complementary service ("customization");
>
> (c) The practice of abusive pricing must have some degree of pervasiveness in the industry. The objective is to eliminate specific price negotiation conflicts and exclude cases with particularities. [...];
>
> (d) The abusive pricing agent must do so for a relevant period of time. The intention is to eliminate cases where price fluctuations are related to seasonal and industry-typical instabilities. [...];
>
> (e) If **the price-setting firm has some exclusivity on the offer of products and services and/or on the use of production techniques**, there are structural conditions for the practice of abusive pricing. In this case, there should be argued the impossibility of obtaining a substitute product or service;
>
> (f) The existence of direct or indirect economic relationships between the price-setting firm and the suppliers or demanders. In this case, we have a vertical relationship that may be related to an exclusionary strategy. [...];
>
> (g) The practice of abusive pricing cannot be confused with price fluctuations related to exogenous shocks to the industry. For example, changes in the prices of intermediate products and services generate changes in the prices of final products and services.[147] [...] (emphasis added).

In light of this proposed testing and other considerations above, it is believed that the sector of medicines and other access-to-health services and goods commands priority attention in terms of exploitative pricing.[148] The competition authority's response to exploitative pricing practices can also contribute to bring to bare problematic structures of patent protection such as those described above.

---

operators to invest and innovate upstream, either ex ante or ex post", which occurs, for example, "*when the dominant company's position in the upstream market was developed under the protection of special or exclusive rights or was financed by State resources*". https://bit.ly/3Cye4Iv, §82.

[144] On the subject, see BAKER, Jonathan B. Beyond Schumpeter vs. Arrow: How Antitrust Fosters Innovation. *Antitrust Law Journal*, vol. 74, No. 03, pp. 575–602, 2007.

[145] For an analysis of the literature on the relationship between competition and innovation, see CASTRO, Bruno Braz de. *A que(m) serve o antitruste? eficiência e rivalidade na política concorrencial de países em desenvolvimento*. 1. ed. São Paulo: Singular, 2019, p. 253.

[146] For a deeper reflection upon this argument, see CASTRO, 2017, *cit, p. 38 et seq.*

[147] White Martins case (2010, cit.). Vote of Councilor Ricardo Machado Ruiz, p. 16.

[148] https://ec.europa.eu/competition/publications/reports/kd0718081enn.pdf , p. 23.

3.1 Competition, Regulation and Remedy

In fact, with regard to medicines, it should be noted that the competitive control of exploitative prices would not necessarily involve the action of the competition authority as a price regulating agent. It is important that the remedy is aimed at solving the structural problems identified in relation to the relevant market.[149] Ruiz ponders that "abusive pricing is not a conjunctural or circumstantial situation, but the result of a structure and conducts that persist over time",[150] which could lead to the pursuit of remedies, such as compulsory licensing, and sale of assets and rights.

In the White Martins case (2010, cit.), the vote of Councilor Arthur Sanchez Badin, representing the technical note issued by the CADE Department of Economic Studies (DEE), also concluded that, in cases dealing with excessive pricing, it is "preferable to adopt measures that do not involve direct price control. For example, the reduction of barriers to entry" (p. 24).

The issue around the efficiency of such remedies also arises with regard to public authorities with competence to regulate prices, as in the case of medicines subject to regulation by CMED.

In relation to this point, there are those who even wonder whether CADE should act at all in the presence of price regulation.[151] The issue is complex.[152]

Brazilian competition law has consolidated the position that the presence of a regulatory agency does not imply sectoral antitrust immunity.[153] In general, the complementarity between competition and regulation is defended in cases of regulatory gap or regulatory failure.[154] Given its institutional mission, CADE could not fail to act, even *ex officio*, in the face of suspicion of regulation with anticompetitive effects.

In a decision by CADE on the subject, Councilor Marcelo Calliari highlighted the importance of the competition authority's action, including in the face of conducts that are allowed but not *imposed* by regulation:

---

[149] On the subject, see OECD, 2011, *cit,* p. 59.

[150] RUIZ, Ricardo Machado. Preços abusivos na política antitruste: uma peça com três atores. *Debates em Direito da Concorrência*, Brasília, pp. 279–295, 2011, p. 288.

[151] Sampaio e Guimarães (2012, *op. Cit., p. 294).* "*As per the principle of specialty, one should recognize that, if State sectoral regulation adopts a rigid structure to set prices (even if cap prices) and monitor readjustment margins, CADE will lose competence to decide whether it is, specifically, a case of arbitrary profit increase. In fact, how to classify an increase expressly admitted by sectoral regulation as "arbitrary"?* In another context, the European Court of Justice (ECJ) jurisprudence establishes that State compulsion defense only applies in contexts in which there is no space for autonomy for the dominant firm, not affecting situations in which regulation merely encourages or facilitates such harmful practices. Cf. WHISH, Richard; BAILEY, David. Competition Law. 7th ed. Nova York: Oxford University Press, 2012, p. 138.

[152] CADE's older case law on medicine pricing reveals that there were situations in which the least State involvement in a given conduct was used as a justification for non-enforcement of competition law. CADE shelved Administrative Proceeding No. 129/92 about representation against the "Pharmaceutical Industry Association of Brazil" (ABIFARMA) with regard to price lists and readjustment indices, based on the fact that such lists and indices would have been proceeded through the Ministry of Health.

[153] Inspired by the discussions on the subject in the US, some authors and CADE precedents attempt to analyze the discussions on competition and regulation in Brazil in the light of theories such as the *state action doctrine* and the *pervasive power doctrine*. It so happens that, in the US, the entire case-law construction around these theories aims to resolve, in light of issues such as the federalist model and the constitutional content of that country, horizontal collisions between a federal law (the Sherman Act) and other federal or state laws. Theories are not easily transplantable to a governing constitution system such as the Brazilian one, in which antitrust policy is not only derived from federal legislation, but is a constitutional principle (CR/88, Art. 170, IV) addressed to all infraconstitutional economic policy. Thus, it would not be possible to conceive of implicit immunity to an entire sector or to an indiscriminate list of conduct by economic agents. On the subject, see CASTRO, Bruno Braz de. Os limites jurídicos entre a legislação federal de defesa da concorrência e a ordenação econômica formulada por Estado ou Município: a contribuição da *state action doctrine*. Revista do IBRAC, v. jan-jul, pp. 92–124, 2010.

[154] In this regard, CADE has signed several cooperation terms with sectoral regulatory agencies and administrative bodies (such as INPI, mentioned above).

In fact, even within a regulatory regime properly instituted and enforced, the behavior of companies, regarding those unregulated conducts, may constitute infringements of competition. (...) **Likewise, when the regulatory framework gives companies a margin of choice regarding their actions, it is possible that one or more of these options, allowed but not imposed by regulation, constitute infringements of competition in a specific case.** There is also the possibility that a regulated company may act contrary to regulation, violating not only regulation but also competition law. In such cases, the norms and eventually punishments provided for in both normative systems would apply. This interrelationship between regulation and competition may be expressed, as in Law No. 9472/97 that created Anatel, or not, but it always exists, in order to ensure that markets operate in accordance with the informing principles of the Economic Order provided for in the Constitution.[155]

In the event of a **regulatory failure** (either in the scope of pricing or in the patent protection system), the competition authority's action plays an important role as it assumes a double duty: by transcending the concern with possible punishment of economic agents, CADE's actions must go further to address the sector's regulatory problems and their competitive impacts.

> (...) there is a residual competence of the competition agency whenever the regulation is non-existent or flawed and/or the supervisory authority proves to be inert or negligent in the supervision and enforcement of the regulation. This removes the reason for shelving, so much trumpeted by the SDE/MJ incumbent. **The action of antitrust agencies has a dual purpose:** to punish agents who, benefiting from the regulatory chaos, are involved in restrictive competition practices, and to put pressure on the regulatory agency to adopt appropriate measures in order to remedy regulatory defects.[156]

In fact, the competition authority's action in the face of unwanted competitive effects of public regulation – known among us as "competition advocacy" – is one of the main axes for CADE's action.

Therefore, as noted above, the focus of the competition authority's action in cases of exploitative prices must be prospective and not merely repressive. Motta and Streel (2007), along these lines, argue that "the appropriate remedy should change the market structure for the future and not punish the firm for the past" (2007, op cit., p. 40).[157]

Furthermore, it does not seem desirable that CADE's purpose, in cases of this nature, is to replace CMED, setting prices in parallel with the government agency. What does not seem correct, in light of the above considerations, is to say that there would be antitrust immunity to medicine pricing due to the existence of CMED, since the infra-constitutional regulatory policy must also be legitimized according to the constitutional principle of free competition (CR/88, Art. 170, IV) and based on the command aimed at repressing the arbitrary increase in profits (CR/88, Art. 173, §4).[158]

---

[155] Administrative Proceeding No. 0800.002605/97-52. Respondent: BHTrans. Vote of Rapporteur Marcelo Calliari. 1999.

[156] BRASIL. Conselho Administrativo de Defesa Econômica. Representation No. 07/93. Petitioner: CEBRACAN. Respondent: RONDONAL. Cited in: BRASIL. Conselho Administrativo de Defesa Econômica. Administrative Proceeding No. 0800.002605/97-52. Vote of Rapporteur Marcelo Calliari.

[157] Fletcher e Jardine (2007, *op cit.,* p. 6) even propose that "firms should not face fines for excessive pricing, and should not face the risk of private damages actions in respect of such behaviour".

[158] The unconstitutionality of a legislative or administrative act contrary to the constitutional principle of free competition has already been pointed out several times by the Federal Supreme Court of Brazil (STF). With regard to medicine retailing, STF has already ruled numerous times for the unconstitutionality of laws that impose a minimum distance between pharmacies and drugstores, even editing Summary Statement No. 646: "*It is an offense to the principle of free competition any municipal law that prevents the installation of commercial establishments of the same branch in a certain area*".

In addition to the competence to exclude or reinclude medicines by pricing control, CMED has the authority to include, among the criteria for price regulation, provisions related to the assessment of the sector's degree of competitiveness. For example, CMED Resolution No. 01/2015 began to establish the Herfindahl-Hirschman index (HHI) as a criterion for calculating the share of the intra-sector relative price adjustment factor (called the Z Factor), with reference to the AC4 level of the classification by the European Pharmaceutical Market Research Association (Article 4). Art. 4 §1 of said Resolution provides for:

> Art. 4 (...) §1 The Z Factor aims to promote competition in various drug markets, adjusting relative prices between the least and the most competitive markets.

Notably, CADE technical expertise will undoubtedly be important for price regulation for adequate handling of competition concerns, which need to go far beyond the mere analysis of static market concentrations.

The main purpose of CADE's action would not be to invalidate the regulatory structure or administrative acts such as price regulation.[159] Instead of being an obstacle, the presence of a sectoral regulator can be a source of synergy for the discussion of competitive issues in the sector, reducing the asymmetry of information between the authority and the dominant company, given that a structure for collecting and monitoring information on costs and pricing policies is already in place. *Competition advocacy*, including cooperation between SBDC and CMED to understand the competitive peculiarities of the sector, therefore seems to be an important path.[160]

The Antitrust Law also recognizes an important role for the Secretariat for Economic Monitoring (SEAE) in this matter.[161] This is illustrated by some recent initiatives within the scope of SEAE with the CMED regulation, including a draft proposal to change the methodology for pricing medicines to include issues such as incremental innovation.[162]

CADE Department of Economic Studies (DEE, Art. 17) has also undertaken several advocacy initiatives[163] related to the regulation of medicine pricing in Brazil, both within the scope of regulatory agencies (Anvisa and CMED) and in the context of legislative discussions (for instance, discussing projects on freezing medicine prices in the pandemic).[164]

---

[159] Even under the argument of unconstitutionality (such as the violation of free competition), CADE is subject to the presumption of legitimacy of administrative acts. For more on the subject, see FIGUEIREDO, Lúcia Valle. *Competências dos Tribunais Administrativos para Controle da Constitucionalidade*. Revista Interesse Público, Porto Alegre, v. 24, pp. 24–28, 2004.

[160] Law 12529/2011, on the subject, establishes, for example, the competence of the General Superintendence to "*Art. 13, XIII - advise the public authorities as to the adoption of any action required for compliance herewith; XIV - carry out studies and researches with a view to improving antitrust policies; XV - advise the public of the various forms of violation of the economic order, as well as the means to curb such violations*". In the same Law, Art. 89 establishes CADE's power-duty to act in the face of legal discussions on the defense of competition, providing that "*CADE shall be invited to take part as assistant in court actions involving application of this Law*".

[161] Art. 19 of Law 12529/2011 recognizes SEAE competence to "*promote competition in government agencies and before the society*", with different powers to opine, manifest about and propose anticompetitive normative acts.

[162] SEAE Public Consultation 02/2021 – Draft Resolution on Medicine Regulation – deals with the pricing of medicines, with proposals related to the pricing of incremental product innovations that "*bring additional clinical benefit to the patient, such as dosage convenience or more adherence to treatment*" and provisions on the pricing of non-new biological medicines and new products and therapies for rare and serious diseases. The justification presented, among others, is that there would be many price requests that would not be adequately handled by the methodology currently adopted. See https://www.gov.br/participamaisbrasil/consulta-publica-seae-n-02-2021-criterios-para-precificacao-de-medicamentos.

[163] In a thoughtful response to this researcher's questioning, DEE-CADE, through Mr. Ricardo Medeiros de Castro, sent a detailed description of the advocacy actions and competition legislation enforcement in the interface between SBDC and regulatory agencies in the pharmaceutical sector (such as Anvisa, ANS and CMED) and in the intersection between supplementary health and access to medicines.

[164] See Proceeding No. 08027.000240/2020-70, Technical Note 15/2020/DEE/CADE. Available at https://bit.ly/3n1xa3V.

Furthermore, noteworthy is DEE study on medicine patent awarding in the scope of the Eli Lilly case, mentioned above. In fact, sectoral studies, such as the Brazilian Survey on Competition in the Pharmaceutical Sector, whose results were discussed above, can support the formulation of well-informed public policies.

3.2 Antitrust and Discussions on Regulatory Failures Within the Scope of CMED

One more example of CADE's action in the event of a regulatory failure is that it, after concluding that a certain regulation is unconstitutional for violating the principle of free competition or the constitutional command to repress the arbitrary increase in profits, may refer the analysis to the Public Prosecutor's Office or other bodies (such as the Federal Court of Accounts), so that the administrative act is adequately controlled by the Judiciary.[165]

Several examples may be cited of this type of discussion on regulatory failures in case of disciplinary measures by CMED against the medicine pricing activity. Miziara (2013)'s survey on medicine pricing evolution in Brazil, with theoretical and empirical literature review on the efficiency of CMED regulation, concluded that:

"CMED regulatory policy does not contribute to refraining the evolution of medicine prices and does not contemplate the real behavior of prices on the market. **This is due to the fact that the price caps established by the regulatory body are, in most cases, much higher than the average medicine prices practiced in the market.** Therefore, the medicine industry, pharmacies and drugstores have great freedom to set and adjust prices that are far below the marketing margin established by CMED."[166] (emphasis added).

In 2012 the Federal Court of Accounts (TCU), analyzing the same issue, carried out an Operational Audit at CMED[167] to determine whether the regulatory action of the body avoided the practice of abusive pricing. The Court identified prices that exceeded by up to 10,000% the values already practiced by entities of the Federation, and concluded that, in such cases, they could not represent a reasonable parameter for public procurement. The Court also assessed that, in the case of active ingredients characterized by situations of "monopoly or oligopoly", the prices charged tended to be very close to the factory price; however, that was not the case with regard to active ingredients guided by competition.[168]

In view of this competitive distortion, the Court also carried out an international comparison based on a sample of 50 (fifty) active ingredients with the highest volume of commercialization in 2010. It concluded that, in 43 (forty-three) of them, Brazil had a price above the international average (in 23 (twenty-three), the highest price among the countries surveyed). Of the 50 (fifty)

---

[165] In CADE's decision for Administrative Proceeding No. 08012.006507/1998-81, Councilor Roberto A. C. Pfeiffer argued: "Thus, it is necessary to analyze the reasonableness of the adopted regulation in order to ascertain whether there might be a conflict with the principle of free competition, then suggest alteration of the regulatory rule, and, if not agreed, ultimately refer the records to the Public Prosecutor's Office or yet, depending on the context, refer determinations to the CADE Attorney's Office".

[166] MIZIARA, Nathália Molleis. Regulação do Mercado de Medicamentos: A CMED e a política de controle de preços. (Master's thesis in Law). 2013. Available at https://bit.ly/37rDk50.

[167] TCU issued recommendations and evaluated improvements in the quality of CMED's regulation. See Summary sheet. BRASIL. Federal Court of Accounts - TCU. Rendering of Account No. 034.197/2011-7. Judgment 3016/2012-TCU-Plenary, 2012. Available at https://bit.ly/2XdiODl .

[168] Ibid.: "As for the active ingredients characterized by monopoly or oligopoly situations, it can be seen that the prices practiced are close to the factory price. This is the case of the medicine *Adalimumab 40 mg*, which is a case of monopoly. One question that has arisen is whether the factory prices of medicines characterized as monopoly or oligopoly are consistent with what would be practiced in an economy with competition, or if they present serious distortions, as verified in most of the presentations of medicines in which there is competition. When this is present, the prices charged are much lower than the factory price. For medicines where there is no competition, due to the existing regulation problems, it is possible that abusive prices are being practiced. International comparison was indeed necessary to answer this question".

medicines with the highest revenue, 13 (thirteen) were believed to be in a monopoly situation. Among the ten medicines with the highest sales, six of them were marketed in a monopoly situation, and in all of these, Brazil had the highest price among all the countries compared.

As pointed out in the comparison, if the maximum prices had been fixed by the international average, the savings would have been BRL 1.1 billion.

The TCU audit culminated in a Term of Conduct Adjustment (TAC) signed by CMED with the Federal Public Ministry, through which "*the power/duty of CMED to carry out negative adjustments in medicine prices is established whenever a specific need is identified, to ensure that medicine prices remain at adequate levels*",[169] having also readjusted the prices of the 43 medicines whose prices were considered above the international average by the TCU. In February 2017, the Public Prosecutor's Office filed a public civil action against CMED, alleging non-compliance with the commitments made in the TAC agreement.

In December 2016, CMED approved Resolution No. 02, which provides for the criteria for positive and negative extraordinary adjustments of medicine prices, pointing out that price adjustment according to the market's economic and competitive reality is among the criteria for the extraordinary *negative* review of prices, including the following:

> Art. 6 The extraordinary negative price adjustment, motivated by reasoned justification of CMED, must observe:
>
> I – price adjustment according to the economic and competitive reality, preserving market balance and competitiveness;
>
> II – the existence of marketing margins for the different links in the market chain;
>
> III – the current tax rates;
>
> IV – the behavior of medicine pricing in the national and international market.

As can be seen, the entire medicine price regulatory system in Brazil is permeated by discussions centered on competition. CADE technical expertise in the field of competition law, in the face of situations of exploitative excessive prices, will be invaluable for the formulation of adequate public policy to promote access to medicines in Brazil, especially in view of the competitive impacts of the architecture of industrial property rights in the sector.

[169] BRASIL. Ministério Público Federal. Ação Civil Pública No. 0008080-74.2017.4.01.3400. Available from https://bit.ly/3fNidhT, accessed on 08 Aug. 2021.

4. CONCLUSION

In CADE case law and in international experience, the issue of access to medicines is closely linked to the discussion about the interface between industrial property and competition.

The Brazilian Constitution, in a peculiar way regarding other legal systems in the world, establishes as unlawful "*the arbitrary increase of profits*". The Brazilian competition law, in addition to repeating this provision, includes quite peculiar provisions regarding abuse of industrial property rights (especially by monopolizing/hoarding or unduly limiting access to markets, and by preventing the economic exploitation thereof). The wealth of legislative content should command an active stance on the response of CADE on the issue, with attention to the legal and economic reality of Brazil, which must assume a major position in analyses rather than just transplanting legal theories from other jurisdictions.

CADE case law in this regard relies on the identification of **legal abuse**, in which the use of industrial property rights is associated with anticompetitive purposes, dissociated from their economic or social purpose. Abuse, in this case, is characterized by two types, divided between those oriented to the legal framework for industrial property protection (obtaining or imposing invalid or ineffective rights) and those translated into the abusive exercise of rights that, in themselves, are valid and effective.

The illegitimate imposition (or extension) of legal or factual exclusivity on a particular medicine has significant impacts. In its exclusionary aspect, it manifests the control, by a dominant economic agent, over opportunities for access and permanence in the market – constraining, for example, legitimate expectations of entry by generic manufacturers. The resulting concentration has a negative impact on the innovation ecosystem (dynamic efficiency) by reducing the variety of centers of trial-and-error experimentation.

From an exploitative point of view, this means to directly exploit market power, or "to arbitrarily increase profits", as constitutionally provided for, through exploitative excessive pricing, reduction of investments in innovation, degradation of quality, etc. Access to health is arguably hampered by excessive pricing, especially with regard to the awarding of patents on medicines.

In Brazil, as described above, several surveys have also shown billions of public expenditures imposed upon the Unified Health System (SUS) for the granting and undue extension of patents, often because of INPI backlog, discussed even by the Federal Supreme Court in 2021. An analysis of the overpricing derived solely from the undue extension of patents because of INPI delays, and considering a small number of medicines procured by the SUS (art. 40, sole paragraph of IPL), as presented above, estimates at least BRL 1.1 billion in losses to the public coffers. In fact, it is questionable whether or not the expansion of the public budget destined to the analysis of these issues (INPI had a budget of BRL 600 million in 2020[170]) would indeed be more economical for the public coffers.

The control of exploitative practices by competition law must assume a prospective focus, directed to the solution of structural problems, instead of guided by the direct regulation of prices. At this point, competition legislation already specifically provides for remedies such as sale of assets or recommendation of compulsory licensing. In the presence of a sectoral regulator, competition advocacy assumes a central position.

[170] Source: Portal da Transparência do Governo Federal [Brazil's Open Budget Transparency Portal]. Available from http://transparencia.gov.br/orgaos/30204?ano=2020, accessed on 9 August 2021.

Just as in the case of INPI, there are other discussions on considerable losses due to failures in medicine price regulation by CMED in public and private procurement, with figures in billion BRL as well. In light of CADE activity in other regulated sectors, there is no evidence that the economic practices in those sectors would be immune from antitrust control by virtue of the presence of a regulator.

The Brazilian medicine price regulation system attributes considerable flexibility to CMED in defining the criteria for inclusion/exclusion of products, as well as their extraordinary positive/negative readjustment. Especially after initiatives within the scope of the Public Prosecutor's Office and the Federal Court of Accounts, many of the criteria currently in force include typically competitive concepts and concerns. This is sufficient evidence to argue that CADE's technical expertise is essential to regulatory quality in the sector.

Finally, it should be noted that the Brazilian experience presented here can provide more general subsidies to developing countries in general. Any attempts at international antitrust harmonization or convergence must take into account the policy choices enshrined in each legal system.[171] Theories of competitive harm are not limited to "pure" economic artifacts, since economic models and assumptions about the behavior of markets are necessarily conjugated to normative precepts that are part of the constitutional economic order – such as the role of the State, the role of a given economic activity in the national development, or the social perception of the phenomena to be promoted or fought.[172]

Besides a **normative** definition, it is crucial to work on a **strategic** definition, one that is aimed at setting **law enforcement policy** priorities, capable of being undertaken by a competition authority with scarce resources.

The competition legislation format and the law enforcement policy priorities by national authorities can have a major impact on promoting the right to health and access to medicines. Ido (2020) points to the existence of a wide public policy space, within the scope of the TRIPS Agreement, in order for developing countries to define decisive elements of their competition policies, such as their purposes, competences and powers of the antitrust authorities and their coordination with other institutions.[173]

It is possible, therefore, that developing countries calibrate their competitive policies to properly handle artificial restrictions on access to medicines, often translated into abuse of dominant position (both from an **exclusionary** and exploitative standpoint) including industrial property rights abuse.

As can be seen above, arguments aimed at non-intervention in the face of abuse of dominant position tend to denote that intervention is undesirable – given the harm that is caused due to unfair convictions, such as harmful effects on incentives for innovation (type I errors – wrongful convictions) – or unnecessary – given the market's tendency to self-correct eventual uncondemned market distortions (type II errors – erroneous acquittals).[174]

---

[171] On the position of developing countries in the face of the international antitrust convergence process, see CASTRO, Bruno Braz de. A que(m) serve o antitruste? eficiência e rivalidade na política concorrencial de países em desenvolvimento. 1. ed. São Paulo: Singular, 2019, cap. 2.

[172] See CASTRO, Bruno Braz de. Eficiência e ideologia: inovação, desigualdade e o custo dos erros na tecnocracia antitruste. Revista de Defesa da Concorrência, v. 6, pp. 58–94, 2018a. Available at https://bit.ly/2XbfKHQ, accessed on 8 August 2021.

[173] Ido, Vitor Henrique Pinto. *Designing Pro-Health Competition Policies in Developing Countries.* Research Paper No. 125 (Geneva, South Centre, December 2020), p. 31.

[174] For a more detailed discussion of the cost of antitrust errors, see CASTRO, Bruno Braz de. Preços exploratórios: por uma nova teoria da decisão. Revista do IBRAC, v. 23, pp. 11–69, 2017. Available from https://bit.ly/3xujHUh, accessed on 8 August 2021.

The pertinence of any legal transplant must, however, be assessed in each specific case, since there are economic circumstances – especially remarkable in developing countries[175] – that suggest the existence of distortions that do not tend to "self-correct" in a reasonable time frame. For this reason, the production of local knowledge about the structure, conduct and innovation processes of the local pharmaceutical sector – such as the production of Sectoral Surveys – can be invaluable.

A minimalist approach to exclusionary/exploitative practices, anchored in the hypothesis of self-correction of type II errors, must be confronted with situations in which the entrenchment of dominant positions is obtained precisely because of the omission of an antitrust policy that deems such correction as a natural phenomenon. As discussed above, supracompetitive pre-entry pricing is no guarantee of adequate post-entry competitive conditions, as vigorous (post-entry) price competition can be suppressed by un-condemned exclusionary abuse of dominance (such as sham litigation, predation, vertical restrictions, etc.), among others. In such a situation, blind adherence to the self-correcting narrative of supracompetitive prices is what, ironically, prevents such a correction from taking place in practice.

Still regarding the estimated loss due to type II errors, it is inappropriate that such measurement be centered on a static and quantitative dimension. The harm resulting from exploitative pricing cannot be summarized as a mere static analysis of the transfer of resources between producers and consumers – or even the loss of allocative efficiency called "the monopolist's dead weight".

Exploitation is a dimension of power and can also play a role in the conformation (or "deformation") of economic relations in a given market, when it distorts incentives for innovation: implementing exploitative practices would assume the character of a competitive variable. Thus, there is a risk that competition will begin to process itself around the construction of strategies that support the charging of supracompetitive prices more effectively and for longer (as in the case of "evergreening").[176]

It is therefore necessary to consider a dynamic and qualitative dimension of exploitation, for instance, the breach of consumers' and suppliers' bargaining power – which definitely affects the course of relations between the links in the production chain over time. The vulnerability of the bargaining power of certain elements in the chain (such as small businesses) can lead to the degradation of contractual terms (reduction in the quality or economic value of contracts, imposition of abusive terms, abusive readjustments and revisions, readjustments in the distribution of risks), and make unfeasible certain business models that could have flourished if they were set in a scenario where abuse of dominance was strictly fought.

In other words, inaction in the face of abuse of dominant position ensures the survival of the most **powerful** company at the expense of the most **efficient** company. The analysis of incentives for innovation, in cases of abuse of a dominant position, must also take into account the losses derived from the elimination of independent centers of learning, trial and error.[177] Exploitation and exclusion appear here as two sides of the same coin: economic power.

---

[175] See CASTRO, Bruno Braz de. Finalidades da Política Concorrencial e Promoção da Rivalidade em Países em Desenvolvimento: Argumentos em Prol de um Foco Renovado no Combate a Abusos de Posição Dominante. Revista do IBRAC, v. 24, pp. 90–136, 2018b. Available from https://bit.ly/2VC9us0.

[176] Also, in the dimension of quality degradation, the example of digital markets should be considered: in a scenario where privacy rights are weakly enforced, privacy degradation can become a competitive variable – that is, competition may then favor the company that best degrades this qualitative contractual element. Such a situation would affect the direction of innovation in these markets. For no other reason, privacy issues have driven the resurgence of the concept of exploitative abuses in jurisdictions such as that of Germany.

[177] For more details on the present argument with reference to evolutionary theory, see CASTRO, Bruno Braz de. A que(m) serve o antitruste? eficiência e rivalidade na política concorrencial de países em desenvolvimento. 1. ed. São Paulo: Singular, 2019, caps. 3 e 4.

If such a scenario was verified in a concrete case, then such “self-correction” of exploitative practices would be an impossible hypothesis due to the fact that, even if prices returned to a “competitive level”, the direction of that economic activity – and its role in the development of a country, for instance the pharmaceutical industry’s role in ensuring the right to health – would have already been irreversibly affected.

REFERENCES

AMARAL, Luciene Ferreira Gaspar; MALVEIRA, Sandra. *Acesso às Patentes de Medicamentos de Interesse da Saúde Pública em Tempo de Pandemia.* Revista Direito.UnB. Maio-Agosto, 2020, V. 04, N. 02 (Tomo II), pp. 17–42. Available from https://bit.ly/2Vzhj1n, accessed 08/08/2021.

BARRIOS, Lucas. O contrato internacional de transferência de tecnologia e o direito da concorrência no Brasil: Análise à luz da recente jurisprudência do CADE. Revista de Defesa da Concorrência, v. 2, n. 2., 2014. Available from https://bit.ly/3fLAkVM , accessed 08/08/2021.

BAKER, Jonathan B. Beyond Schumpeter vs. Arrow: How Antitrust Fosters Innovation. *Antitrust Law Journal*, vol. 74, No. 03, pp. 575–602, 2007.

BINOTTO, Anna. Cooperação e Concentração: o empreendimento comum e a nova disciplina dos contratos associativos. In: Revista de Defesa da Concorrência – RDC, Vol. 6, nº. 1, Maio 2018, p. 232–260. Available from https://bit.ly/3yAKhwy, accessed 08/08/2021.

BRASIL. Câmara dos Deputados. *Relatório da CPI-Medicamentos.* Relator Deputado Ney Lopes. Available from https://bit.ly/3fMLuJK , accessed 08/08/2021.

BRASIL. MINISTÉRIO PÚBLICO FEDERAL. Ação Civil Pública nº 0008080-74.2017.4.01.3400. Available from https://bit.ly/3fNidhT , accessed 08/08/2021.

BRASIL. Supremo Tribunal Federal. ADI 5529 MC/DF. Relator Min. Dias Toffoli. Julgamento 07/04/2021. Available from https://bit.ly/3CyWVi3 , accessed 08/08/2021.

BRASIL. TRIBUNAL DE CONTAS DA UNIÃO. Tomada de Contas nº 034,197/2011-7. Acórdão 3.016/2012-TCU-Plenário, 2012. Available from https://bit.ly/2XdiODl .

BRASIL. TRIBUNAL DE CONTAS DA UNIÃO. Tomada de Contas nº 015.369/2019-6, Relatório de Auditoria, 2020. Available from https://bit.ly/3AoH83m .

CASTRO, Bruno Braz de. Os limites jurídicos entre a legislação federal de defesa da concorrência e a ordenação econômica formulada por Estado ou Município: a contribuição da *state action doctrine*. Revista do IBRAC, v. jan-ju, p. 92–124, 2010. Available from https://bit.ly/3yELW48, accessed 08/08/2021.

CASTRO, Bruno Braz de. *Sham Litigation: o abuso do direito de petição com efeitos concorrenciais*. Revista do IBRAC, v. jul-dez, p. 58–74, 2010. Available from https://bit.ly/3yELW48 , accessed 08/08/2021.

CASTRO, Bruno Braz de. PREÇOS EXPLORATÓRIOS: POR UMA NOVA TEORIA DA DECISÃO. REVISTA DO IBRAC, v. 23, p. 11–69, 2017. Available from https://bit.ly/3xujHUh, accessed 08/08/2021.

CASTRO, Bruno Braz de. Eficiência e ideologia: inovação, desigualdade e o custo dos erros na tecnocracia antitruste. REVISTA DE DEFESA DA CONCORRÊNCIA, v. 6, p. 58–94, 2018a. Available from https://bit.ly/2XbfKHQ, acessed 08/08/2021.

CASTRO, Bruno Braz de. *Finalidades da Política Concorrencial e Promoção da Rivalidade em Países em Desenvolvimento: Argumentos em Prol de um Foco Renovado no Combate a Abusos de Posição Dominante*. REVISTA DO IBRAC, v. 24, p. 90–136, 2018b. Available from https://bit.ly/2VC9us0, accessed 08/08/2021.

CASTRO, Bruno Braz de. A que(m) serve o antitruste? eficiência e rivalidade na política concorrencial de países em desenvolvimento. 1. ed. São Paulo: Singular, 2019.

CUEVA, Ricardo Villas Bôas. A proteção da propriedade intelectual e a defesa da concorrência nas decisões do CADE. Revista do IBRAC, São Paulo, v. 15, n. 1, p. 121–147, 2009. Available from https://bit.ly/3fOTvxH , accessed 08/08/2021.

DEVLIN, Alan; JACOBS, Michael. Antitrust Error. *William & Mary Law Review*, Williamsburg, vol. 52, p. 75, 2010. Available from https://bit.ly/3fPEhse , accessed 08/08/2021.

EVANS, David S.; PADILLA, A Jorge. Excessive prices: using economics to define administrable legal rules. CEPR Discussion Paper nº 4626, 2004. Available from https://bit.ly/3yzn9P3 , accessed 08/08/2021.

EZRACHI, Ariel; GILO, David. Are excessive prices really self-correcting? *Journal of Competition Law and Economics*, [s.l.], vol. 5, No. 2, pp. 249–268, 2009. Available from: https://bit.ly/3lMGU1P , accessed 08/08/2021.

FILHO, Calixto Salomão. Teoria Crítico-Estruturalista do Direito Comercial. Marcial Pons: São Paulo, 2015.

FIUZA, Eduardo P. S. LISBOA, Marcos de B. *Bens Credenciais e Poder de Mercado: Um Estudo Econométrico da Indústria Farmacêutica Brasileira*. Texto para Discussão nº 846. Instituto de Pesquisa Econômica Aplicada (Ipea), 2001. Available from https://bit.ly/3fLUpek, accessed 08/08/2021.

FLETCHER, Amelia. Jardine, Amelia. Towards an Appropriate Policy for Excessive Pricing. 12th Annual Competition Law and Policy Workshop, 2007. https://bit.ly/3AoeO15

FORGIONI, Paula A. Os fundamentos do antitruste. 9ª Edição. São Paulo: Revista dos Tribunais, 2016, p. 417.

IDO, Vitor Henrique Pinto. *Designing Pro-Health Competition Policies in Developing Countries.* Research Paper No. 125. Geneva: South Centre, 2020. Available from https://bit.ly/3iuNaJI, accessed 08/08/2021.

KREIN, Julia. Contratos Associativos: na contramão da lei nº 12.529/11. Revista do IBRAC, n.1, 2021. Available from https://bit.ly/2XdjCYP, accessed 08/08/2021.

LYONS, Bruce. The paradox of the exclusion of exploitative abuse. In: SWEDISH COMPETITION AUTHORITY. The pros and cons of high prices. Kalmar: Lenanders Grafiska, 2007, pp. 65–87. Available from https://bit.ly/2VKSQGE , accessed 08/08/2021.

OCDE. Competition, Patents and Innovation II, 2009. Available from https://bit.ly/3jwA1yQ, accessed 08/08/2021.

OCDE. *Excessive prices. DAF/COMP(2011)18*. 2011. Available from: https://bit.ly/3lUI23o, accessed 09/08/2021.

OCDE. Revisão por Pares da OCDE sobre Legislação e Política de Concorrência: Brasil. 2019. Available from https://bit.ly/37JLd65, accessed 08/08/2021.

MACHADO, Kenys Menezes. *Uma Análise Da Recomendação Da Jurisprudência Recente Do Cade Ao Uso De Triagem Em Casos Envolvendo Preço Abusivo*. Revista do Ibrac, v. 19, n. 21, pp. 37–55, jan./jul., 2012.

MATTHEWS, Duncan. GURGULA, Olga. Patent Strategies and Competition Law in the Pharmaceutical Sector: Implications for Access to Medicines. Queen Mary University of London, School of Law Legal Studies Research Paper No. 233/2016. Available from https://bit.ly/3CvvJ3E , accessed 08/08/2021.

MAZZUCATO, Paolo Zupo. *Medicamentos e Livre Concorrência.* Revista de Informação Legislativa, a. 42, n. 167, jul/set/2005.

MIZIARA, Nathália Molleis. Regulação do Mercado de Medicamentos: A CMED e a política de controle de preços. (dissertação – Mestrado em Direito). 2013. Available from https://bit.ly/37rDk50 , accessed 08/08/2021.

MOTTA, Massimo; STREEL, Alexandre de. *Excessive pricing in competition law*: never say never? In: SWEDISH COMPETITION AUTHORITY (Org.). *The pros and cons of high prices*. Kalmar: Lenanders Grafiska, 2007. pp. 14–46. Available from https://bit.ly/3iAIH8q, accessed 08/08/2021.

PARANHOS, Julia. MERCADANTE, Eduardo. HASENCLEVER, Lia. *O custo da extensão da vigência de patentes de medicamentos para o Sistema Único de Saúde*. Cadernos de Saúde Pública, 2020. Available from https://bit.ly/3s3Aa0I, accessed 08/08/2021.

PEREIRA, Dárcio Gomes. FIUZA, Eduardo P. S. *Os Direitos de propriedade intelectual nas estratégias de ciclo de vida para medicamentos de segunda geração : resultados parciais do inquérito brasileiro sobre a concorrência do setor farmacêutico*. Radar : tecnologia, produção e comércio exterior, Brasília, n. 29, 70 p., out. 2013. Available from https://bit.ly/3yyOoJt , accessed 08/08/2021.

POSSAS, Mario Luiz. MELLO, Maria Tereza Leopardi, Antitrust and Intellectual Property: Conflicts and Convergences. In *Knowledge Governance: Reasserting the Public Interest*, BURLAMAQUI, Leonardo. *et al.* (editors). New York: Anthem Press, 2012.

RENZETTI, Bruno Polonio. *Tratamento do Sham Litigation no Direito Concorrencial Brasileiro à Luz da Jurisprudência do CADE*. Revista de Defesa da Concorrência. Vol. 5, nº 1. Maio 2017. Available from https://bit.ly/2U5rkDd, accessed 08/08/2021.

RUIZ, Ricardo Machado. Preços abusivos na política antitruste: uma peça com três atores. *Debates em Direito da Concorrência*, Brasília, p. 279–295, 2011, p. 288.

SAFATLE, Leandro Pinheiro. LEAL, João Carvalho. BARBOSA, Luiz Coimbra. Castro, Bruno Ribeiro de. *Procedimentos para a definição e análise antitruste de mercados relevantes de medicamentos*. Contrato SDE/MJ nº 1/2003. ANPEC-IPEA. Available from https://bit.ly/3xzCs8M, accessed 08/08/2021.

SAMPAIO, Patricia Regina Pinheiro. GUIMARÃES, Heitor Campos de. Competências da Autoridade Concorrencial em Setores Regulados: Considerações à luz da jurisprudência do Cade no setor de medicamentos. *Economic Analysis of Law Review*, vol. 3, No. 2, pp. 281–306, Jul-Dez, 2012. Available from https://bit.ly/2VE7X4D, accessed 08/08/2021.

STIGLITZ, Joseph E., Economic Foundations of Intellectual Property Rights. *Duke Law Journal* vol. 57, p. 1693, 2008. Available from https://bit.ly/3Cp58VM, accessed 08/08/2021.

UNIÃO EUROPEIA. Comissão Europeia. Competition Enforcement in the Pharmaceutical Sector (2009-2017). Luxemburgo: Publications Office of the European Union, 2019. Available from https://bit.ly/3s1dZbs , accessed 08/08/2021.

UNIÃO EUROPEIA. Comissão Europeia. *Pharmaceutical Sector Inquiry*, 2009. Available from https://bit.ly/2VEMY1N , accessed 08/08/2021.

UNIÃO EUROPEIA. Corte Europeia de Justiça. C-27/76 *United Brands*. 1978. Available from https://bit.ly/3xySdwX.

WHISH, Richard; BAILEY, David. *Competition Law. 7th ed*. Nova York: Oxford University Press, 2012.

ZUCOLOTO, Graziela; MIRANDA, Pedro; PORTO, Patrícia. *A propriedade Industrial Pode Limitar o Combate à Pandemia?* Nota Técnica nº 61 – DISET – Instituto de Pesquisa Econômica Aplicada, Maio de 2020. Available from https://bit.ly/37sKiGX, accessed08/08/2020.

LIST OF CADE CASES CONSULTED

BRASIL. CONSELHO ADMINISTRATIVO DE DEFESA ECONÔMICA.

AC nº 08012.003189/2009-10. Requerentes: Sanofi-Aventis Farmacêutica Ltda e Medley S.A. Indústria Farmacêutica. Voto do Conselheiro-Relator César Costa de Alves Mattos. 2010. Available from https://bit.ly/3CwA5aJ .

AC nº 08700.004123/2012-86. Requerentes: Takeda Farmacêutica do Brasil Ltda. e Multilab Indústria e Comércio de Produtos Farmacêuticos. Parecer Técnico nº 100 da Superintendência Geral. 2013. Available from https://bit.ly/3jBQ0Mm

AC nº. 08012.002870/2012-38; nº 08012.006706/2012-08; nº. 08700.003898/2012-34; e nº. 08700.003937/2012-01. Voto do Conselheiro-Relator Elvino de Carvalho Mendonça. 2013. Available from https://bit.ly/2VynDqq .

AC nº 08700.004957/2013-72. Requerentes: Monsanto do Brasil e Bayer S.A. Voto do Conselheir-Relator Alessandro Octaviani Luis. 2014. Available from https://bit.ly/2VD7nE3.

AC nº 08700.009834/2014-09. Requerentes: União Química Farmacêutica Nacional S.A. e Novartis Biociências S.A. Parecer nº 6/2015/CGAA1/SGA1/SG. 2015. https://bit.ly/2VIrvVA

AC nº 08700.008607/2014-66. Requerentes: GSK e Novartis. Parecer nº 13/2015/CGAA1/SGA1/SG. 2015. Available from: https://bit.ly/3fEWiJV.

AC nº 08700.003575/2017-55. Requerentes: ARES TRADING S.A. E PFIZER, INC. Parecer nº 180/2017/CGAA5/SGA1/SG. 2017. Available from https://bit.ly/2X0uRnd .

AC nº 08700.006640/2017-02. Requerentes: ASTRAZENECA UK LIMITED E MERCK ONCOLOGY GMBH. Parecer nº 297/2017/CGAA5/SGA1/SG. Available from https://bit.ly/3xBA4i1.

AC nº 08700.001206/2019-90. Requerentes: GSK e Pfizer.

- Voto da Conselheira-Relatora Paula Farani de Azevedo, 2019. Available from https://bit.ly/2X229SY .

- Parecer da Superintendência-Geral nº 11/2019/CGAA1/SGA1/SG, 2019. Available from https://bit.ly/3lLYqmR .

AC nº 08700.002074/2019-13. Requerentes: AMBEV S.A. E RED BULL DO BRASIL LTDA. Parecer da Supreintendência-Geral nº 19/2019/CGAA3/SGA1/SG/CADE. 2019. Available from https://bit.ly/3Avxpsb,

AC nº 08700.000831/2019-14. Requerentes: GLAXOSMITHKLINE PLC. E ARES TRADING S.A. Parecer nº 83/2019/CGAA5/SGA1/SG. 2019. Available from https://bit.ly/3jys6kK

***

AP nº 08012.000295/1998-92. Representante: Sindicato da Indústria Mecânica, Metalúrgico e Material Elétrico de Ipatinga/SA. Representada: White Martins S/A. Available from https://bit.ly/3ivX7qg .

AP nº 08012.005727/2006-50. Representada: Alcoa Alumínio S.A. Voto do Conselheiro-Relator César Mattos. 2010. Available from https://bit.ly/37JR7UN

****

Consulta nº 08700.008419/2016-08. Requerentes: Warner Bros Home Entertainment Inc. e EA Swiss Sàrl. Voto-Vogal da Conselheira Cristiane Alkmin Junqueira Schmidt. Available from https://bit.ly/37ufrK3 .

****

IA nº 08012.011615/2008-08. Representante: Cristália Produtos Químicos Farmacêuticos Ltda. Representados: Abbvie Farmacêutica Ltda. e Abbott Laboratories Inc. Nota Técnica 1/2019/CGAA1/SGA1/SG/CADE. 2019. Available from https://bit.ly/3jGzLNN .

****

PA nº 0800.002605/97-52. Representada: BHTrans. Voto do Relator Marcelo Calliari. 1999.

PA nº 08012.009088/1999-48. Representante: Conselho Regional de Farmácias do Distrito Federal. Representados: ABIFARMA e laboratórios associados. 1999. Available from https://bit.ly/2VDc94r .

PA nº 08012.007514/2000-79. Representante: CPI dos Medicamentos. Representado: Laboratório Teuto-Brasileiro Ltda. Voto-Vogal da Conselheira-Presidente Elizabeth Farina. 2007. Available from https://bit.ly/3iA05Kw .

PA nº 08012.000966/2000-01. Representante: CPI dos Medicamentos. Representado: Laboratórios Pfizer Ltda. Voto do Conselheiro Luiz Carlos Delorme Prado. 2008. Available from https://bit.ly/3jIxbHr.

PA nº 08012.000581/2000-16. Representante: CPI dos Medicamentos. Representada: Abbot Laboratórios e outros. Nota Técnica da Secretaria de Direito Econômico (SDE), 2008. Available from https://bit.ly/3xyz6mJ .

PA nº 08012.00172/1998-42. Representada: Matec. Representante: Power-tech. Voto do Conselheiro-Relator Ronaldo Porto Macedo Júnior. 2002. Available from https://bit.ly/3yuEWXv.

PA nº 08012.010648/2009-11. Representados: Abióptica e outros. Voto do Conselheiro-Relator Eduardo Pontual Ribeiro. 2014. Available from https://bit.ly/3xxrJfd .

PA nº 08012.011508/2007-91. Representante: Associação Brasileira das Indústrias de Medicamentos Genéricos Pró-Genéricos. Representadas: Eli Lilly do Brasil Ltda e Eli Lilly and Co. Voto da Conselheira Ana Frazão. 2015. Available from https://bit.ly/2VKigEk.

PA nº 08700.010811/2014-47. Representadas Lundbeck Brasil Ltda e H. Lundbeck A/S. Nota Técnica nº 16/2018/CGAA1/SGA1/SG/CADE. 2018. Available from https://bit.ly/3AqGlyL .

PA nº 08012.006377/2010-25. Representados: Lundbeck Brasil LTDA. e H. Lundbeck A/S. Voto da Conselheira-Relatora Polyana Ferreira Silva Vilanova. 2018. Available from https://bit.ly/3iAD5uR .

PA nº 08012.002673/2007-51. Representante: Associação Nacional dos Fabricantes de Autopeças (Anfape). Representada: Volksagen do Brasil e outras.

- Voto do Conselheiro-Relator Carlos Emmanuel Joppert Ragazzo. 2010. Available from https://bit.ly/3s1rY0Q .
- Voto do Conselheiro-Relator Paulo Burnier. 2017. Available from https://bit.ly/2U4gwoJ..

PA nº 08012.007147/2009-40. Representadas Genzyme do Brasil Ltda. e Genzyme Corporation. Nota Técnica nº 10/2019/CGAA1/SGA1/SG/CADE. 2019. Available from https://bit.ly/2VJri44

***

PPIA nº 08700.008409/2014-00. Representante: TCT Mobile Telefones Ltda; Representado: Telefonaktiebolaget L M Ericsson. Nota Técnica nº 11/2015/CGAA1/SGA1/SG/CADE. Available from https://bit.ly/2U2usQ4 .

PPIA nº 08700.001354/2020-48. Representados: Empresas dos mercados hospitalar, farmacêutico, distribuição de materiais hospitalares, medicamentos e afins. Available from https://bit.ly/2VyVDmy

RECENT SOUTH CENTRE RESEARCH PAPERS

Nº	Date	Title	Authors
91	February 2019	Key Issues for BAPA+40: South-South Cooperation and the BAPA+40 Subthemes	Vicente Paolo B. Yu III
92	March 2019	Notification and Transparency Issues in the WTO and the US' November 2018 Communication	Aileen Kwa y Peter Lunenborg
93	March 2019	Regulating the Digital Economy: Dilemmas, Trade Offs and Potential Options	Padmashree Gehl Sampath
94	April 2019	Tax Haven Listing in Multiple Hues: Blind, Winking or Conniving?	Jahanzeb Akhtar y Verónica Grondona
95	July 2019	Mainstreaming or Dilution? Intellectual Property and Development in WIPO	Nirmalya Syam
96	Agosto 2019	Antivirales de acción directa para la Hepatitis C: evolución de los criterios de patentabilidad y su impacto en la salud pública en Colombia	Francisco A. Rossi B. y Claudia M. Vargas P.
97	August 2019	Intellectual Property under the Scrutiny of Investor-State Tribunals Legitimacy and New Challenges	Clara Ducimetière
98	September 2019	Developing Country Coalitions in Multilateral Negotiations: Addressing Key Issues and Priorities of the Global South Agenda	Adriano José Timossi
99	September 2019	Ensuring an Operational Equity-based Global Stocktake under the Paris Agreement	Hesham AL-ZAHRANI, CHAI Qimin, FU Sha, Yaw OSAFO, Adriano SANTHIAGO DE OLIVEIRA, Anushree TRIPATHI, Harald WINKLER, Vicente Paolo YU III
100	December 2019	Medicines and Intellectual Property: 10 Years of the WHO Global Strategy	Germán Velásquez
101	December 2019	Second Medical Use Patents – Legal Treatment and Public Health Issues	Clara Ducimetière
102	February 2020	The Fourth Industrial Revolution in the Developing Nations: Challenges and Road Map	Sohail Asghar, Gulmina Rextina, Tanveer Ahmed y Manzoor Illahi Tamimy (COMSATS)
103	February 2020	Eighteen Years After Doha: An Analysis of the Use of Public Health TRIPS Flexibilities in Africa	Yousuf A Vawda y Bonginkosi Shozi
104	March 2020	Antimicrobial Resistance: Examining the Environment as Part of the One Health Approach	Mirza Alas
105	March 2020	Intersección entre competencia y	María Juliana Rodríguez Gómez

		patentes: hacia un ejercicio pro-competitivo de los derechos de patente en el sector farmacéutico	
106	March 2020	The Comprehensive and Progressive Agreement for the Trans-Pacific Partnership: Data Exclusivity and Access to Biologics	Zeleke Temesgen Boru
107	April 2020	Guide for the Granting of Compulsory Licenses and Government Use of Pharmaceutical Patents	Carlos M. Correa
108	April 2020	Public Health and Plain Packaging of Tobacco: An Intellectual Property Perspective	Thamara Romero
109	May 2020	Non-Violation and Situation Complaints under the TRIPS Agreement: Implications for Developing Countries	Nirmalya Syam
110	May 2020	Estudio preliminar del capítulo sobre propiedad intelectual del acuerdo MERCOSUR – UE	Alejandra Aoun, Alejo Barrenechea, Roxana Blasetti, Martín Cortese, Gabriel Gette, Nicolás Hermida, Jorge Kors, Vanesa Lowenstein, Guillermo Vidaurreta
111	May 2020	National Measures on Taxing the Digital Economy	Veronica Grondona, Abdul Muheet Chowdhary, Daniel Uribe
112	June 2020	La judicialización del derecho a la salud	Silvina Andrea Bracamonte y José Luis Cassinerio
113	June 2020	La evolución de la jurisprudencia en materia de salud en Argentina	Silvina Andrea Bracamonte y José Luis Cassinerio
114	June 2020	Equitable Access to COVID-19 Related Health Technologies: A Global Priority	Zeleke Temesgen Boru
115	July 2020	Special Section 301:US Interference with the Design and Implementation of National Patent Laws	Dr. Carlos M. Correa
116	August 2020	The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic	Frederick Abbott
117	September 2020	Data in Legal Limbo: Ownership, sovereignty, or a digital public goods regime?	Dr. Carlos M. Correa
118	September 2020	Re-thinking Global and Local Manufacturing of Medical Products After COVID-19	Dr. German Velásquez
119	October 2020	TRIPS Flexibilities on Patent Enforcement: Lessons from Some Developed Countries Relating to Pharmaceutical Patent Protection	Joshua D. Sarnoff
120	October 2020	Patent Analysis for Medicines and Biotherapeutics in Trials to Treat COVID-19	Srividya Ravi

121	November 2020	The World Health Organization Reforms in the Time of COVID-19	German Velásquez
122	November 2020	Analysis of the Overcapacity and Overfishing Pillar of the WTO Fisheries Subsidies Negotiations	Peter Lunenborg
123	November 2020	The United Nations Declaration on the Rights of Peasants and Other People Working in Rural Areas: One Step Forward in the Promotion of Human Rights for the Most Vulnerable	Maria Natalia Pacheco Rodriguez y Luis Fernando Rosales Lozada
124	November 2020	Practical Implications of 'Vaccine Nationalism': A Short-Sighted and Risky Approach in Response to COVID-19	Muhammad Zaheer Abbas, PhD
125	December 2020	Designing Pro-Health Competition Policies in Developing Countries	Vitor Henrique Pinto Ido
126	December 2020	How Civil Society Action can Contribute to Combating Antimicrobial Resistance	Mirza Alas Portillo
127	December 2020	Revisiting the Question of Extending the Limits of Protection of Pharmaceutical Patents and Data Outside the EU – The Need to Rebalance	Daniel Opoku Acquah
128	February 2021	Intellectual Property in the EU–MERCOSUR FTA: A Brief Review of the Negotiating Outcomes of a Long-Awaited Agreement	Roxana Blasetti Em colaboração com Juan I. Correa
129	March 2021	The TRIPS waiver proposal: an urgent measure to expand access to the COVID-19 vaccines	Henrique Zeferino de Menezes
130	April 2021	Misappropriation of Genetic Resources and Associated Traditional Knowledge: Challenges Posed by Intellectual Property and Genetic Sequence Information	Nirmalya Syam
131	June 2021	TRIPS Flexibilities and TRIPS-plus Provisions in the RCEP Chapter on Intellectual Property: How Much Policy Space is Retained?	Vitor Henrique Pinto Ido
132	June 2021	Interpreting the Flexibilities Under the TRIPS Agreement	Carlos M. Correa
133	August 2021	Malaria and Dengue: Understanding two infectious diseases affecting developing countries and their link to climate change	Mirza Alas
134	September 2021	Restructuring the Global Vaccine Industry	Felix Lobo
135	September 2021	Implementation of a TRIPS Waiver for Health Technologies and Products for COVID-19: Preventing Claims Under Free Trade and Investment Agreements	Carlos M. Correa, Nirmalya Syam y Daniel Uribe

136	September 2021	Canada’s Political Choices Restrain Vaccine Equity: The Bolivia-Biolyse Case	Muhammad Zaheer Abbas
137	October 2021	The Ocean Economy: trends, impacts and opportunities for a post COVID-19 Blue Recovery in developing countries	David Vivas Eugui, Diana Barrowclough y Claudia Contreras
138	October 2021	Beyond Corporate Social Responsibility: Strengthening Human Rights Due Diligence through the Legally Binding Instrument on Business and Human Rights	Daniel Uribe Terán
139	October 2021	Governing Seed for Food Production: The International Treaty on Plant Genetic Resources for Food and Agriculture	Nina Isabelle Moeller
140	November 2021	Del SIDA al COVID-19: La OMS ante las crisis sanitarias globales	Germán Velásquez
141	November 2021	Utilising Public Health Flexibilities in the Era of COVID-19: An Analysis of Intellectual Property Regulation in the OAPI and MENA Regions	Yousuf A Vawda y Bonginkosi Shozi
142	January 2022	Competition Law and Access to Medicines: Lessons from Brazilian Regulation and Practice	Matheus Z. Falcão, Mariana Gondo y Ana Carolina Navarrete

SOUTH CENTRE

International Environment House 2
Chemin de Balexert 7-9
POB 228, 1211 Geneva 19
Switzerland

Telephone: (41) 022 791 8050
E-mail: south@southcentre.int

Website:
http://www.southcentre.int

ISSN 1819-6926