

The Role of Courts in Implementing TRIPS Flexibilities: Brazilian Supreme Court Rules Automatic Patent Term Extensions Unconstitutional

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Introduction

On 6 May 2021, the Brazilian Federal Supreme Court ruled – by a 9-2 majority vote – that automatic patent term extensions are unconstitutional under the Brazilian Constitution of 1988.¹ The ruling refers to the constitutionality of Article 40, Sole Paragraph of the Industrial Property Code of Brazil (Law 9.279 of 1996), which states that innovation patents shall be valid for at least 10 years.² This creates an automatic extension of the patent term (in addition to the regular 20 years of protection) when examination takes longer than 10 years.³ No limit was placed on the period of extension, which, in effect, allowed patents in Brazil to last over 30 years.

Since patents are legal monopolies which allow patent right holders to prevent competitors from entering markets, the increased term of patents restricts compe-

tion for longer, and therefore, delays price drop and ampler access. This is particularly problematic in the case of medicines.⁴ Moreover, the provision allowing patent term extension was a clear example of a “TRIPS-Plus” measure, which Brazil was **not** required to introduce in order to comply with the WTO TRIPS Agreement.⁵

This policy brief provides a background, summary and analysis of the decision, and concludes that the decision will have a positive impact on access to medicines in Brazil and may serve as a precedent for other countries.

The Brazilian Industrial Property Code Article 40 and its Implications for Access to Medicines

Pursuant to the adoption of the TRIPS Agreement, Brazil was required to amend its national legislations

Abstract

This policy brief provides a background, summary and analysis of the Brazilian Federal Supreme Court decision of 6 May 2021 that ruled automatic patent term extensions unconstitutional, striking down Article 40, Sole Paragraph, of the Brazilian Industrial Property Code of 1996. It concludes that this is a landmark ruling that contributes to the implementation of a more balanced patent regime in Brazil, with a positive impact on access to medicines in the country. It is an important precedent in relation to the role that courts may play in defining the contours of intellectual property protection and the TRIPS flexibilities.

Este informe sobre políticas proporciona antecedentes, un resumen y un análisis de la decisión del Tribunal Supremo Federal de Brasil del 6 de mayo de 2021 que declaró inconstitucionales las extensiones automáticas de los plazos de las patentes, anulando el Artículo 40, Párrafo Único, del Código de Propiedad Industrial de Brasil de 1996. Concluye que se trata de una sentencia histórica que contribuye a la aplicación de un régimen de patentes más equilibrado en Brasil, con un impacto positivo en el acceso a los medicamentos en el país. Es un precedente importante en relación con el papel que pueden desempeñar los tribunales en la definición de los contornos de la protección de la propiedad intelectual y las flexibilidades del ADPIC.

Ce rapport sur les politiques fournit le contexte, le résumé et l'analyse de la décision de la Cour suprême fédérale du Brésil du 6 mai 2021 qui a déclaré inconstitutionnelle la prolongation automatique de la durée des brevets, en invalidant l'article 40, paragraphe unique, du code brésilien de la propriété industrielle de 1996. Le document conclut qu'il s'agit d'une décision historique qui contribue à la mise en œuvre d'un régime de brevets plus équilibré au Brésil, avec un impact positif sur l'accès aux médicaments dans le pays. Il s'agit d'un important précédent en ce qui concerne le rôle que les tribunaux peuvent jouer dans la définition des limites de la protection de la propriété intellectuelle et des flexibilités de l'ADPIC.

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on intellectual property. The previous Industrial Property Code did not grant, for example, protection for pharmaceutical products and processes, which is an obligation under Article 27.1 of TRIPS.⁶ Although Brazil could have benefited from the transition general period granted to developing countries to amend its legislation until 2000 (and until 2005 in relation to patents for pharmaceuticals and agrochemicals),⁷ the pressures in the Congress by certain influence groups led to the entry into force of the new law in 1996.⁸

Article 40, Sole Paragraph, of the Brazilian Industrial Property Code was introduced in one of the draft bills during legislative discussions, but unlike other topics, including patentability of living organisms and pipeline patents, did not gain much attention.⁹ The general justification for its inclusion was to “compensate patent applicants” for potential delays in examination processes, but the provision had no equivalent in the world in terms of scope and duration, since it provided an automatic extension without a time cap.¹⁰

According to an amicus brief submitted in the referred to case by the Law and Poverty Research Group (Grupo Direito e Pobreza – GDP, in Portuguese), University of São Paulo (USP) on behalf of the Brazilian Interdisciplinary AIDS Association (ABIA), the average length of patent term in Brazil was substantially longer than in virtually any other country in the world, and by far the longest among BRICS countries (Brazil, Russia, India, China and South Africa).¹¹ The same brief highlighted that Article 40, Sole Paragraph established an **undetermined** duration of patents in Brazil, which opposes the constitutional provision of patents as “temporary privileges”. According to the brief, this would harm competitors and the public and undermine the achievement of health and other constitutional goals.¹² Additionally, patent applicants already enjoy protection even before a patent is granted. Under the Brazilian Industrial Property Code, infringement claims may be made retroactively regarding facts that occurred between the date of patent filing and the grant of the patent (Article 44). If a competitor utilized the invention during this period (although a formal patent had not been granted), it could be sued and ordered to pay a compensation to the right holder. This creates a significant obstacle to generic competition due to the risks related to a potential infringement claim.¹³

Another amicus brief by the Federal University of Rio de Janeiro Institute of Economy (IE/UFRJ) estimated that the Brazilian public health system, which is the biggest procurer of medicines in the country, would save between R\$1.1 billion and R\$3.8 billion

(around 200 million USD and 716 million USD) in the procurements related to 9 high-cost medicines protected by patent term extensions, in case the article was ruled unconstitutional.¹⁴ A study by the Federal Audit’s Tribunal of Brazil estimated the potential savings to be at least R\$1 billion (around 188 million USD).¹⁵

Those in favor of the constitutionality of Article 40, Sole Paragraph argued that given the country’s patent backlog—which was responsible for long delays in the examination of patent applications—a compensation mechanism was needed as the term of protection from the date of the grant of the patent was insufficient to reward the inventor.

Unconstitutionality Claim and the Brazilian Supreme Court’s Decision

In 2016, the then Prosecutor General, Rodrigo Janot, made a Direct Action of Unconstitutionality¹⁶ (ADI 5529) claim. The basis of the claim was that intellectual property protection is temporary under the Brazilian Constitution, and that Article 40, Sole Paragraph has the potential to render patents indeterminate in their duration. The Prosecutor General highlighted the negative impact of that provision for competitors (“strong harm to social rights and to the economic order, since others interested in exploiting the industrial creation cannot predict or plan a start for their activities”) and for the consumer (“who becomes a hostage of prices and products defined by the monopoly holder, without perspective of when there will be access to new possibilities”).¹⁷

It should be further stressed that the Brazilian 1988 Constitution required intellectual property to be in line with both the “social interest” and the “technological and economic development of the country” (Article 5, XXIV).¹⁸ The provision contained in Article 40, Sole Paragraph provides monopoly extensions without balancing the interest of the patent applicant with the public interest.

Following the start of legal proceedings, multiple institutions provided amicus briefs, including associations representing the interests of patent holders (particularly pharmaceutical companies but also agriculture and technology firms), as well as civil society organizations that focus on advancing the right to health.¹⁹ The judgment of this case was postponed several times until it was finally delivered by the Court. It took 5 years.

On 7 April 2021, the Rapporteur of the collegiate decision for this case,²⁰ Justice José Antonio Dias Toffoli, issued a preliminary injunction to suspend the effects of Article 40, Sole Paragraph, with respect to pharmaceutical patents (products and processes) and medical equipment.²¹ In his analysis, he noted the following arguments regarding the unconstitutionality of the

automatic patent term extension (many of them reflected in the final decision):

- i. Intellectual property provides a temporary privilege in the form of exclusivity for the economic exploitation of the protected subject matter. Under the Brazilian Constitution, this refers to a **temporary** protection based on the **social interest** and the **technological and economic development** of the country, not being therefore a purely individual right, but related to the society and the country's development;
- ii. The TRIPS Agreement set minimum standards of protection. Brazil is not obliged to protect above the threshold set by the Agreement.²² Article 33 of the TRIPS Agreement requires a minimum term of protection of 20 years from the date of filing, and not from the date of grant of the patent. As such, the lack of patent term extension would not violate any international obligations of Brazil and would not stem from an obligation to comply with the TRIPS Agreement. Article 40, Sole Paragraph introduced therefore a TRIPS-plus provision;
- iii. The patent protection does not begin with the granting of the patent in accordance with the Brazilian law. Patent applications already restrict competition, since an applicant has the right to seek retroactive damages for the unauthorized exploitation of the patented object for the period between the publication of the application and the grant of the patent (Art. 44, Industrial Property Code). There is a presumption of legitimate claim in favor of the patent applicants (Art. 6, §1, Industrial Property Code). This creates a chilling effect to competition, since competitors will not join markets if the risk of a patent being granted exists (also see arguments above on the same issue);
- iv. Art. 40, Sole Paragraph establishes a variable duration of protection, which can be above the 20 years for invention patents (or 15 years for utility patents). This renders the duration of the patent **indeterminate**; the duration of the patent de facto contains no limitation, since it is always dependent on an administrative procedure. This enables the creation of monopolies for an undetermined and excessive period of time, violating legal certainty, the principle of efficiency in public administration, the principles of the economic order and the right to health;
- v. There is no international equivalent of the patent term extension provision of Article 40, Sole Paragraph. Other jurisdictions contain extensions that have narrower applicability, are limited to specific cases (mostly reduced to certain technological sectors), are not automatically granted, and do not have unlimited duration;
- vi. The challenged system creates incentives for applicants to adopt strategic behaviors towards extending the period of patent examination, benefitting from the restriction of competition ("a pending application is better than no patent at all"). The Brazilian IP office cannot be liable for the patent backlog in Brazil, given the lack of financial and staff resources that limit its operations. Strategies such as evergreening through patent applications and a large amount of patent applications which are withdrawn in Brazil highlight the strategic misuses of the current system;²³
- vii. Brazilian average duration of patent protection is much higher than BRICS, Latin America and even many developed countries in the case of pharmaceutical patents (including Switzerland, Italy, UK, USA and Sweden), as reported by the Research Group Law and Poverty, University of São Paulo;
- viii. Furthermore, Brazil has a major disadvantage in the international scenario to ensure access to medicines and realizing the right to health: the high costs of medicines contrasts with the relatively modest GDP per capita, and limited capacity for R&D as compared to other countries. Only 20 per cent of patent applications in Brazil come from Brazilian inventors or institutions, which further elicits this disparity;
- ix. The provision of Art. 40, Sole Paragraph has particular consequences for access to medicines and the rights to life and health, particularly given the fact that most pharmaceuticals were protected under this extension period. The impact to public health systems has been proven, and managing the COVID-19 pandemic requires a management of all public health budgets and treatments in a systemic way. The high costs in one area impact therefore the right to health in all other areas. As a consequence, the extension of patent protection privileges private interests, to the detriment of the society, thereby affecting in an extreme manner the public health services in the country and the right to health;
- x. The indeterminate duration of patents harms legal certainty and impedes competitors from elaborating strategies to enter markets once the patent expires. The lack of a clear deadline

paves the way for arbitrary and opportunistic behaviors, which subvert the foundations upon which intellectual property protection is based under the Brazilian Constitution;

- xi. In conjunction with Articles 7 and 8 (Objectives and Principles) of the TRIPS Agreement, the removal of the rule of Article 40, Sole Paragraph brings the Brazilian IP system closer to the standards and balancing required in the Agreement between public and private interests;
- xii. The provision also harms the social function of intellectual property (Art. 5, XXIX and Art. 170, III, Brazilian Federal Constitution), the free competition and consumer protection provisions (Art. 160, IV and C, Brazilian Federal Constitution), as the undue restriction of competition enables what the Constitution sought to combat, i.e. market dominance, suppression of competition and arbitrary increase of profits, deepening inequalities, thereby transforming Article 40, Sole Paragraph into an unconstitutional rule.

On 6 May 2021, the final judgment was adopted after the vote of the 11 Justices of the Court. Justice Dias Toffoli reiterated the arguments made in relation to the preliminary injunction, reasserting the elements that led to the conclusion of Article 40, Sole Paragraph being unconstitutional. The decision was supported by 8 other Justices (Marco Aurélio Mello, Gilmar Mendes, Ricardo Lewandowski, Cármen Lúcia, Rosa Weber, Edson Fachin, Alexandre de Moraes and Kassio Nunes Marques).

Justices Luís Roberto Barroso and Luiz Fux dissented. Their opinions were based on the understanding that legislative reform would be necessary, and that the protection of intellectual property between the filing and the granting of a patent would not be sufficient to justify the restriction. However, they also did acknowledge the constitutional mandates regarding social interest and technological development as part of the intellectual property system under the Brazilian Constitution.

Based on the arguments held by the majority, in summary the Brazilian Supreme Court decision (9-2) amply acknowledged the imbalances in Article 40, Sole Paragraph, highlighting that patents are “temporary monopolies” which should be conducive to socio-economic and technological development, and not restrain the right to health, free competition and consumer protection. Importantly, the decision is fully TRIPS-compliant as Brazil law continues to grant protection for 20 years for innovation patents.

In parallel, the decision also calls the Federal Government of Brazil to ensure that more resources are allocated to the national industrial property office (*Instituto Nacional da Propriedade Industrial – INPI*), including an increase in the number of patent examiners.

Retroactive Applicability of the Decision to Patents on Pharmaceutical and Medical Devices

One important element in the Supreme Court decision is that it further ruled that it will be retroactively applicable to patents on pharmaceutical and medical devices,²⁴ in view of the burden of the COVID-19 pandemic to public health budget and the need to allocate additional funds and efforts towards combatting it. For legal certainty purposes, pre-existing contracts and other legal agreements completed prior to the decision are to be respected, however. This has a direct effect on multiple medicines which were already patented beyond their 20 years original terms, including Isentress (raltegravir, for HIV/AIDS), Nexavar (sorafenib tosylate, for cancer) and favipiravir (potential treatment for COVID-19).²⁵

The decision for the immediate application of the provisions of the ruling was unanimous among all the 11 Justices of the Supreme Court that declared the unconstitutionality of the challenged provision. Three of them (Edson Fachin, Rosa Weber and Marco Aurélio Melo) were of the view that the decision should be applicable to all patents, regardless of the technological sector.

Political Pressures Prior to the Decision

Two days before the judgement, a letter by the ambassadors of Belgium, Denmark, France, Japan, United Kingdom and Sweden (dated 26 April 2021) was annexed to the main proceedings on behalf of Interfarma, the Brazilian association of foreign pharmaceutical companies.²⁶ In the letter, the ambassadors stated that the Supreme Court’s decision to strike down the automatic patent term extensions under Article 40, Sole Paragraph would “negatively affect industry and patent holders, and bring enormous legal uncertainty to Brazil, being able to shatter confidence of foreign investors in the country and lead to a degradation of the Brazilian business environment”, also noting that it would lead to “investment diversion [to other countries], and the risk of reducing the interest of these investors in bringing new technologies to the Brazilian market”. The letter also stated that the decision “could be inconsistent with international treaties, such as the WTO TRIPS”.

This unfortunate exercise of political pressure on developing countries in order to support TRIPS-plus protections is not new.²⁷ It has been a recurrent practice by some developed countries to pressure developing

countries not to implement TRIPS flexibilities, including by threatening to sue them under WTO rules—although the TRIPS Agreement and the Doha Declaration on IP and Public Health (2001) clearly assert the legitimacy of national policies adopted in the framework of the Agreement to achieve public health goals. Such countries often argue that foreign companies will not invest and innovation will be undermined in case some of the TRIPS flexibilities, notably compulsory licenses, are implemented.²⁸ In this case, the pressure was channeled through a business association and not openly made through formal communications to the concerned authorities as, for instance, in the case of Colombia in relation to a possible compulsory license for imatinib.²⁹

Significantly, the Brazilian Supreme Court was not swayed by such arguments. As a matter of fact, the decision is by no means non-compliant with the TRIPS Agreement, particularly as Brazil continues to grant protection of 20 years for patents from the date of filing and in all technological sectors, as required under the Agreement. Furthermore, the retroactivity in the specific sector of pharmaceutical and medical devices does not constitute “technological discrimination” under WTO rules, which allow for differentiation of treatment according to the field of technology in order to pursue legitimate purposes such as public health.³⁰

Conclusion

The Federal Supreme Court decision is a landmark ruling that contributes to the implementation of a more balanced patent regime in Brazil. It is also an important precedent in relation to the role that courts may play in defining the contours of intellectual property protection and the TRIPS flexibilities.

This is the first time that the Brazilian Federal Supreme Court has ruled a case on patent law.³¹ The decision reaffirmed some of the most important elements that should be embedded in intellectual property law in line with articles 7 and 8 of the TRIPS Agreement: the need to strike a balance between protection of private rights and the public interest at large; the acknowledgment that intellectual property should be conducive to technological development; and the need to ensure that intellectual property rules do not impede legitimate public policy goals, including access to medicines. The court applied a comprehensive and contextual analysis to decide, with the limitations noted above, the retroactive application of the decision to pharmaceuticals and health equipment, noting that the high burdens related to COVID-19 required all means to reduce expenses and ensure more access.³² By ensuring that patents are not extended indefinitely, the ruling provides more legal certainty to competitors and

encourages an earlier entry of generic products into the market. Importantly, it supports the goal of advancing access to medicines and other medical products in Brazil, while respecting the international obligations of the country.

Endnotes:

¹ See all the documents and timeline of the case: Supreme Federal Court of Brazil. Direct Action of Unconstitutionality (ADI 5529). Rapporteur: Justice Dias Toffoli. Available from <http://portal.stf.jus.br/processos/detalhe.asp?incidente=4984195>; see also D’Agostino, Rosanne. Supremo decide que extensão de patentes é inconstitucional, G1, 6 May 2021, available from <https://g1.globo.com/politica/noticia/2021/05/06/supremo-decide-que-extensao-de-patentes-e-inconstitucional.ghtml>.

² See “Art. 40, Parágrafo único. O prazo de vigência não será inferior a 10 (dez) anos para a patente de invenção e a 7 (sete) anos para a patente de modelo de utilidade, a contar da data de concessão, ressalvada a hipótese de o INPI estar impedido de proceder ao exame de mérito do pedido, por pendência judicial comprovada ou por motivo de força maior.” (author’s translation: “Art. 40, Sole paragraph. The term of validity will not be less than 10 (ten) years for an invention patent and 7 (seven) years for a utility model patent, counted from the grant date, except in case the INPI is prevented from proceeding with the examination of the application, due to a proven pending judicial decision or due to force majeure.”)

³ The same provision also established a minimum duration of 7 years for utility model patents, meaning that patent applications taking longer than 8 years would also be granted an extension beyond the original 15 years of protection. See footnote 2.

⁴ For an overview of the issue, see UN Secretary-General High-Level Panel on Access to Medicines. Report – Promoting Innovation and Access to Health Technologies, 2016. Available from <http://www.unsgaccessmeds.org/final-report>; see also the resources provided by the South Centre on ensuring a public health approach to intellectual property: <https://ipaccessmeds.southcentre.int/>

⁵ See Chaves, Gabriela Costa, and Oliveira Maria Auxiliadora, “A proposal for measuring the degree of public health-sensitivity of patent legislation in the context of the WTO TRIPS Agreement”. *Bulletin World Health Organization*, 85(1):49–56, 2007. doi:10.2471/blt.06.033274.

⁶ Article 27. Patentable Subject Matter. 1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article,

patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

⁷ Article 65. Transitional Arrangements. 1. Subject to the provisions of paragraphs 2, 3 and 4, no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the WTO Agreement. 2. A developing country Member is entitled to delay for a further period of four years the date of application, as defined in paragraph 1, of the provisions of this Agreement other than Articles 3, 4 and 5. See also Article 70, Paragraph 8: Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall: (a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed; (b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and (c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).

⁸ For a comprehensive analysis, see Reis, Renata Camile Carlos. *Redes invisíveis : grupos de pressão na Câmara dos Deputados – o processo de aprovação da Lei de Propriedade Industrial brasileira*, PhD Thesis, Federal University of Rio de Janeiro, Institute of Economy, Graduate Program in Public Policies, Strategies and Development, 2015; see also, Vanni, Amaka, *Patent Games in the Global South: Pharmaceutical Patent Law-Making in Brazil, India and Nigeria*. Bloomsbury, 2020.

⁹ Salomão Filho, Calixto; Portugal Gouvêa, Carlos; Kastrup, Gustavo; Barone, Victor; Ido, Vitor; Bezerra, Cynthia M. Santos; Kanarek, Marina; Calixto de Abreu, Thaís; Baruhm Diegues, Michelle; Castro, Bernardo; Caramalac, Pietra; Câmara, Maria Clara; Schneider, Gustavo; Ricarte, Joyce; Feitoza, Laura; Casanovas Reis, Paloma; Jarouche, Tárik; Fucci, Paulo. *A Inconstitucionalidade do Artigo 40, Parágrafo Único, da Lei de Propriedade Industrial sob uma Perspectiva Comparada* (8 December 2020). Available from SSRN: <https://ssrn.com/abstract=3745372> or <http://dx.doi.org/10.2139/ssrn.3745372>.

¹⁰ Although some national laws do contain patent term extensions, as well as additional data exclusivities (which are all TRIPS-plus measures, therefore not obli-

gations under the TRIPS Agreement), none had the characteristics of being granted automatically and without limitation of how long it would last. See also, Boru, Zeleke Temesgen, *The Comprehensive and Progressive Agreement for the Trans-Pacific Partnership: Data Exclusivity and Access To Biologics*, Research Paper No. 106 (Geneva, South Centre, March 2020); Correa, Carlos, *Intellectual Property in the Trans-Pacific Partnership: Increasing the Barriers for the Access to Affordable Medicines*, Research Paper No. 62R (Geneva, South Centre, July 2017).

¹¹ Salomão Filho et al, op cit.

¹² Salomão Filho et al, op cit. This position was also articulated by several scholars, such as Grau-Kuntz, Karin. *Miopia aguda e uma inconstitucionalidade no sistema de patente brasileiro*. Migalhas, 28 April 2021, Available from <https://www.migalhas.com.br/depeso/344565/miopia-aguda-e-uma-inconstitucionalidade-no-sistema-de-patente>.

¹³ “By fixing compensations that can be obtained under excessively high criteria, and mainly by not specifically differentiating a suitable indemnity in cases of improper exploitation that occurred before or after the patent was granted, Brazilian law creates disincentives to innovation and to competition, since it places an excessive risk on third parties. These criteria go beyond what the TRIPS Agreement and other national legislation on the subject determine. In the specific case of medicines, LPI creates a system that limits access to medicines and, consequently, the right to health, to the extent that it provides excessive protection to the applicant of a patent application, which will often not even be granted, thus making access to medicines more difficult, even through the public health system”. (p. 128); “Brazilian law provides greater protection to the patent holder and the mere applicant than that determined by the WTO TRIPS Agreement and also than that established in the legislation of other countries. We shall see shortly what TRIPS says and how national laws of the United States, European Union, India, Thailand and Argentina.” (p. 129, author’s translation). See Costa Chaves, Gabriela, Vieira, Marcela, Costa, Roberta Dorneles F. Da, and Vianna, Marianni Nunes Sadock. *Medicamentos em situação de exclusividade financiados pelo Ministério da Saúde: Análise da Situação Patentária e das Compras Públicas*. Fiocruz & Escola Nacional de Saúde Pública, Rio de Janeiro, Dezembro 2018.

¹⁴ Julia Paranhos, Eduardo Mercadante and Lia Hasenclever, “O custo da extensão da vigência de patentes de medicamentos para o Sistema Único de Saúde”. *Cadernos de Saúde Pública* [online]. v. 36, n. 11, 2020. Available at: <https://scielosp.org/article/csp/2020.v36n11/e00169719/pt/#>.

¹⁵ Tribunal de Contas da União. *Auditing in Process* 015.369/2019-6, May 2020.

¹⁶ This refers to a legal instrument under Brazilian Constitutional law to challenge the constitutionality of a certain provision, with effects erga omnes (towards all cases and disputes).

¹⁷ Prosecutor General of the Republic. Initial Complaint, ADI 5529, May 2016.

¹⁸ Article 5, XXIX, Brazilian Federal Constitution of 1988 – “The law shall grant authors of industrial inventions temporary privilege for their use, as well as protection for industrial creations, brand ownership, company names and other distinctive signs, in view of the social interest and the technological and economic development of the country (author’s translation)”.

¹⁹ For a few examples: Associação Brasileira Interdisciplinar de Aids - ABIA, Associação das Empresas de Biotecnologia na Agricultura e Agroindústria - AGRO-BIO; Associação Brasileira de Propriedade Intelectual - ABPI; Associação da Indústria Farmacêutica de Pesquisa - INTERFARMA; Associação Nacional de Defesa Vegetal - ANDEF; Associação Brasileira das Indústrias de Química Fina, Biotecnologia e suas Especialidades - ABIFINA. See <http://portal.stf.jus.br/processos/detalhe.asp?incidente=4984195>.

²⁰ Under Brazilian Constitutional Law, Supreme Court decisions follow a majority rule out of the 11 Justices’ individual votes. Even when a Justice decides to follow a majority opinion, he/she/they continues to deliver a vote. This may lead to a variety of arguments being deployed, but the binding content of the decision is more limited.

²¹ See the content of the preliminary injunction by Justice Dias Toffoli on 7 April 2021, which would later be largely replicated in his final vote on 6 May 2021, becoming the majority opinion: <http://www.stf.jus.br/arquivo/cms/noticiaNoticiaStf/anexo/ADI5529liminar.pdf>.

²² See Article 1.1 of the TRIPS Agreement: Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

²³ As noted by Justice Dias Toffoli, in verbis: “When specifically analyzing the processes related to drug patents, the Federal Auditor’s Court audit also identified the practice by pharmaceutical companies of strategies aimed at maximizing the period of exclusivity in the exploration of certain products. This is the so-called evergreening, which consists of the successive filing of patent applications derived from an original patent, in order to prolong the exclusive exploitation, considering that the mere filing already has the effect of inhibiting competition given the possibility of retroactive compensation become a patent holder (art. 44 of the LPI). (p. 37). [I]n fact, there are sufficient elements in the case to point to the fact that the norm to be judged feeds into the backlog, contributing to generate the

phenomenon that seeks to circumvent, in direct affront to the principles of reasonable duration of the process (art. and administrative efficiency (art. 37, caput, CF) (p. 44)”. (author’s translations).

²⁴ See Federal Supreme Court of Brazil, 2021. Decision: The Court, by majority, modulates the effects of the decision to declare unconstitutionality of the sole paragraph of art. 40 of the LPI, giving effect to it *ex nunc*, from the publication of the minutes of this judgment, in order to remain as the previous term granted based on the legal precept, thus maintaining the validity of the patents already granted and still effective as a result of the aforementioned precept, being exempt from modulation (i) as lawsuits filed until April 7, 2021, including (data from the partial granting of the precautionary measure in this case) and (ii) as patents that were granted with extension of the deadline related to pharmaceutical products and processes and to equipment and / or materials for use in health, operating in both situations, the *ex tunc* effect, which will result in the loss of the deadlines granted based on the sole paragraph Make art. 40 of the LPI, respecting the term of validity of the patent established in the caput of art. 40 of Law 9.279 / 1996 and safeguarding certain concrete effects already found due to the extension of patents. All in terms of the vote of the Rapporteur, defeated by Ministers Edson Fachin, Rosa Weber and Marco Aurélio. Ministers Roberto Barroso and Luiz Fux (President) modulated the effects of the decision to a greater extent. Plenary, 12/05/2021 (Session held by videoconference - Resolution 672/2020 / STF). (author’s translation) Available from <http://portal.stf.jus.br/processos/detalhe.asp?incidente=4984195>.

²⁵ See a preliminary list here: https://politica.estadao.com.br/blogs/fausto-macedo/wp-content/uploads/sites/41/2021/05/estudomediamentospatentesestendidasnobrasil11_120520215234.pdf.

²⁶ See Amado, Guilherme, “Reino Unido, Japão e Outros Quatro Países dizem que redução de tempo das patentes prejudica Brasil”. *Época*, 28 April 2021, Available from <https://epoca.globo.com/guilherme-amado/reino-unido-japao-outros-quatro-paises-dizem-que-reducao-de-tempo-das-patentes-prejudica-brasil-1-24991032>.

²⁷ An outstanding example is the continued use of the Special Section 301 by USTR to question the utilization of TRIPS flexibilities and seek TRIPS-plus protection. See, e.g., Jorge, Maria Fabiana, “United States: An obsolete trade practice undermines access to the most expensive drugs at more affordable prices”. Policy Brief No. 83 (South Centre, August 2020); Correa, Carlos, Special Section 301:US Interference with the Design and Implementation of National Patent Laws, Research Paper No. 115 (Geneva, South Centre, July 2020). Available from <https://www.southcentre.int/research-paper-115-july-2020/>.

²⁸ One example is the case of Thailand: “The European Trade Commissioner wrote to the Thai Government criti-

cizing its use of compulsory licenses as “detrimental” to medical innovation, noting that such approaches could lead to Thailand’s isolation from the global biotechnology investment community and urging negotiations with Sanofi-Aventis and other right holders. The United States Trade Representative elevated Thailand to its Priority Watch List in the Special 301 Report and withdrew duty-free access to the American market for three Thai products under the United States Generalized System of Preferences.” (United Nations Secretary-General High-Level Panel on Access to Medicines, op. cit.)

²⁹ “During the process leading to the public interest declaration, the Ministry of Health of Colombia received communications from the State Secretariat for Economic Affairs (SECO) of the Swiss Confederation, from officials of Colombian embassy in United States after meetings with U.S. Senate staff and the United States Trade Representative, from officials from the Colombian Patent Office, from Novartis Colombia and from Novartis International A.G., attempting to both misinform and dissuade the Government of Colombia from granting a compulsory license. The pressure included factual inaccuracies, distortions of international trade and intellectual property rules, threats of dispute settlement claims and even implied or perhaps explicit threats to suspend promised United States funding for the Colombian peace process via the “Paz Colombia” initiative if the compulsory license process were to proceed, as was widely reported

following the leak of several memos from officials of the Colombian Embassy in the United States”. CIMUN, Ifarma, Misión Salud. Open Letter to the Co-Chairs of the UN Secretary-General’s High-Level Panel on Access to Medicines. Bogotá, 30 June 2016, available from <https://www.mision-salud.org/2016/07/carta-abierta-al-panel-de-alto-nivel-sobre-acceso-a-medicamentos-de-las-naciones-unidas/>.

³⁰ See DS 114, Canada – Patent Protection of Pharmaceuticals, available from https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm. For an analysis applied to the case herein analyzed; see also, Jardim, Flávio, Silveira, André, Velloso, João Carlos, Nóbrega Neto, Elias da., O prazo das patentes e a modulação dos efeitos. Jota, 11 May 2021, Available from <https://www.jota.info/opiniao-e-analise/artigos/o-prazo-das-patentes-e-a-modulacao-dos-efeitos-11052021>.

³¹ See Salomão Filho, Calixto, and Ido, Vitor Henrique Pinto, “Courts and pharmaceutical patents: From formal positivism to the emergence of global law”, in Access to Medicines: Implementing Flexibilities Under International Intellectual Property Law, Correa, Carlos; Hilty, Reto, eds. (Springer, forthcoming).

³² Also in this regard, see Rossi Silva, Alan, Gaspar, Walter Britto, Villardi, Pedro, “A extensão do prazo de patentes e o combate à Covid-19”. Jota, 24 October 2020, Available from <https://www.jota.info/opiniao-e-analise/artigos/extensao-prazo-patentes-combate-covid-24102020>.



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