

CAN VS. COULD: THE EFFECTS OF DIRECT ACTION OF UNCONSTITUTIONALITY NO. 5,529 ON PHARMACEUTICAL PATENT TERMS

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1. Introduction. 2. From Inequality Costs to Underdevelopment: The Case of the Brazilian Healthcare System. 3. The Turning Point: A Brief History of DAU 5,529. 4. Winds of Change or Wasted Potential? 4.1. The Concrete Effects of DAU 5,529 on patent terms. 4.2. Finding a Way Around It: Administrative Strategies. 5. Conclusion.

ABSTRACT

The landmark ruling of the Direct Action of Unconstitutionality No. 5,529 (DAU 5,529) declared the unconstitutionality of Section 40, sole paragraph, of the Brazilian Industrial Property Code, which proposed an automatic and indeterminate patent term extension. However, four years later, there has been no public effort to identify the patents affected by the decision and to monitor its implementation by the Brazilian patent office (INPI). This short paper therefore aims to begin filling this data gap through exploratory research, analyzing a sample of 500 patents whose protection periods were adjusted by the INPI. The hypothesis presented here is that the DAU 5,529 had very limited effects on expanding access to healthcare thus far, since most patents affected by the decision are still in force and patent holders

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have been using administrative strategies to extend their invention's term. The results of the empirical research confirm the hypothesis and indicate that a more in-depth and comprehensive analysis of the outcomes of DAU 5,529 is necessary.

1. INTRODUCTION

The judgment of the Direct Action of Unconstitutionality No. 5,529 (DAU 5,529), which declared the unconstitutionality of Section 40, sole paragraph, of the Brazilian Industrial Property Code (IPC), brought forth various possibilities for expanding access to healthcare. Observers and experts anticipated that the decision would stimulate the national pharmaceutical industry to produce generic drugs and, consequently, reduce the expenses of the Universal Healthcare Program (*Sistema Único de Saúde* – SUS) in acquiring medications by billions of Brazilian reais.

But almost four years later, it is necessary to assess the concrete effects of the DAU 5,529 on the protection period of pharmaceutical patents. However, after the decision was published, there was no public initiative to identify patents affected by the unconstitutionality of the extended term or to monitor the implementation of the Supreme Court's ruling by the national patent and trademark office (*Instituto Nacional da Propriedade Intelectual* – INPI). Hence, this paper proposes exploratory research on the administrative effects of extinguishing the sole paragraph of Section 40 through the analysis of a sample of five hundred patents whose validity periods were adjusted by the INPI.

The hypothesis of this paper is that DAU 5,529 has not yielded significant effects on access to medicines thus far. Such a limited outcome would result from most patents affected by the decision still being in force and the administrative strategies employed by patent holders to extend the invention's term.

To test these propositions, I will first present how access to healthcare in Brazil perpetuates and exacerbates inequality costs. The second part of the paper provides a brief history of

DAU 5,529, unveiling the lobbying efforts of affected industries. The third part presents the results of the empirical research I conducted, divided into two subtopics to analyze, respectively, the effects of DAU 5,529 on the terms of pharmaceutical patents and the strategies used by patent holders to extend their validity period. The final part concludes.

This paper, therefore, aims to provide a starting point for more in-depth research on the effects of DAU 5,529 on the Brazilian right to health. After all, it is only by gathering data that it will be possible to effectively implement public policies that reflect the full transformative potential that this landmark ruling can bring.

2. FROM INEQUALITY COSTS TO UNDERDEVELOPMENT: THE CASE OF THE BRAZILIAN HEALTHCARE SYSTEM

The rapid rise of industrial capitalism in the 19th century questioned the foundational principles of intellectual property, fundamentally based on Lockean ideas. Classical scholars considered knowledge a common good, and labor on it should be protected by property rights³⁵¹ – specifically, patents or copyrights. However, this conception loses its relevance in the context of an industrialized economy. Determining when knowledge qualifies as a common good becomes challenging, as it becomes difficult to sustain its non-excludable nature.

Despite the challenges that industrial development posed to IP rights, its principles remain unchanged to this day. The World Trade Organization's (WTO's) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of 1994 crystallized the traditional concept of private property applied to IP by setting a list of minimum standards of protection that WTO members are obliged to adopt.³⁵²

351 LOCKE, John. *Second Treatise of Government*. Indianapolis: Hackett, 1980, p. 19.

352 MIYAMOTO, Tomoko. International treaties and patent law harmonization: today and beyond. In: TAKENAKA, Toshiko (ed.). *Research Handbook on Patent Law and Theory*. Cheltenham: Edward Elgar, 2019.

The TRIPS Agreement, therefore, aimed at harmonizing IP legislation throughout the globe to facilitate international trade and foreign investment, but created significant challenges for developing nations. Pharmaceutical patents, for example, were not covered by IP rights in most developing countries,³⁵³ including Brazil, but their protection became mandatory for a minimum period of twenty years counted from the filing date.³⁵⁴

But besides TRIPS' minimum protection, developed countries pressured their commercial partners into adopting even stricter provisions through bilateral and regional agreements.³⁵⁵ Those "TRIPS-plus" commitments often assumed the form of longer protection periods for patents, such as patent term extensions (PTE) and patent term adjustments (PTA). The Brazilian approach, however, drifts apart from this logic: although there is no parallel agreement demanding it, the country unilaterally adopted an additional protection period for invention patents of at least ten years after the request is granted by the INPI.

Section 40. An invention patent shall be valid for twenty (20) years and a utility model patent for fifteen (15) years counted from the filing date.

Sole paragraph. The term of protection shall not be less than ten (10) years for an invention patent and seven (7) years for a utility model patent, counting from the granting date, except in the event that the INPI is prevented from examining the merits of the

353 SUBHAN, Junaid. Scrutinized: the TRIPS agreement and public health. *McGill Journal of Medicine*, v. 9, n. 2, p. 152-159, 2006.

354 TRIPS Agreement, Article 33: "The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date." Available at: <https://www.wto.org/english/docs_e/legal_e/27-trips.pdf>. Access on January 28, 2024. See SHADLEN, Kenneth C.; SAMPAT, Bhaven N.; KAPCZYNSKI, Amy. Patents, trade and medicines: past, present and future. *Review Of International Political Economy*, v. 27, n. 1, p. 75-97, June 2019.

355 DREYFUSS, Rochelle; PILA, Justine. Intellectual Property Law: An Anatomical Overview. In: DREYFUSS, Rochelle; PILA, Justine (ed.). *The Oxford Handbook of Intellectual Property Law*. Oxford: Oxford University Press, 2018, p. 26-27.

application due to a proven pending court case or for reasons of force majeure.³⁵⁶

Section 40's sole paragraph of the IPC therefore proposed an automatic and indeterminate patent term extension since it was not possible to know when the patent would expire until its grant date. In practice, it meant that patents filed in Brazil could have up to 30 years of protection. This provision was particularly relevant in terms of access to healthcare because most pharmaceutical products were covered by the additional protection³⁵⁷ and it hindered proper production planning by the generic drug industry.

Besides long-lasting higher prices for pharmaceuticals purchased by the population, the variable mechanism provided by Section 40, sole paragraph is especially significant when considered in the context of public healthcare. In Brazil, SUS is a decentralized system created in 1990 with the aim of narrowing health inequalities by improving nationwide coverage and free access to healthcare.³⁵⁸ The SUS has federal, state and municipal administrative responsibilities, which includes providing hospitals and public care services with a set of drugs covered by the National List of Essential Medicines (*Relação Nacional de Medicamentos Essenciais* – RENAME), a unified list periodically updated and approved by the Ministry of Health.

356 Informal translation. The original in Portuguese reads as follows: “Art. 40. A patente de invenção vigorará pelo prazo de 20 (vinte) anos e a de modelo de utilidade pelo prazo 15 (quinze) anos contados da data de depósito. 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.” Law No. 9,279, of May 14, 1996. Brazilian Industrial Property Code. Available at: <https://www.planalto.gov.br/ccivil_03/leis/19279.htm>. Access on January 28, 2024.

357 IDO, Vitor Henrique Pinto. The Role of Courts in Implementing TRIPS Flexibilities: Brazilian Supreme Court Rules Automatic Patent Term Extensions Unconstitutional. *South Centre Policy Brief*, n. 94, June 2021. Available at: <<https://www.southcentre.int/wp-content/uploads/2021/06/PB-94-1.pdf>>. Access on January 28, 2024.

358 CASTRO, Marcia C. *et al.* Brazil's unified health system: the first 30 years and prospects for the future. *The Lancet Health Policy*, v. 394, n. 10195, p. 345-356, July 2019.

Pharmaceuticals included in the RENAME are purchased through public bidding (*licitação*), waiver of bidding (*dispensa de licitação*), or non-bidding (*inexigibilidade de licitação*).³⁵⁹ However, experts estimate that the extension mechanism outlined in Section 40, sole paragraph, of the IPC contributes up to BRL 3.9 billion to SUS' expenditures³⁶⁰ – and given the scarcity of resources, if the provision of certain services sees increased spending, it results in a lower budget for all others.

This is the exact application of what contemporary scholars have named “*inequality costs*”, which are additional expenses imposed on economic agents, hindering the most productive allocation of resources.³⁶¹ Section 40, sole paragraph, created additional costs that prevented economic agents – in this case, the SUS – from efficiently allocating its resources and, therefore, amplified inequalities due to the lower offer of public healthcare services.

Doubt lingers, however, about the reasons that led to the inclusion of this provision in the IPC. There was no prior justification for its inclusion, but only a later narrative construction that the provision served to compensate depositors for INPI's delay in granting patents, similar to the PTE and PTA mechanisms. But as I explore in the next section, Brazilian authorities started to question these arguments.

3. THE TURNING POINT: A BRIEF HISTORY OF DAU 5,529

On May 17, 2016, the former Attorney General, Rodrigo Janot, filed DAU 5,529, requiring the declaration of unconstitutionality of

359 MINISTÉRIO DA SAÚDE. *Aquisição de Medicamentos para Assistência Farmacêutica no SUS: Orientações básicas*. Brasília: Círculo de Brasília, 2006. Available at: <<http://www.ensp.fiocruz.br/portal-ensp/judicializacao/pdfs/284.pdf>>. Access on January 28, 2024.

360 This amount refers to only four high-cost medications, which means that SUS' total expenses should be significantly higher. See 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*, v. 36, n. 11, 2020. Available at: <<https://www.scielo.br/j/csp/a/37vfpd7rVJzFDhzbStQ9YM/abstract/?lang=pt&format=html>>. Access on January 28, 2024.

361 PORTUGAL GOUVÊA, Carlos. *Análise dos Custos da Desigualdade: Efeitos institucionais do círculo vicioso de desigualdade e corrupção*. São Paulo: Quartier Latin, 2021, p. 215.

Section 40, sole paragraph of the IPC. Janot claimed that the legal device allowed for the establishment of undetermined protection periods for IP rights, which would contravene the principle of the temporality of patent protection, as provided in Section 5, item XXIX of the Federal Constitution.³⁶²⁻³⁶³

The case had little activity until 2020 when the COVID-19 pandemic threatened the public health system's ability to bear the expenses related to disease containment.³⁶⁴ Several *amici curiae*, representing national associations of generic drug producers, public-interest organizations advocating for access to healthcare, and transnational pharmaceutical companies, joined the legal proceeding to express their views.

A true mediatic war took place in the first semester of 2021. Industries affected by the potential decision hired experts and renowned scholars to defend that the Supreme Court did not have the authority to invalidate the legislator's choice regarding patent term extension.³⁶⁵ Debates, interviews and numerous branded contents

362 Section 5, item XXIX, of the Brazilian Federal Constitution: "Section 5. All people are equal before the law, without any distinction whatsoever. Brazilians and foreigners residing in the country are ensured the inviolability of their right to life, liberty, equality, security, and property, under the following terms: [...] XXIX - the law shall ensure the inventors of industrial inventions a temporary privilege for their use, in addition to protection of industrial creations, ownership of trademarks, company names and other distinctive signs, taking into account the interest of society and the technological and economic development of the country." Official translation by the Brazilian Supreme Court. Available at: <https://www.stf.jus.br/arquivo/cms/legislacaoConstituicao/anexo/brazil_federal_constitution.pdf>. Access on January 28, 2024.

363 BRAZIL. Supreme Court. Direct Action of Unconstitutionality No. 5,529. Justice Rapporteur Dias Toffoli. Judged on May 12, 2021.

364 CABRAL, Mário André Machado. Automatic Patent Term Extensions Ruled Unconstitutional in Brazil: better late than never? *IIC - International Review Of Intellectual Property And Competition Law*, v. 53, n. 1, p. 160-168, January 2022.

365 "The Supreme Court does not have the authority to debate the legislator's choice regarding patent terms. Ellen Gracie, Floriano de Azevedo Marques, and Carlos Ari Sundfeld concluded that the provision in patent law does not violate the Federal Constitution." Informal translation. The original headline in Portuguese reads as follows: "Não é competência do STF debater escolha do legislador sobre vigência de patente. Ellen Gracie, Floriano de Azevedo Marques e Carlos Ari Sundfeld avaliaram que dispositivo na lei de patentes não fere CF." Available at: <<https://www.jota.info/casa-jota/competencia-stf-vigencia-patentes-13102020>>. Access on January 28, 2024.

explicitly stating that the declaration of unconstitutionality of Section 40, sole paragraph, would hinder economic recovery and national development filled newspapers and websites.³⁶⁶ Later, a report by *The Intercept* exposed that the lobby against the waiver of pharmaceutical patents before the Supreme Court's decision paid approximately BRL 1.5 million to newspapers.³⁶⁷

On April 7, 2021, symbolically chosen for being World Health Day, Justice Rapporteur Dias Toffoli issued a preliminary injunction that suspended the effects of Section, 40, sole paragraph of the IPC on pharmaceutical patents. The decision is noteworthy for being based on a research report from 2020 by the Law and Poverty Group (*Grupo Direito e Pobreza – GDP*) of the University of São Paulo. This report systematically analyzed the relevant legislation of thirty jurisdictions and gathered over five thousand administrative decisions on patent grants. The conclusion drawn was that Section 40, sole paragraph, lacks parallels in the other studied countries. Consequently, Brazilian pharmaceutical patents ended up having an average protection period longer than those observed in the international community.³⁶⁸

366 See, for example, the promotional cover of the newspaper “*Valor Econômico*” from March 28, 2021, which read as follows: “The Attorney General’s Office goes to the Supreme Court to invalidate more than 30,000 patents and threatens economic recovery” and “Attacks on the Industrial Property Code hinder national development”. Informal translations. The originals in Portuguese read as follows: “*Procuradoria-Geral da República vai ao Supremo para invalidar mais de 30 mil patentes e ameaça retomada da economia*” and “*Ataques à LPI prejudicam desenvolvimento nacional*”. Available at: <https://www.intercept.com.br/wp-content/plugins/seox-image-magick/imagick_convert.php?width=713&height=491&format=webp&quality=91&imagick=uploads.intercept.com.br/2023/03/jornal-valor2.jpg> and <https://www.intercept.com.br/wp-content/plugins/seox-image-magick/imagick_convert.php?width=713&height=491&format=webp&quality=91&imagick=uploads.intercept.com.br/2023/03/jornal-valor3.jpg>. Access on January 28, 2024.

367 DIAS, Tatiana. Lobby contra quebra de patentes de medicamentos pagou R\$ 1,5 milhão a jornais. *The Intercept*. April 28, 2021. Available at: <<https://www.intercept.com.br/2021/04/28/lobby-contra-quebra-de-patentes-pagou-jornais/>>. Access on January 28, 2024.

368 See SALOMÃO FILHO, Calixto; PORTUGAL GOUVÊA, Carlos *et al.* *A Inconstitucionalidade do Artigo 40, Parágrafo Único, da Lei de Propriedade Industrial sob uma Perspectiva Comparada*. December 8, 2020. Available at: <<https://ssrn.com/abstract=3745372>>. Access on January 28, 2024.

Justice Rapporteur Dias Toffoli quoted GDP's report eight times and attached it to his vote, which was distributed to the offices of the other members of the Supreme Court. The plenary rendered a decision on May 12, 2021, declaring the unconstitutionality of Section 40, sole paragraph, with a vote of nine to two. GDP's report was also quoted by Justices Marco Aurelio and Ricardo Lewandowski, and Justices Luís Roberto Barroso and Luiz Fux dissented.

Concern expressed by various *amici curiae* representing the industry led the Supreme Court to propose a modulation of the outcomes of the decision, where the unconstitutionality of Section 40, sole paragraph, would only have retroactive effects (*ex tunc*) in relation to patents for pharmaceutical products and medical equipment. Meanwhile, other patents already granted by the INPI would maintain their original term, with the application of the validity extension. Nevertheless, as an *ex nunc* effect, no patent granted from the date of the judgment's publication could benefit from the mechanism provided in Section 40, sole paragraph.

In the following weeks, the INPI published several lists containing all patent numbers affected by the decision, which would have their term adjusted to twenty years counting from the filing date. The Brazilian patent office applied the guidelines of DAU 5,529 to at least 6,119 patents, making the Supreme Court's decision the most important in Brazilian history in terms of intellectual property and public health.³⁶⁹ Three years later, it is now time to understand how the Brazilian government implemented the decision and examine its actual impact on the right to health.

369 GDP. *Grupo Direito e Pobreza Repercutindo o Julgamento da Ação Direta de Inconstitucionalidade nº 5.529*. May 17, 2021. Available at: <<https://www.direitoepobreza.org.br/post/grupo-direito-e-pobreza-repercutindo-o-julgamento-da-a%C3%A7%C3%A3o-direta-de-inconstitucionalidade-n-5-529?fbclid=IwAR2og3sV7hadvRcdsaDDJSrTeFDmEyNbMz28Bl-j6HfTLTDW5tObjNLBqrQ>>. Access on January 29, 2024.

4. WINDS OF CHANGE OR WASTED POTENTIAL?

The results of DAU 5,529 had the potential to inform the design of various public policies aimed at promoting access to healthcare. However, although following a historic judgment, there is no record of public or private initiatives to analyze the patents affected by the decision. There was not even data on the total number of impacted IP rights. This paper's first contribution, as mentioned in the previous section, is revealing that at least 6,119 patents had their terms adjusted because of the decision.

But before exploring whether the Brazilian government had effectively succeeded in reducing SUS' expenses on high-cost medicines through the acquisition of generic drugs, as I first intended to do, it was necessary to take a step back. Given that Brazil faces a data gap regarding the concrete results of DAU 5,529, examining the new term of validity for the patents adjusted by INPI was crucial. This would allow determining which ones are still in force and for how long.

But given the lobbying efforts by patent holders in the period leading up to the judgment of DAU 5,529, explored in the previous section, it was also anticipated that affected industries would seek a way to defend their interests. This short paper, therefore, departs from a global hypothesis that DAU 5,529 has not yielded significant effects on access to medicines thus far. Such a limited outcome would result from the majority of patents affected by the decision still being in force and the administrative strategies employed by patent holders to extend the invention's term.

To test these propositions, I compiled an exploratory sample of five hundred pharmaceutical³⁷⁰ patents that had their terms modified

370 According to the International Patent Classification, pharmaceutical patents are those classified as A61K or A61P. The sample does not include A61K 6/00 and A61K 8/00 patents, which respectively refer to preparations for dentistry and cosmetics or similar toilet preparations. See WIPO. World Intellectual Property Organization. *IPC Publication*. 2024.01 version. Available at: <<http://ipc.inpi.gov.br/classifications/ipc/ipcpub/?notion=scheme&version=20240101&symbol=non&cwid=none&tree=no&searchmode=smart>>. Access on January 30, 2024.

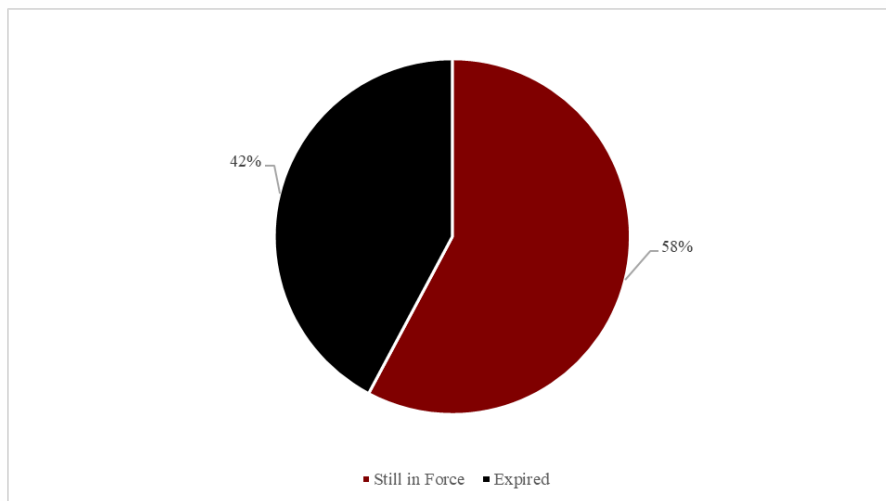
by the INPI, according to the lists published in the Industrial Property Gazette (*Revista de Propriedade Industrial – RPI*) following the ruling on DAU 5,529, and examined data such as filing date, grant date, validity period, owner, and observations by the patent office. All data is organized into charts, which can be found in the other tabs of Appendix I.

This chapter is thus divided into two main sections. Section 4.1 offers a quantitative analysis of the protection periods of the patents in the sample, while section 4.2 examines whether patent owners attempted to employ administrative strategies to bypass the declaration of unconstitutionality of Section 40, sole paragraph, of the IPC.

4.1 THE CONCRETE EFFECTS OF DAU 5,529 ON PATENT TERMS

Despite the significant effects announced by the affected industries, as I presented in Section 3, the information gathered indicates that most pharmaceutical patents affected by DAU 5,529 are still in force. Nearly two-thirds of the sample had not expired by the submission date of this research on January 31, 2024. This finding is significant because it shows that one of the claims made by interest groups opposing the unconstitutionality of Section 40, sole paragraph, was not accurate. These groups claimed that the decision would invalidate the majority of filed patents, which did not happen.

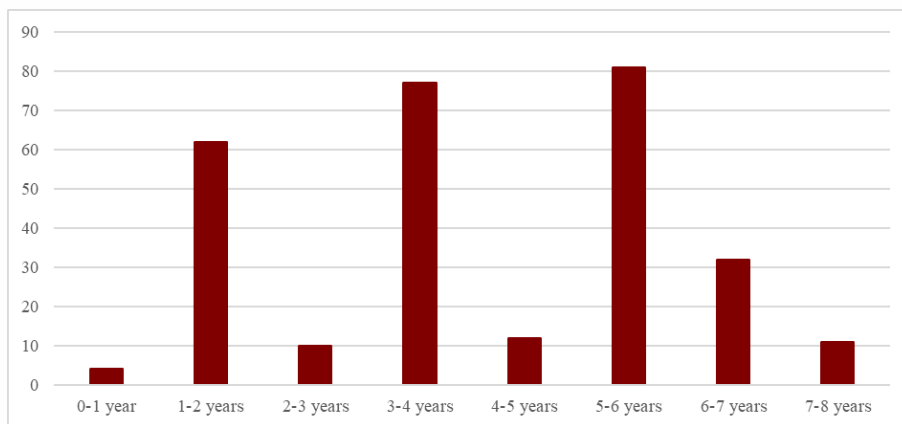
Figure 1. Validity of patents affected by the DAU 5,529



Source: compiled by the author.

However, having 42% of the patents in the sample already expired is not an insignificant number and provides room for the formulation of public policies and private sector planning to offer such medications at competitive prices. But the biggest downside to having most affected patents still in force is that the generic drug industry cannot start producing the medications, which means that SUS' expenses continue at the same levels as before DAU 5,529. To properly plan how to expand long-term access to healthcare, it is therefore important to analyze for how long such patents will remain in force as well.

Figure 2. Years until the expiration date of pharmaceutical patents



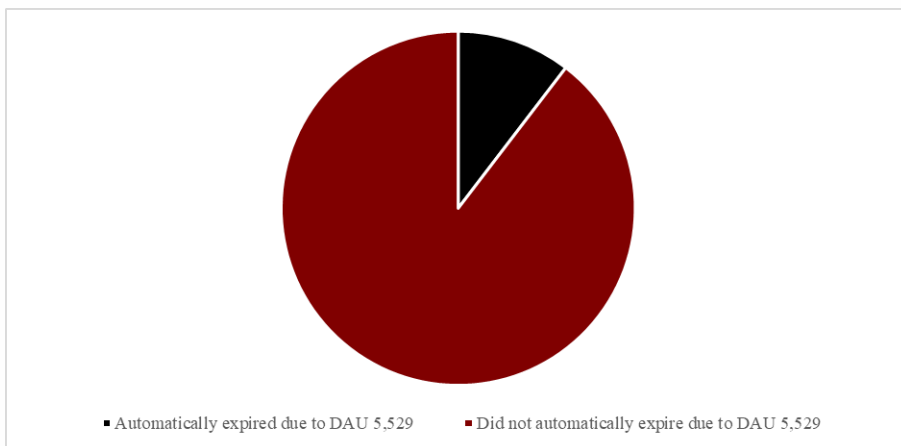
Source: compiled by the author.

Figure 2 shows that approximately 28% of the patents still in force will remain valid for five to six years, with eleven of them potentially extending to an additional eight years of validity. Considering the total sample, the average period until the patent expiration date is 4.08 years. However, SUS may remain subject to the same high prices already practiced by patent holders for a longer period, as medications are purchased through bidding processes that may have longer durations than the term of the patent. In this scenario, even if a laboratory managed to organize the production of generic drugs, the Public Administration would have to request a review or the economic rebalancing of the existing contract with the former patent holder, which could lead to additional legal disputes and complicate the purchase of generic pharmaceuticals.

The existence of prolonged periods of patent protection even after DAU 5,529 also contradicts the common perspective of an outstanding backlog at the INPI. As Section 2 shows, the variable term came to be commonly justified in national doctrine as a way to compensate applicants for INPI's unreasonable delay in analyzing patent applications, as there was a fear of patents being granted after their expiration – that is, whose examination took more than twenty years.

That, however, is not the case, as only 10.40% of the examined patents automatically expired after the declaration of unconstitutionality of Section 40, sole paragraph, of the IPC.

Figure 3. Pharmaceutical patents that automatically expired after DAU 5,529



Source: compiled by the author.

According to Figure 3, 89.60% of the sample remained in force immediately after the Supreme Court's decision. This shows that the INPI did not have as large of a backlog as reported, and that the media campaign to raise public awareness against DAU 5,529 was not supported by concrete data. Actually, until now, the decision has only led to the extinction of 111 out of the 500 analyzed patents. In other words, the sum of patents that expired immediately after DAU 5,529 with those that reached their term by January 2024 reveals that only 22.20% of the sample was affected by the decision. The other expired patents indicated in Figure 1 mostly lost their protection due to non-payment of INPI annual fees.


The compiled data indicates, thus, that DAU 5,529 has had a very limited impact on healthcare access so far, given that most of the affected patents are still in force. This information serves as a valuable planning resource for both generic drug manufacturers and SUS, facilitating proper pharmaceutical production and public expenditure

planning. However, it is essential to further analyze whether the patents that were supposed to expire due to the decision have indeed had all their effects extinguished, as I propose to do in the following section.

4.2 FINDING A WAY AROUND IT: ADMINISTRATIVE STRATEGIES

It was quite curious to notice that some of the patents examined had the following observation in their history of administrative orders:

Figure 4. Administrative orders to extend patent term

RPI	Data RPI	Dispatch	Img	Order Supplement
2679	10/05/2022	16.3		Rectification ref. RPI 2323, of 07/14/2015. Validity period: 10 years from 07/14/2015, subject to legal conditions. Patent granted in accordance with ADI 5.529/DF, with an apostille of the validity period of the protection of the matter relating to pharmaceutical products and processes and equipment and/or materials for use in health, for application in humans.
2678	03/05/2022	21.9	-	- The publication of code 21.1 in RPI nº 2630 of 06/01/2021 was annulled as it was inappropriate.
2678	03/05/2022	16.2	-	- The publication of code 16.3 in RPI nº 2629 of 05/25/2021 was annulled as it was improper.
2668	22/02/2022	22.5	-	- Requirement formulated for adequacy or compliance with legal provisions within 60 (sixty) days of this date.
2630	01/06/2021	21.1	-	- Patent expired on 01/19/2020
2629	25/05/2021	16.3	-	- Validity period: 20 (twenty) years from 01/19/2000, subject to legal conditions. Patent granted according to ADI 5.529/DF

Source: INPI Patent Data Base.³⁷¹

The figure above is one of the examples in which a patent's term was adjusted according to the instructions provided by DAU 5,529 but was subsequently readjusted to reinstate the application of Section 40, sole paragraph, of the IPC. As a result, the patent regained protection for at least ten years from the grant date. Nine pharmaceutical patents in the sample presented the same exception to the rule provided by the Supreme Court's decision, causing their protection periods to extend for over 28 years.

Tabela 1. Patents with protection periods longer than 20 years

Patent No.	Patent Holder	Filing Date	Grant Date	Patent Term	Pro-tection Period
PI0011152	Lipotec, S.A.	02/18/00	03/13/18	02/13/28	28.01

³⁷¹ Informal translation using a text translation feature directly on INPI's data base. The original in Portuguese reads as follows: "Retificação ref. RPI 2323, de 14/07/2015. Prazo de validade: 10 anos contados a partir de 14/07/2015, observadas as

Patent No.	Patent Holder	Filing Date	Grant Date	Patent Term	Pro-tection Period
PI0512563-4	Destiny Pharma Limited	06/22/05	04/13/21	04/13/31	25.82
PI0512563	Destiny Pharma Limited	06/22/05	04/13/21	04/13/31	25.82
PI0513500	N.V. Nutricia	07/18/05	03/09/21	03/09/31	25.66
PI0000126	Zoetis Services LLC	01/19/00	07/14/15	07/14/25	25.50
PI0004827	Exsymol S.A.M. / Pierre Emile Claude Jean Bondon	10/13/00	09/30/14	09/30/24	23.98
PI0512528	N. V. Nutricia	06/22/05	02/06/18	02/06/28	22.64
PI0718183	Boehringer Ingelheim Animal Health USA INC. (US)	26/10/2007	17/03/2020	17/03/2030	22.41
PI0309918	S.S. Steiner, INC.	05/15/03	07/28/15	07/28/25	22.22

Source: compiled by the author.

The INPI decided to maintain the original protection period of the patents above based on its understanding that these patents included incidental claims or part of their description relative to the pharmaceutical area, but their focus was on processes/products

condições legais. Patente concedida conforme a ADI 5.529/DF, com apostilamento do prazo de validade da proteção da matéria relativa a produtos e processos farmacêuticos e equipamentos e/ou materiais de uso em saúde, para aplicação em humanos. / Anulada a publicação código 21.1 na RPI nº 2630 de 01/06/2021 por ter sido indevida. / Anulada a publicação código 16.3 na RPI nº 2629 de 25/05/2021 por ter sido indevida. / Formulada exigência para adequação ou cumprimento de disposições legais no prazo de 60 (sessenta) dias desta data. / Patente extinta em 19/01/2020 / Prazo de Validade: 20 (vinte) anos contados a partir de 19/01/2000 observadas as condições legais. Patente concedida conforme ADI 5.529/DF.” INPI. Patent Data Base. 2024. Available at: <<https://busca.inpi.gov.br/pePI/servlet/PatenteServletController?Action=detail&CodPedido=540644&SearchParameter=PI0000126%20%20%20%20%20%20%20&Resumo=&Titulo=>>>. Access on: February 2, 2024.

in areas adjacent to healthcare, such as veterinary medicine and pesticides. Since DAU 5,529 only provided for *ex tunc* effects for “pharmaceutical products and processes, as well as health equipment and/or materials”³⁷², the Patents, Computer Programs, and Integrated Circuit Topographies Office (*Diretoria de Patentes, Programas de Computador e Topografia de Circuitos Integrados – DIRPA*) requested the INPI to annotate the patent certificates that were not related to pharmaceutical products so that they could regain their original protection period.³⁷³

Therefore, the holders of affected patents had to request the INPI to reconsider and annotate the relevant patent certificates, as they should not have been subject to the effects of DAU 5,529. But there are borderline situations in which the disputed patent can encompass both content related to human health and to other technologies. For example, patent No. PI0011152, which has a protection period of 28.01 years, refers to “peptides inhibiting neuronal exocytosis, a mixture of peptides, cosmetic and pharmaceutical compositions, the use of a peptide, and a method for cosmetic treatment of facial wrinkles and/or facial asymmetry in humans”.³⁷⁴ The patent certificate does not mention any other application of the product besides in humans,

372 BRAZIL. Supreme Court. *Proposal for modulation of the effects of DAU 5,529*. Justice Rapporteur Dias Toffoli. Judged on May 12, 2021.

373 PGF. Federal Attorney General’s Office. *Opinion No. 00047/2021/CGPI/PFE-INPI/PGF/AGU*. November 3, 2021. Available at: <<https://www.gov.br/inpi/pt-br/central-deconteudo/legislacao/arquivos/documentos/parecer-n-00047-2021-cgpi-pfe-inpi-pgf-agu-com-carater-normativo.pdf>>. Access on February 2, 2024.

374 Informal translation with emphasis added. The original in Portuguese reads as follows: “*peptídeos inibidores da exocitose neuronal, mistura de peptídeos, composições cosméticas e farmacêuticas, utilização de um peptídeo, e método para o tratamento cosmético em um ser humano das rugas faciais e/ou da assimetria facial*”. BALLESTER, Gregorio Fernández et al. *Peptídeos inibidores da exocitose neuronal, mistura de peptídeos, composições cosméticas e farmacêuticas, utilização de um peptídeo, e método para o tratamento cosmético em um ser humano das rugas faciais e/ou da assimetria facial*. Patent holder: Lipotec S.A. BR PI 0011152-0. Filing date: February 18, 2000. Grant date: March 13, 2018. Available at: <<https://busca.inpi.gov.br/pePI/servlet/PatenteServletController?PI0011152%20%20%20%20%20%20&Resumo=&Titulo=>>>. Access on February 2, 2024.

which would require a better understanding of INPI's motivations for granting the term extension in this case.³⁷⁵

Nonetheless, for such borderline situations, INPI proposed that these patents shall have two protection periods: one for the portion of the content applicable to human health, not exceeding twenty years from the filing date, and another for the content related to other technologies, subject to the term-extending effects of Section 40, sole paragraph. Since the patent certificate cannot showcase two protection periods, the expiration of the patent would only be published on the later expiration date.³⁷⁶

This mechanism, however, creates significant legal uncertainties regarding the effects of DAU 5,529. Firstly, it opens a loophole for patents that have application only in human healthcare, like the aforementioned PI0011152, to gain access to a term extension that the Supreme Court declared unconstitutional. Additionally, among the nine patents that present this type of annotation, none explicitly clarifies what is the content related to human health to which the twenty-year term applies. This, therefore, reproduces the harmful effects on competition of Section 40, sole paragraph, as generic manufacturers cannot be certain about which portion of the patent is expired or not. Consequently, it becomes economically disadvantageous to initiate production before the patent reaches its full expiration.

Moreover, patent holders may also be employing another strategy to ensure the continuity of their applications beyond the twenty years stipulated by law. In some instances, INPI identified on its lists that the patent should have its term adjusted but refrained from publishing the decree declaring its expiration. As a result, the holders continue to pay

375 DIRPA is required to provide internal documentation justifying all annotations made on patent certificates. While not automatically published, interested parties can obtain it upon request. However, up until this paper's date of submission, no requests were granted. See INPI. *Revista da Propriedade Industrial* n° 2666. Comunicados. February 8, 2022. Available at: <<https://www.gov.br/inpi/pt-br/servicos/patentes/informacoes-relacionadaos26661.pdf>>. Access on February 2, 2024.

376 INPI. *Revista da Propriedade Industrial* n° 2666. Comunicados. February 8, 2022. Available at: <https://www.gov.br/inpi/pt-br/servicos/patentes/copy_of_Comunicados26661.pdf>. Access on February 2, 2024.

annual fees as if the patents were still in force, creating uncertainties about its protection period. This is the case of patent No. PI0008405, used for the treatment of Hemophilia A, which should have expired on February 22, 2020. However, there are no administrative orders declaring the patent extinction and its owners continue to pay INPE's fees. They may be leveraging an error from the patent office to extend their rights beyond the legal protection period.

Figura 5. Payment of annual fees of patent No. PI0008405 beyond the legal protection period

20th annual installment :
Status: OK Type: Annual Fee GRU: 29409161901628743 Value: R\$ \$2,005.00 Payment Date: 02/22/2019
21st annual installment :
Status: OK Type: Annual Fee GRU: 29409161916283372 Value: R\$ \$2,005.00 Payment Date: 02/28/2020
22nd annual installment :
Status: OK Type: Annual Fee GRU: 29409161930425294 Value: R\$ \$2,005.00 Payment Date: 02/23/2021
23rd annual fee :
Status: OK Type: Annual Fee GRU: 29409161946804184 Value: R\$ \$2,005.00 Payment Date: 02/22/2022
24th annual installment :
Status: OK Type: Annual Fee GRU: 29409162300331876 Value: R\$ \$2,005.00 Payment Date: 02/23/2023
25th annual installment :
Status: Contains no releases

Source: INPI Patent Data Base.³⁷⁷

377 Informal translation using a text translation feature directly on INPI's data base. The original in Portuguese reads as follows: "20ª anuidade: Status: OK. Tipo: Anuidade. GRU: 29409161901628743. Valor: R\$ \$2,005.00. Data Pagamento: 22/02/2019. 21ª anuidade: Status: OK. Tipo: Anuidade. GRU: 29409161916283372. Valor: R\$ \$2,005.00. Data Pagamento: 28/02/2020. 22ª anuidade: Status: OK. Tipo: Anuidade. GRU: 29409161930425294. Valor: R\$ \$2,005.00. Data Pagamento: 23/02/2021. 23ª anuidade: Status: OK. Tipo: Anuidade. GRU: 29409161946804184. Valor: R\$ \$2,005.00. Data Pagamento: 22/02/2022. 24ª anuidade: Status: OK. Tipo: Anuidade. GRU: 29409162300331876. Valor: R\$ \$2,005.00. Data Pagamento: 23/02/2023. 25ª anuidade: Status: Não contém lançamentos". Available at: <<https://busca.inpi.gov.br/pePI/servlet/PatenteServletController?Action=detail&CodPedido=589244&SearchParameter=PI%200008405%20%20%20%20%20%20&Resumo=&Titulo=#>>. Access on February 2, 2024.

There are many other patents that continued to pay annual fees beyond the patent's 20th anniversary. But at this point it is not possible to confirm if these other cases are really using an administrative strategy to keep their patent in force, since most of them have only paid one additional fee thus far. The example above is the only one that has paid a significant number of undue fees, raising questions about the actual expiration term of the patent.

As this paper is intended to showcase exploratory results from a 500-patent sample, these are the only two potential strategies identified thus far to extend the term of patents. However, there could be other mechanisms employed by the owners of the inventions in the remaining portion of the total sample. Consequently, these findings call for a thorough analysis of INPI's approach to DAU 5,529. The decision had an enormous potential to expand access to health in Brazil, but that depends on the correct application of its provisions by the patent office. Using these strategies to circumvent the unconstitutionality of Section 40, sole paragraph, of the IPC represents another way of perpetuating inequality costs in the country and could jeopardize the entire potential of DAU 5,529.

5. CONCLUSION

The DAU 5,529 stands on the threshold of possibilities. Its potential to reduce inequality costs is enormous but has not been fully utilized thus far. To truly adopt an institutionalist approach, data collection is necessary to guide the formulation of public policies. However, there is a data blackout regarding the effects of the unconstitutionality of Section 40, sole paragraph. There has been no national public effort to try to identify the patents affected by the decision, and the only groups that seem genuinely mobilized are those interested in maintaining long periods of patent protection.

This is not, however, a critique to the DAU 5,529 itself. The decision was historic and marks a turning point in Brazilian approach to inequalities in access to healthcare. But as David Kennedy states,

we will not avoid the difficulties presented here “by avoiding their articulation, discussion, assessment”.³⁷⁸ Without prompt attention, the DAU 5,529 will soon become wasted potential.

378 KENNEDY, David. The International Human Rights Movement: Part of the Problem? In: *Harvard Human Rights Journal*, v. 15, 2002, p. 125.

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