204 Research Paper
24 July 2024

Negotiating Health and Autonomy: Data Exclusivity, Healthcare Policies and Access to Pharmaceutical Innovations

Henrique Zeferino De Menezes, Julia Paranhos, Ricardo Lobato Torres, Luciana Correia Borges, Daniela De Santana Falcão and Gustavo Soares Felix Lima

SOUTH CENTRE

RESEARCH PAPER

204

NEGOTIATING HEALTH AND AUTONOMY: DATA EXCLUSIVITY, HEALTHCARE POLICIES AND ACCESS TO PHARMACEUTICAL INNOVATIONS[1]

Henrique Zeferino De Menezes,[2] Julia Paranhos,[3] Ricardo Lobato Torres,[4] Luciana Correia Borges,[5] Daniela De Santana Falcão[6] and Gustavo Soares Felix Lima[7]

SOUTH CENTRE

24 JULY 2024

[1] This paper was originally published in Portuguese at Oikos: Journal of International Political Economy. Available from https://revistas.ufrj.br/index.php/oikos/article/view/54534/32252.

[2] Henrique Zeferino De Menezes | hzmenezes@gmail.com | Federal University of Paraíba
[3] Julia Paranhos | juliaparanhos@ie.ufrj.br | Federal University of Rio de Janeiro
[4] Ricardo Lobato Torres | torres.rl@hotmail.com | Federal University of Paraná
[5] Luciana Correia Borges | lborges@nevada.unr.edu | University of Nevada Reno
[6] Daniela De Santana Falcão | danifalcao1813@gmail.com | Federal University of Rio de Janeiro
[7] Gustavo Soares Felix Lima | gustavosfl@outlook.com | Federal University of Paraíba

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 in X: South_Centre 

ABSTRACT

This paper analyzes the debate over the international dissemination of data exclusivity as a form of protection for clinical trial data. This is a critical demand for pharmaceutical companies seeking larger market shares and longer periods of monopoly in order to recover investments in research and development and greater profitability. However, this is a sensitive issue with economic and social repercussions for developing countries that adopt this protection regime. This paper highlights critical issues for the political economy of innovation and presents a review of empirical studies that show that data exclusivity delays the entry of generic drugs into the market, increasing prices and reducing access. At the same time, its adoption has no benefits because there are no positive effects on internal technological innovation, nor reduction of the "International drug lag", nor the development of drugs for specific epidemiological demands.

Este documento analiza el debate sobre la difusión internacional de la exclusividad de los datos como forma de protección de los datos de ensayos clínicos. Se trata de una exigencia crítica para las empresas farmacéuticas que buscan mayores cuotas de mercado y periodos más largos de monopolio con el fin de recuperar las inversiones en investigación y desarrollo y una mayor rentabilidad. Sin embargo, se trata de una cuestión delicada con repercusiones económicas y sociales los países en desarrollo que adopten este régimen de protección. Este documento destaca cuestiones críticas para la economía política de la innovación y presenta una revisión de estudios empíricos que demuestran que la exclusividad de datos retrasa la entrada de medicamentos genéricos en el mercado, aumentando los precios y reduciendo el acceso. Al mismo tiempo, su adopción no tiene beneficios porque no hay efectos positivos en la innovación tecnológica interna, ni en la reducción del "International drug lag", ni en el desarrollo de medicamentos para demandas epidemiológicas específicas.

Ce document analyse le débat sur la diffusion internationale de l'exclusivité des données en tant que forme de protection des données d'essais cliniques. Il s'agit d'une exigence essentielle pour les entreprises pharmaceutiques qui cherchent à obtenir des parts de marché plus importantes et des périodes de monopole plus longues afin de récupérer leurs investissements réalisés dans le domaine de la recherche et du développement et d'accroître leur rentabilité. Toutefois, il s'agit d'une question sensible qui a des répercussions économiques et sociales pour les pays en développement qui adoptent ce régime de protection. Ce document souligne des questions cruciales pour l'économie politique de l'innovation et présente un examen des études empiriques qui montrent que l'exclusivité des données retarde l'entrée des médicaments génériques sur le marché, ce qui augmente les prix et réduit l'accès. Par ailleurs, son adoption ne présente aucun avantage, car elle n'a pas d'effets positifs sur l'innovation technologique interne, ni sur la réduction du "retard international en matière de médicaments", ni sur le développement de médicaments répondant à des demandes épidémiologiques spécifiques.

TABLE OF CONTENTS

INTRODUCTION 7
1. THE GLOBAL TEST DATA PROTECTION LANDSCAPE 9
1.1 The International Diffusion of Data Exclusivity 10
2. THE POLITICAL ECONOMY OF TEST DATA PROTECTION: EFFECTS ON HEALTH AND INNOVATION 15
3. FINAL CONSIDERATIONS 19
REFERENCES 20

INTRODUCTION

The COVID-19 pandemic and the race to develop a safe and effective vaccine have shed light on a particular and relevant dimension of the process of developing new drugs and immunizers – the production of clinical trials for the marketing authorization of new pharmaceutical technology. This authorization requires the submission of a considerable amount of information and data to regulatory agencies proving the product's quality, efficacy, and safety – the so-called clinical trial dossiers.

Although it is a health obligation aimed at protecting the health of individuals and the safety of public health systems, the data produced for registering a pharmaceutical or agrochemical product is a highly contested scientifically intensive economic asset. In this sense, the production of test dossiers and the institutional responses produced by the responsible bodies have significant economic and commercial effects in determining the possibility of introducing a new product onto the market. Thus, control of the information in dossiers and the ability to directly or indirectly access it has competitive effects on highly profitable markets and sectors, also impacting the production of generic drugs and the development of incremental innovations.

Transnational pharmaceutical companies from high-income countries, such as the United States (US), countries of the European Union (EU), Japan, and the members of the European Free Trade Association (EFTA) have demanded the dissemination of a specific intellectual property (IP) right that particularly protects test data submitted to regulatory agencies – protection known as data exclusivity. The dissemination of this model and the guarantee of a period of exclusive use of the information contained in the dossiers impact in diverse ways the economic interests of innovative companies, companies producing generic drugs, and those dedicated to incremental innovation.

On the other hand, this specific instrument of private appropriation of information subject to public regulation has effects on sensitive public policies, especially health and pharmaceutical care policies, due to the change in the periods of monopoly on medicines and other technologies, affecting the production of generic medicines and the development of improvements and adaptations of medicines for specific populations. Developing countries, including Brazil, have received special attention in the negotiation of preferential trade agreements that require the adoption of data exclusivity rules.

This paper has two particular but directly related objectives. On the one hand, we analyze the political phenomenon of the international dissemination of data exclusivity, emphasizing the relationship between pharmaceutical companies and governments in shaping an IP maximalist agenda that advances the protection of clinical trial data. To this end, the paper is based on the analysis of a set of information and documents, seeking to understand the position of pharmaceutical companies and their demands related to the dissemination of data exclusivity. Public position papers from business associations and demands submitted to negotiating bodies, especially the United States Trade Representative (USTR), are analyzed, as well as US and European trade reports that assess the protection systems of their trading partners. In addition, a wide range of preferential trade agreements are analyzed in order to understand the breadth of their requirements.

On the other hand, we analyze the effects and social costs caused by the introduction of data exclusivity in the legislation of developing countries, especially considering the impact on access to medicines and aspects related to technological innovation and the introduction of new products in these markets. The aim is to verify the claims that data exclusivity would stimulate innovation and access to pharmaceutical technologies —as supported by its

advocates by reviewing the existing empirical evidence on its effects. This analysis is based on a particular field of study in the political economy of innovation, seeking to present a balance of the most relevant empirical findings on data exclusivity in light of the more traditional discussions of the relationship between IP, technological innovation, and access to medicines.

Methodologically, a review was conducted of the empirical studies that have evaluated the impact of data exclusivity on the period of monopoly, the time it takes for new competitors to enter the market, and changes in prices, spending, and the budget for purchasing medicines. Evaluating the existing empirical evidence on the effects of this instrument can help to reduce uncertainties about the efficiency and effects of data exclusivity, by making it possible to systematize a greater amount of information pertinent to the subject and to produce well-founded answers to complex problems in an objective and less biased way (KHAN *et al.*, 2001; PETTICREW; ROBERTS, 2006). In the specific case of this work, the review aimed to answer the general question about the effects of data exclusivity on local pharmaceutical markets and access to medicines, making it possible to summarize categorical evidence related to the effects of data exclusivity and to counter existing empirical findings with demands for the introduction of this type of protection in the international legal framework for IP protection.

Searches were conducted in the three most relevant databases for the object of study, using combinations of terms that reflected studies that evaluated the real or prospective impacts of the introduction of data exclusivity.[8] In addition, Google searches were conducted using the same terms. A relevant initial finding is that we found more empirical studies as "grey literature" type, six in total, published as research reports by scientific organizations, international organizations, or civil society.

Another research finding is that there are practically no empirical studies that have measured the real effects in countries that have introduced data exclusivity rules in their protection systems. There are also a few studies that have estimated potential changes (*ex-ante)* based on real information. This is an important and surprising gap, given the high relevance of this issue for the right to health and access to medicines, but also for pharmaceutical innovation policies.

The next section analyses the global scenario of test data protection, highlighting the process of international diffusion of this type of protection. The following section discusses the social and economic impacts of this type of protection, considering the most relevant theoretical issues for the field.

[8] The Scopus, PubMed, and Web of Sciences databases were used, and the combinations applied were "evaluation + data exclusivity" and "impact + data exclusivity" in the titles, abstracts, and keywords. The first combination resulted in only four articles for the three databases, while the second combination generated a total of 38 scientific articles in the three databases. Reading the abstracts and excluding texts that did not conduct empirical studies to measure the effects of introducing data exclusivity rules on access to medicines left only four articles in the database. However, one of these was excluded from the sample because it presented a critical conflict of interest, having been funded by an association of innovative pharmaceutical companies, and presenting categorical conclusions without presenting data or the methodologies applied.

1. THE GLOBAL TEST DATA PROTECTION LANDSCAPE

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) harmonized international IP rules and homogenized national protection systems, establishing a mandatory minimum standard for all members of the World Trade Organization (WTO). TRIPS still provided a certain amount of discretion for countries in producing specific rules, interpreting criteria and requirements for granting rights, and defining rules on exceptions and exhaustion of rights (WATAL, 2001). Concerning test data submitted for the approval of pharmaceutical and agrochemical products, TRIPS is the first and only multilateral agreement to regulate the protection of this information. Section 7 of the agreement deals specifically with the protection of confidential information, or industrial secrets, making unprecedented progress in establishing specific rules for the protection of test results or other undisclosed data that are a condition for marketing pharmaceutical or agrochemical products.

The protection of test data can be found in Article 39 of the agreement, which establishes protection against unfair competition. In particular, article 39(2) establishes the protection of confidential information, or industrial secrets, while section 39(3) establishes undisclosed test data submitted to regulatory agencies for marketing authorization as a specific type of IP, industrial secret (undisclosed information), and protection against disclosure and unfair commercial use.

The main theoretical and political controversy over what is established in TRIPS concerns the possible obligation to grant a period of exclusivity in the use of test data. In other words, would it be mandatory to establish a system of "data exclusivity" in which health regulatory authorities could not rely on data previously submitted by an originator company to authorize the marketing of generic pharmaceutical products? Although apparently technical, this controversy implies different systems of IP protection and pharmaceutical innovation, as well as different policies on generics and access to medicines. To move forward in this discussion, we need to explain what a data exclusivity regime would be.

Tests to prove the efficacy and safety of medicines are divided into pre-clinical and clinical studies. The latter are subdivided into four phases. In phase 1, the toxicity, tolerance, safety and possible unexpected and unwanted reactions of a new chemical or biological entity are assessed. In phase 2, the therapeutic efficacy of the new drug is evaluated, while the third phase expands the population, seeking to determine the efficacy of the drug and the risk-benefit determination with the anticipation of side effects. The last phase evaluates all the elements mentioned with the product already on the market (PIANETTI; CÉSAR, 2016; RUMEL; NISHIOKA; SANTOS, 2006). In summary, the data produced by these tests enables health authorities to assess whether they should authorize the marketing of a new pharmaceutical technology.

Clinical trials tend to be time-consuming, costly, and risky, requiring significant investment by companies and/or governments. Once approved, a new medicine is called a reference medicine, and because it is innovative, it is usually protected by patents. A generic drug, conversely, contains the same active ingredient, dosage, and pharmaceutical form as the reference drug and therefore has equivalent efficacy and safety. The generic drug can, therefore, be interchanged with the reference drug. Therapeutic equivalence tests guarantee the safety of substitution between the two. Two drugs are considered to be therapeutically equivalent if, after administration of the same dose, their effects are the same, which is assessed through bioequivalence tests (PIANETTI; CÉSAR, 2016; STORPIRTIS et al., 2004). As a result, generic medicines do not need to undergo the same tests as reference medicines, which tends to reduce their sales prices, facilitating and speeding up access to

medicines through public purchases or reduced private spending (CALIARI; RUIZ, 2014; QUENTAL; FILHO, 2006).

From a business perspective, test dossiers should be treated as proprietary and exclusive assets. To this end, health agencies should be prevented from evaluating or approving applications for authorization of a generic drug for a certain period of time previously established in the legislation. In other words, data exclusivity protects test dossiers because it is impossible for third parties, including regulatory agencies, to rely on the existing and known efficacy and safety results of a reference medicine to authorize the marketing of an interchangeable, generic medicine for a certain period of time. (MERCURIO, 2018; REICHMAN, 2006).

The US and the EU are pioneers in introducing data exclusivity into their national IP protection systems. The Hatch-Waxman Act defines a five-year period of data exclusivity for new chemical compounds authorized for marketing by the Food and Drug Administration (FDA), during which the evaluation of generic marketing applications is prohibited. An additional three-year protection period has also been defined if the company presents new clinical studies on new uses or improvements to a known drug. Protection for biological products follows a specific rule laid down in the Biologics Price Competition and Innovation Act (BPCIA). For these products, the protection period is up to 12 years (BAGLEY, 2013; PACUD, 2019).

Current European legislation treats chemical and biological products similarly, with the protection scheme known as the 8+2+1 rule, adopted by European Commission Directive 2004/27. In this case, an initial eight years of data exclusivity are granted, during which the European agency is prohibited from receiving an application to market a generic product, complemented by a further two years of protection against the marketing of a generic and another year if the holder of the application obtains authorization to market a new therapeutic indication for the same drug (ACQUAH, 2014; ADAMINI et al., 2009).

Despite the legal changes undertaken in these countries and the demands and pressure to incorporate data exclusivity into the TRIPS text, Article 39(3) does not provide for this type of protection – i.e., it does not prohibit regulatory agencies from relying on the results of registration tests for a reference drug to assess the safety and efficacy of a generic (ACQUAH, 2014; ARRIVILLAGA, 2003; CORREA, 2011; REICHMAN, 2006). Article 1.1 of TRIPS clarifies that countries are free to interpret the extent of the protection afforded to test data within the minimum limits set by the agreement, including considering the literal interpretation of what is provided for in Article 39(3). It is also important to note that there is no WTO Dispute Settlement Body decision interpreting Article 39(3) to mean that data exclusivity must be granted.

This regulatory freedom has been the subject of international dispute. Multinational pharmaceutical companies and representatives of high-income countries are demanding that the article be interpreted in such a way as to accommodate data exclusivity as a means of complying with TRIPS obligations. To this end, they have undertaken strategies to disseminate data exclusivity as a model for protecting test data.

1.1 The International Diffusion of Data Exclusivity

Since the negotiation of TRIPS, the term "unfair commercial use" has been understood by high-income countries as synonymous with "non-reliance," requiring the granting of a period of data exclusivity. The US and the EU have converging interpretations on the subject and seek to spread this legal form by negotiating preferential trade agreements. In a USTR document, the US negotiator's reading is clear. "The TRIPS Agreement recognizes that the

original applicant should be entitled to a period of exclusivity during which other entrants cannot rely on the data that the innovative company has produced" (USTR, 2003). According to European trade representatives, data exclusivity is also the precise way to comply with TRIPS requirements. In a document, they explain that "Article 39(3) of TRIPS contains the obligation to protect test data against unfair commercial use, and it seems that the most effective way to fulfill this obligation is to use the test data in a way that is compatible with the TRIPS Agreement objective (...) is to provide data exclusivity for a reasonable period of time (...)". In another passage, the EU position is more explicit in demanding that "regulatory authorities should not rely on such data for a reasonable period of time to authorize the marketing of subsequent products"[9] (EUROPEAN COMMISSION, 2000).

In fact, the negotiating agenda of these countries reflects the interests of the multinational pharmaceutical industry, which is interested in controlling this information and reducing competition. In various position papers from business associations, such as the Pharmaceutical Research and Manufacturers of America (PhRMA), the International Federation of Pharmaceutical Manufacturers Associations (IFPMA),[10] as well as the Biotechnology Industry Organization (BIO), the US Chamber of Commerce and the European Federation of Pharmaceutical Industries (DIEPENDAELE et al., 2017), the proprietary nature of test data and the importance of data exclusivity for the economic interests of this production sector are made explicit.

The link between business interests and the building of trade policy agendas and strategies in high-income countries is nothing new, and it is even more pronounced when it comes to the protection of pharmaceutical technologies (DREYFUSS, 2010; SELL, 2007). Reports from the USTR's advisory committees, especially those related to IP-intensive sectors, reinforce the importance of data exclusivity for the interests of US companies. US trade legislation provides for formal consultations with advisory committees comprising various segments of US society. Various "Intellectual Property Provisions Reports" on the negotiation of preferential trade agreements produced by the "Industry Trade Advisory Committee on Intellectual Property Rights" (ITAC-15) and the "Industry Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters" (IFAC-3) are unanimous in their demand for the introduction or extension of data exclusivity in the agreements negotiated by the US.

To this end, different strategies have been launched to spread data exclusivity, emphasizing the negotiation of preferential trade agreements and unilateral pressure on trading partners (MENEZES, 2015; MUZAKA, 2011; SELL, 2010; YU, 2019). As a result, many developing and least-developed countries have adhered to data exclusivity as part of these negotiations. Globally, over thirty preferential trade agreements have clauses establishing data exclusivity in their chapters regulating IP rules. The table below lists an almost exhaustive set of recently negotiated preferential trade agreements containing data exclusivity provisions.

[9] Excerpts from the *European Union Commission* report*, Questions on TRIPs and Data Exclusivity,* quoted by Mercurio (2018).
[10] See, for example, the reports *Data exclusivity: Encouraging development of new medicines*, available at https://ifpma.org/publications/data-exclusivi- ty- encouraging-development-of-new-medicines/. [last accessed on 04/03/2023] and *PhRMA Special 301 Submission* 2020, available at https://phrma. org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/0-9/PhRMA-2020-Special-301-Submission.pdf [last accessed on 04/03/2023].

Table 1
Test data protection models in preferential trade agreements

Agreement	Scope of protection	Duration of protection
EFTA-Tunísia, EFTA-Peru EUA-Austrália, EUA-Bahrain, EUA-CAFTA-DR, EUA-Chile, EUA-Coréia do Sul, EUA-Marrocos EUA-Oman, EUA-Singapura UE-PE&CO, UE-Singapura	Market exclusivity	At least 5 years
EFTA-Líbano EU México	Market exclusivity	At least 6 years
EUA-Panamá, EUA-Peru, EUA-Colômbia UE-Vietnam, UE-Coréia do Sul	Data exclusivity	At least 5 years
UE-Canadá	Market and data exclusivity	At least 6 years (data) and 2 years (market)
Trans-pacific Partnership Agreement (TPP)	Market exclusivity	At least 5 + 3 years (new clinical trials)
United States-Mexico-Canada Agreement (USMCA)	Market exclusivity	At least 5 years
Regional Comprehensive Economic Partnership Agreement (RCEP)	information protection non-disclosed in accordance with paragraph 2 of Article 39 of TRIPS	N/A

Source: own elaboration based on the texts of the preferential trade agreements

As can be seen from the information in the table, there is a certain pattern in the normative content (scope of protection and duration of the right) of the different agreements analyzed. Despite the distinction between data and market exclusivity, the five-year time limit is the almost standard norm, with few exceptions. There is a technical distinction between these two forms of protection, however it is irrelevant to this paper, leaving only the explanation that, in the second case, the agencies can receive and authorize the marketing of a generic medicine, but it can only enter the market after the exclusivity period has expired. In the case of data exclusivity, the agencies are prohibited from receiving and evaluating applications for the duration of the exclusivity period. Thus, data exclusivity provides an additional period of de facto exclusivity equal to the time it takes the regulatory agency to evaluate the application and grant authorization.

The normative content of the Trans-pacific Partnership Agreement (TPP), the United States-Mexico-Canada Agreement (USMCA), and the Regional Comprehensive Economic Partnership Agreement (RCEP) portray two essential elements of the debate on data exclusivity that deserve to be highlighted. On the one hand, the TPP and the USMCA represent the most advanced model of the demands of developed countries and make explicit the current importance of exclusivity for the most recent trade negotiations. On the other hand, we can see a split between the offensive demands of high-income countries and the less protective stance presented in the IP chapter negotiated by the RCEP member countries – an agreement led by China.

Another instrument for disseminating IP policies is economic pressure on trading partners (MORIN; GOLD, 2014). The "Special 301" report, published annually by the USTR, identifies

and evaluates the trade practices and IP legislation of US partners. Countries are classified and listed in two categories, "watch list and priority watch list". The European Commission also publishes a similar report, the "Report on the protection and enforcement of intellectual property rights in third countries" . In both the North American and European models, the priority countries are not necessarily those with legislation inconsistent with international rules, but those with rules at odds with the commercial interests of those countries. The table below summarizes the information in these reports on the relevance of data exclusivity for the US and the EU.

Table 2
Requirement for data exclusivity rules in Special 301 and Report, in percentages

	Special 301		**Report**		
Year	Priority watch list	Watch list	Priority 1	Priority 2	Priority 3
2010	82	38	-	-	-
2011	67	34	-	-	-
2012	69	38	-	-	-
2013	100	30	-	-	-
2014	90	19	-	-	-
2015	85	25	100	100	42
2016	82	35	-	-	-
2017	82	30	-	-	-
2018	58	29	100	83	71
2019	73	24	-	-	-
2020	80	22	-	-	-
2021	-	-	100	75	63
Average	79%	30%	100%	86%	59%

Source: own elaboration based on Special 301 reports and the Report on the protection and enforcement of intellectual property rights in third countries (Report)

In the case of Americans, the lack of data exclusivity is a concern in 80 per cent of the countries on the priority watch list. When contrasted with the list of countries on the "watch list" this figure drops to 30 per cent. In the three reports produced by the European Commission, the priority countries are linked to the absence of data exclusivity rules. All those listed as "Priority 1" and 86 per cent of those listed as "Priority 2" do not have data exclusivity in their legislation. In summary, the reports produced by the USTR and the European Commission express concern about the need for their business partners to comply with their companies' interest protection standards, with an important emphasis on granting data exclusivity.

Analysis of preferential trade agreements and the position reports of the US and EU trade agencies show the importance of data exclusivity for transnational pharmaceutical companies, which seek to secure larger shares and longer periods of monopoly in a highly profitable market. However, this is a sensitive issue for the international political economy, with significant economic and social repercussions, as well as being the object of resistance and criticism from international organizations and non-governmental organizations.

In the next section, we examine whether or not the existing empirical evidence confirms the

claims that data exclusivity would stimulate innovation, availability, and access to pharmaceutical technologies, including in peripheral markets. Similarly, we analyze the social costs produced by increasing exclusivity periods, especially considering the impacts on access to medicines and the entry of new products in these markets.

2. THE POLITICAL ECONOMY OF TEST DATA PROTECTION: EFFECTS ON HEALTH AND INNOVATION

In this last section, we analyze the effects of the introduction of data exclusivity rules on access to medicines and technological innovation, as well as the entry of new pharmaceutical products into lower income markets. The analysis is based on the theoretical literature that has evaluated the relationship between the expansion and strengthening of IP rules and innovation and access to health, and the empirical studies that have measured the real impacts of the introduction or expansion of data exclusivity rules. As mentioned in the introduction, periods of data exclusivity tend to affect competition in the pharmaceutical market, generating substantial social and economic impacts.

Among the arguments that affirm the benefits of data exclusivity is the thesis that it would stimulate technological innovation, investment in the production of clinical trials, attract foreign investment, and the entry of innovative drugs into peripheral markets. This argument is based on a similar type of "incentive theory" that underpins the demand for the construction of IP regimes, with data exclusivity being a particular mechanism for stimulating the development of new drugs, secondary drugs, and the carrying out of clinical trials, through the recouping of investments through the exercise of a quasi-monopoly right (MASKUS; REICHMAN, 2005). Data exclusivity would also remedy unfair competition practices because companies producing generic drugs would benefit commercially by presenting data that is considered simpler and less costly (CARVALHO, 2008; SKILLINGTON; SOLOVY, 2003).

These arguments underpin the pressure from pharmaceutical companies for proprietary treatment of test data (GRABOWSKI; LONG; MORTIMER, 2011; SHAIKH, 2016; WEISSMAN, 2006). On the other hand, the reduction in pharmaceutical innovation, visible in the decrease in the volume of new patentable entities, puts pressure on pharmaceutical companies to exploit existing products by developing new combinations, new formulations, or new indications for known drugs, making data exclusivity the most profitable protection strategy (CORIAT et al., 2023; CORREA, 2009).

The literature that has analyzed these hypotheses shows that the benefits of data exclusivity for developing countries are not effectively observed. In reality, it has a negative impact on the registration of generics, with effects on prices and access to medicines, without any significant stimulus for internal innovation that could possibly offset the costs. Diependale et al. (2017) and Spina Ali (2019) explain that data exclusivity is an obstacle to technological innovation, even radical innovation, by limiting investment in the development of novel solutions to chronic or emerging problems.

"Data exclusivity might not prevent, but instead discourage innovation, by incentivizing low-risk investment. Especially for non-innovative drugs, data exclusivity offers the industry a lucrative opportunity since the development of such drugs costs significantly less and, despite the lack of patent protection, a market monopoly for several years can be obtained through data exclusivity" (DIEPENDAELE et al., 2017, p. 08).

Regarding the effects of data exclusivity in developing economies, the results also do not confirm the expectations of those who defend the mechanism. In other words, there would be no reason to affirm positive effects on incremental innovation and investment attraction. A public policy can aim to stimulate the development of non-innovative pharmaceutical products, which are therefore not patentable but which produce some therapeutic or economic benefit. The pharmaceutical industry, which operates in processes and products with a lower innovation profile, could benefit from this type of protection to advance in the development of

new drugs based on incremental innovations, and thus meet specific epidemiological profiles by developing drugs that are suitable for certain regions and populations. The question that arises is whether data exclusivity is the best way to stimulate incremental innovation. Moreover, what are the costs and competitive risks – such as the registration of medicines by foreign companies as a defensive strategy to extend monopoly periods on essential medicines? Even more relevant would be to question the relationship between radical or incremental innovation efforts and the epidemiological profile and demands of developing and less developed economies.

The argument that adopting data exclusivity would increase investment in the development of drugs for endemic diseases in poor countries and populations is also untenable. Pharmaceutical companies base their commercial and development strategies on three main markets: the USA, Europe, and Japan. It would, therefore, be unreasonable to imagine the exclusivity of data in peripheral markets as a factor determining the interests and investments of innovative companies. Similarly, it cannot stimulate investment in incremental innovation or to treat so-called neglected diseases (CORREA, 2011; DIEPENDAELE et al., 2017; OGUAMANAM, 2010; SPINA ALI, 2019).

Another problem developing countries face is delays or negligence in registering innovative drugs, a phenomenon known as "international drug lag.” Empirical evidence shows that lengthy delays in the entry of new drugs into peripheral markets would not be minimized by adopting a system of data exclusivity because they result from a lack of interest in smaller markets. In the same way, investment in research and development, as well as the economic and commercial calculations when defining the registration of new drugs, are determined based on a smaller group of high-income countries (SPINA ALI, 2019; WILEMAN; MISHRA, 2010).

The effects of data exclusivity on access to medicines is perhaps the most relevant dimension of analysis. Data exclusivity is a type of IP that is independent and autonomous from patents, and it should not be confused with the rules that provide for the patent term extension due to delays in the approval or authorization to market a product. However, patents and data exclusivity intersect, producing different effects. In one scenario, the overlap between the term of a patent and data exclusivity means that the latter has no function or impact because the patent already protects the registered drug. In another scenario, the patent protection period may end before data exclusivity ends. In this case, data exclusivity guarantees protection that extends the monopoly period beyond the patent period. In yet another scenario, data exclusivity occurs in the absence of a patent. Medicines based on an already known molecule, resulting from incremental innovations, the development of new formulations, or new uses, generally do not meet patentability standards. In this case, data exclusivity functions as the only formal mechanism for appropriation and exclusion of competitors from the market for a defined period of time (RAGAVAN, 2017a, 2017b).

In the second and third scenarios, there are social effects resulting from granting or extending monopoly periods on medicines and vaccines, reducing competition or delaying the entry of generics into the market. A study published by the Institute for Healthcare Informatics in 2016 shows that eliminating exclusivity rights on medicines leads to a continuous reduction in prices. According to the report, generic drugs launched between 2002 and 2014 reduced the prices of competing drugs by 51 per cent on average, reaching reduction rates of up to 74 per cent for some specific segments (SPINA ALI, 2019).

Several empirical studies have evaluated the effects of granting data exclusivity on the price and access to medicines, considering the effects of extending monopoly periods on different medicines or segments. The studies analyzed in this paper mostly deal with the effects on developing countries. However, some focus on markets in high-income countries, such as

Canada and Australia, which have adopted this protection model due to preferential trade agreements.

Of all the texts with empirical analyses of the phenomenon, one set was based on a specific method for estimating the effects of changes in IP rules, known as the "Intellectual Property Rights Impact Aggregate Model" (IPRIA) (ROVIRA; ABBAS; CORTÉS, 2009). This model allows for "ex-post" analyses, in which the effects of legal changes made in the past are measured, as well as "ex-ante" analyses, in which effects on prices and access to medicines are estimated due to legal changes, including the introduction of data exclusivity.

Empirical studies conducted using this model as the methodological reference have produced convincing results regarding the increase in public and private costs for the acquisition of medicines and the consequent reduction in access due to the introduction of data exclusivity in the legislation of several specific countries. The essential cause lies precisely in the increase in the effective periods of monopoly and the delay in the entry of competitors (CHAVES; GASPAR; VIEIRA, 2017; GAMBA, M; RODRIGUEZ; CORNEJO, 2009; HERNANDEZ-GONZALEZ; VALVERD; MURILLO, 2009; JACINTO; CORNEJO; GAMBA, 2013).

Other empirical studies have constructed specific methodological forms and approaches with a similar aim of estimating the effects of granting data exclusivity on access to and prices of medicines as a result of negotiating preferential trade agreements. The empirical findings are important. On the one hand, it has been estimated that granting data exclusivity would effectively lead to an increase in monopoly periods for certain medicines, with effects on prices (BEALL et al., 2019; GAMBA, M; BUENAVENTURA; SERRANO, 2012; GLESSON; LOPERT; MOIR, 2014; PALMEDO, 2023). Furthermore, the delay in generics entering the market leads to increased public spending on medicines and an effective reduction in access (AKALEEPHAN et al., 2009; SHAFFER; BRENNER, 2009).

In order to illustrate the arguments presented in aggregate, we present some of the relevant empirical findings. The text by Hernandez-Gonzalez, Valverd, and Murrilo (2009) estimates that granting a five-year data exclusivity period in Costa Rica would generate an increase in spending on the purchase of medicines of around US$ 176 million by 2030 due to the number of APIs under monopoly from 9 per cent to 24 per cent between 2010 and 2030. Chaves, Gaspar, and Vieira (2017), on the other hand, point to an increase in spending of around US$ 447 million and US$ 684 million in the period 2015-2050, just on the purchase of antiretrovirals, with the adoption of exclusivity for five and eight years respectively in Brazil. They also claim that there would be a reduction in sales by national producers of around US$ 43 million and US$ 78 million in the same scenarios.

Gamba, Rodriguez, and Cornejo (2009), on the other hand, show that extending the period of data exclusivity to 10 years in Colombia could imply an increase in spending on medicines of more than 340 million dollars, the equivalent of spending on medicines for the 2.8 million inhabitants belonging to the poorest 20 per cent of the country. In Peru, it would mean a 15 per cent increase in drug prices and would translate into an increase in public spending on medicines of around 250 million dollars – equivalent to the health spending for 2.7 million Peruvians.

Gamba, Buenaventura, and Serrano's (2012) article analyzes the accumulated "ex-post" effects of 10 years of data exclusivity in Colombia. The analysis shows an increase in public spending on medicines of around US$ 396 million. The analysis by Akaleephana (2009), on the other hand, evaluates the effects that the inclusion of TRIPS-plus standards in Thailand's protection system, including data exclusivity, would bring cumulative increases in spending of US$ 6.2 million in the first year, reaching US$ 5.2 billion in the case of all protected medicines over a cumulative period of ten years.

What is interesting to note is that even though they are based on different methodologies, there is a strong convergence in the conclusions between the studies, even between studies on less developed countries and high-income countries. In general, data exclusivity broadens the scope of protected medicines, as well as the duration of exclusivity periods, either as supplementary protection to a patent or in the protection of non-patented products. In general, there is an increase in average prices with impacts on public health systems and private spending on medicines.

3. FINAL CONSIDERATIONS

Article 39(3) of TRIPS allows countries to protect data submitted to regulatory agencies only against disclosure and unfair competition. However, it also guarantees countries the possibility of legislating to grant limited periods of exclusivity, during which the agencies responsible for authorizing the marketing of medicines cannot evaluate or approve the entry of medicines onto the market as long as they submit their own clinical trial dossiers. In other words, international legislation guarantees countries the freedom to define the system for protecting test data most responsive and appropriate to national interests and to innovation, health and pharmaceutical care policies.

However, the proprietary control of this data is highly demanded on the trade agenda of high-income countries, especially the US and EU, but data exclusivity is also part of trade negotiations in Japan, EFTA and South Korea. This is a demand from pharmaceutical companies interested in increasing control over critical scientific information with regulatory relevance and enormous commercial potential. As mentioned, data exclusivity allows for the extension of the period of real monopoly over patent-protected medicines, as well as the production of a specific legal protection instrument to exclude competitors over non-patented pharmaceutical products. In any case, as shown by the data available in the empirical studies analyzed, data exclusivity delays the entry of generic drugs onto the market, increasing the average prices charged. This reduces access to medicines for families and increases public spending.

In other words, regarding health and pharmaceutical care policies, developing countries find no benefit in introducing this type of IP into their legislation. Furthermore, there are no positive effects derived from the introduction of this rule on the levels of internal technological innovation, the development of technologies associated with the epidemiological demands of peripheral countries, or the reduction of the "International drug lag".

The rules of data exclusivity, although not mandatory in TRIPS, have mostly spread through the negotiation of preferential trade agreements, and this has been the strategic option for developed countries to advance their regulatory preferences. The economic asymmetries and bargaining power between developed and developing countries do not allow the latter much choice. Considering the potential negative effects of data exclusivity for developing countries, especially concerning health policies and access to medicines, they should be cautious in trade negotiations.

In the case of opting for data exclusivity, it is possible to establish safeguards to ensure, for example, that innovative medicines enter the market as quickly as possible. Some legislation establishes a mandatory maximum period for applying for authorization to market a product, based on its first registration in the world, or the requirement of a period for the effective marketing of the new drug locally in order to enjoy the right to exclusivity. Although this kind of rule does not guarantee a solution to the major problems related to data exclusivity, it can minimize negative effects and guarantee faster access to new pharmaceutical technologies.

REFERENCES

ACQUAH, D. (2014). Extending the limits of protection of pharmaceutical patents and data outside the EU - Is there a need to rebalance? IIC International Review of Intellectual Property and Competition Law, v. 45, n. 3, p. 256–286.

ADAMINI, S. et al. (2009). Policy making on data exclusivity in the European Union: from industrial interests to legal realities. Journal of Health Politics, Policy and Law, v. 34, n. 6, p. 979–1010.

AKALEEPHAN, C. et al. (2009). Extension of market exclusivity and its impact on the accessibility to essential medicines, and drug expense in Thailand: Analysis of the effect of TRIPs-Plus proposal. Health Policy, v. 91, n. 2, p. 174–182.

ARRIVILLAGA, L. R. (2003). An International Standard of Protection for Test Data Submitted to Authorities to Obtain Marketing Authorization for Drugs: TRIPS Article 39.3. The Journal of World Intellectual Property, v. 06, p. 139–154.

BAGLEY, M. (2013). Patent Term Restoration and Non-Patent Exclusivity in the United States. In. DREXL, J.; LEE, N. (Org.). Pharmaceutical Innovation, Competition and Patent Law: a Trilateral Perspective. Edward Elgar, p. 111–140.

BEALL, R. F. et al (2019). How will recent trade agreements that extend market protections for brand-name prescription pharmaceuticals impact expenditures and generic access in Canada? Health Policy, v. 123, n. 12, p. 1251–1258.

CALIARI, T.; RUIZ, R. M. (2014). Brazilian pharmaceutical industry and generic drugs policy: Impacts on structure and innovation and recent developments. Science and Public Policy, v. 41, n. 2, p. 245–256.

CARVALHO, N. P (2008). The TRIPS regime of antitrust and undisclosed information. Kluwer Law International BV.

CHAVES, G. C.; GASPAR, W. B.; VIEIRA, M. F. (2017) Mercosur-EU Free Trade Agreement: Impact analysis of TRIPS-plus measures proposed by the EU on public purchases and domestic production of HIV and Hepatitis C medicines in Brazil. Ministerio da Saúde, Brazil.

CORIAT, B. et al (2023). Health and Access to care: why it is necessary and urgent to switch from global public good to commons based approach. Laboratory of Economics and Management (LEM), Sant'Anna School of Advanced Studies, Pisa, Italy.

CORREA, C. (2009). Intellectual Property Rights and Inequalities in Health Outcomes. In. LABONTE, R. (Org.). Globalization and Health: pathways, evidence and policy. London: Routledge.

_____. (2011). Test Data protection: rights conferred under the TRIPS Agreement and some effects of FTA TRIPS-plus standards. In. DREYFUSS, R. (Org.). The Law and Theory of Trade Secrecy: a handbook of contemporary research. Cheltenham: Edward Elgar Publishing Limited.

DIEPENDAELE, L. et al (2017). Raising the Barriers to Access to Medicines in the Developing World - The Relentless Push for Data Exclusivity. Developing World Bioethics, v. 17, n. 1, p. 11–21.

DREYFUSS, Rochelle. (2010). TRIPS and essential medicines: must one size fit all? Making the WTO responsive to the global health crisis. In. POGGE, THOMAS; RIMMER, MATTHEW; RUBENSTEIN, K. (Org.). Incentives for Global Public Health: patent law and access to essential medicines. Cambridge: Cambridge University Press.

GAMBA, M; RODRIGUEZ, J.; CORNEJO, D. (2009). Estudio de impacto acceso a medicamentos en el TLC EU: impacto sobre el precio y consumo de medicamentos del Acuerdo Comercial (TLC) con la Unión Europea para Perú y Colombia. Instituto IFARMA, 2009.

GAMBA, M; BUENAVENTURA, F.; SERRANO, M. (2012). Impacto de 10 años de Protección de Datos en Medicamentos en Colombia. Instituto IFARMA.

GLESSON, D.; LOPERT, R.; MOIR, H. (2014) Proposals for extending data protection for biologics in the TPPA: Potential consequences for Australia. Submission to the Department of Foreign Affairs and Trade. [S.l.]: [s.n.].

GRABOWSKI, H.; LONG, G.; MORTIMER, R. (2011). Data exclusivity for biologics. Nature Publishing Group, v. 10, p. 15–16.

HERNANDEZ-GONZALEZ, G; VALVERD, M.; MURILLO, C. (2009). Evaluación del Impacto de las Disposiciones de ADPIC+ en el Mercado Institucional de Medicamentos de Costa Rica. Programa de ICTSD sobre Propiedad Intelectual y Desarrollo Sostenible.

JACINTO, J.; CORNEJO, E.; GAMBA, M. (2013). Impacto de la protección de datos de prueba a productos biotecnológicos, en el acceso a medicamentos.

Lima KHAN, K. et al. (2001). Undertaking Systematic Reviews of Research on Effectiveness: CRD's Guidance for those Carrying Out or Commissioning Reviews. New York: NHS Centre for Reviews and Dissemination.

MASKUS, K.; REICHMAN, J. (2005). The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods. In. MASKUS, K.; REICHMAN, J. (Org.). International Public Goods and Transfer of Technology under a globalized intellectual property rights regime. Cambridge: Cambridge University Press.

MENEZES, H. Z. (2015). A Estratégia Norte-Americana de Forum Shifting para Negociação de Acordos TRIPS-Plus com Países da América Latina. Contexto Internacional, v. 37, n. 2, p. 435–468.

MERCURIO, B. (2018). Drugs, Patents, and Policy: A Contextual Study of Hong Kong. Cambridge: Cambridge University Press.

MORIN, J. F.; GOLD, E. R. (2014), An Integrated Model of Legal Transplantation: The Diffusion of Intellectual Property Law in Developing Countries. International Studies Quarterly. v. 58, n. 4, p. 781–792.

MUZAKA, V. (2011). The Politics of Intellectual Property Rights and Access to Medicines. 1st. ed. London: Palgrave Macmillan.

OGUAMANAM, C. (2010). Patents and Pharmaceutical R&D: Consolidating Private-Public

Partnership Approach to Global Public Health Crises. The Journal of World Intellectual Property, vol. 13, n. 04.

PACUD, Z. (2019). Patents, supplementary protection certificates and data exclusivity at the service of pharmaceuticals. In. FRANKEL, S. (Org.). The Object and Purpose of Intellectual Property. Cheltenham: Edward Elgar Publishing, p. 2018–239.

PALMEDO, M. (2023). Evaluating the Impact of Data Exclusivity on the Price per Kilogram of Pharmaceutical Imports. Journal of Globalization and Development https://doi.org/10.1515/jgd-2021-0016.

PETTICREW, M.; ROBERTS, H. (2006). Systematic reviews in the social sciences: A practical guide. Oxford: Blackwell Publishing.

PIANETTI, G. A.; CÉSAR, I. (2016). Registro e autorização: atendimento aos requisitos mínimos de qualidade, eficácia e segurança. Organização Pan-Americana da Saúde/Organização Mundial da Saúde (OPAS/OMS), v. 1, n. 6, p. 1–8.

QUENTAL, C.; FILHO, S. S. (2006). Ensaios clínicos: Capacitação nacional para avaliação de medicamentos e vacinas. Revista Brasileira de Epidemiologia, v. 9, n. 4, p. 408–424.

RAGAVAN, S. (2017a). The Significance of the Data Exclusivity and Its Impact on Generic Drugs. Intellectual Property Studies, v. 01, n. 01, p. 131–141.

_____. (2017b). Data exclusivity: a tool to sustain market monopoly. Jindal Global Law Review, v. 8, n. 2, p. 241–260.

REICHMAN, J. (2006). The International Legal Status of Undisclosed Clinical Trial Data: from private to public goods? In. ROFFE, P.; TANSEY, G.; VIVAS-EUGUI, D. (Org.). Negotiating Health: intellectual property and access to medicines. Geneva: International Center for Trade and Sustainable Development.

ROVIRA, J.; ABBAS, I.; CORTÉS, M. (2009). Guide to the IPRIA (Intellectual Property Rights Impact Aggregate) Model.

RUMEL, D.; NISHIOKA, S. SANTOS, A. (2006). Intercambialidade de medicamentos: abordagem clínica e o ponto de vista do consumidor. Revista de Saúde Pública, v. 40, n. 5, p. 921–927.

SELL, S. K. (2007). TRIPS-plus free trade agreements and access to medicines. Liverpool Law Review, v. 28, n. 1, p. 41–75.

_____.(2010). TRIPS was never enough: vertical forum shifting, FTAS, ACTA, and TPP. J. Intell. Prop. L, v. 18, n. 2, p. 458.

SHAFFER, E. R.; BRENNER, J. (2009). Trade Agreement's Impact on Access to Generic Drugs. Health Affairs, set, v. 28, n. 5.

SHAIKH, O. H. (2016). Access to Medicine Versus Test Data Exclusivity: safeguarding flexibilities under international Law. Berlin: Springer.

SKILLINGTON, G. L.; SOLOVY, E. M. (2003). The Protection of Test and Other Data Required by Article 39.3 of the TRIPS Agreement. Northwestern Journal of International Law & Business, v. 24, n. 1, p. 1–52.

SPINA ALI, G. (2019). Sweetening a Bitter Pill: Of Drug Prices, Drug Delays and Data Exclusivity. Asia Pacific Journal of Health Law & Ethics, v. 12, n. 02, p. 1–51.

STORPIRTIS, S. et al. (2004). Equivalência Farmacêutica no Contexto da Intercambialidade Entre Medicamentos Genéricos e de Referência: Bases Técnicas e Científicas. Infarma. v. 16, n. 9/10, p. 9–10.

WATAL, J. (2001). Intellectual Property Rights in the WTO and Developing Countries. Alphen aan den Rijn: Kluwer Law International.

WEISSMAN, R. (2006). Data Protection: options for implementation. In. ROFFE, P.; TANSEY, G.; VIVAS-EUGUI, D. (Org.). Negotiating Health: intellectual property and access to medicines. Geneva: International Center for Trade and Sustainable Development.

WILEMAN, H.; MISHRA, A. (2010). Drug Lag and Key Regulatory Barries in the Emerging Markets. Perspectives in Clinical Research, v. 01, n. 02, p. 51–56.

YU, P. K. (2019). Data exclusivities and the limits to TRIPS harmonization. Florida State University Law Review, v. 46, n. 3, p. 641–708.

RECENT SOUTH CENTRE RESEARCH PAPERS

No.	Date	Title	Authors
128	February 2021	Intellectual Property in the EU–MERCOSUR FTA: A Brief Review of the Negotiating Outcomes of a Long-Awaited Agreement	Roxana Blasetti In collaboration with 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 and Thamara Romero
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	By 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 and 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 and 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 and Bonginkosi Shozi

142	4 January 2022	Competition Law and Access to Medicines: Lessons from Brazilian Regulation and Practice	Matheus Z. Falcão, Mariana Gondo and Ana Carolina Navarrete
143	11 January 2022	Direito Brasileiro da Concorrência e Acesso à Saúde no Brasil: Preços Exploratórios no Setor de Medicamentos	Bruno Braz de Castro
144	27 January 2022	A TRIPS-COVID Waiver and Overlapping Commitments to Protect Intellectual Property Rights Under International IP and Investment Agreements	Henning Grosse Ruse-Khan and Federica Paddeu
145	9 February 2022	The Right to Health in Pharmaceutical Patent Disputes	Emmanuel Kolawole Oke
146	16 February 2022	A Review of WTO Disputes on TRIPS: Implications for Use of Flexibilities for Public Health	Nirmalya Syam
147	28 February 2022	Can Negotiations at the World Health Organization Lead to a Just Framework for the Prevention, Preparedness and Response to Pandemics as Global Public Goods?	Viviana Muñoz Tellez
148	7 March 2022	Marine Genetic Resources Beyond National Jurisdictions: Negotiating Options on Intellectual Property	Siva Thambisetty
149	8 March 2022	The International Discourse on the Right to Development and the Need to Reinvigorate its Implementation	Yuefen Li, Daniel Uribe and Danish
150	21 March 2022	The Liability of Internet Service Providers for Copyright Infringement in Sri Lanka: A Comparative Analysis	By Ruwan Fernando
147	28 February 2022	Les négociations au sein de l'Organisation mondiale de la santé peuvent-elles aboutir à un cadre juste pour la prévention, la préparation et la riposte aux pandémies en tant que bien public mondial?	Viviana Muñoz Tellez
147	28 February 2022	¿Podrán las negociaciones en la organización mundial de la salud resultar en un marco justo para la prevención, la preparación y la respuesta ante pandemias como bienes públicos globales?	Viviana Muñoz Tellez
151	19 April 2022	Escaping the Fragility/Conflict Poverty Trap: How the interaction between service delivery, capacity development and institutional transformation drives the process of transition out of fragility	Mamadou Dia
152	21 April 2022	An Examination of Selected Public Health Exceptions in Asian Patent Laws	Kiyoshi Adachi

153	26 April 2022	Patent Analysis for Medicines and Biotherapeutics in Trials to Treat COVID-19	Srividya Ravi
154	9 May 2022	COVID-19 Vaccines as Global Public Goods: between life and profit	Katiuska King Mantilla and César Carranza Barona
155	27 May 2022	Manufacturing for Export: A TRIPS-Consistent Pro-Competitive Exception	by Carlos M. Correa and Juan I. Correa
156	1 June 2022	A Tough Call? Comparing Tax Revenues to Be Raised by Developing Countries from the Amount A and the UN Model Treaty Article 12B Regimes	Vladimir Starkov and Alexis Jin
157	3 June 2022	WTO Moratorium on Customs Duties on Electronic Transmissions: How much tariff revenue have developing countries lost?	Rashmi Banga
158	15 June 2022	Twenty Years After Doha: An Analysis of the Use of the TRIPS Agreement's Public Health Flexibilities in India	Muhammad Zaheer Abbas, PhD
156	1 June 2022	Un choix cornélien ? Comparaison des recettes fiscales à engranger par les pays en développement au titre des régimes du Montant A et de l'Article 12B du Modèle de convention des Nations Unies	Vladimir Starkov et Alexis Jin
159	15 July 2022	Reaping the Fruits of Research on Microorganisms: Prospects and Challenges for R&D and Industry in Sri Lanka	Ruwan Fernando
160	21 July 2022	Movement Forward on ABS for the Convention on Biological Diversity: Bounded Openness Over Natural Information	Joseph Henry Vogel, Manuel Ruiz Muller, Klaus Angerer, and Christopher May
161	26 July 2022	Two Pillar Solution for Taxing the Digitalized Economy: Policy Implications and Guidance for the Global South	Irene Ovonji-Odida, Veronica Grondona, Abdul Muheet Chowdhary
162	11 August 2022	The Proposed Standing Multilateral Mechanism and Its Potential Relationship with the Existing Universe of Investor – State Dispute Settlement	Danish and Daniel Uribe
163	19 August 2022	The Human Right to Science: From Fragmentation to Comprehensive Implementation?	Peter Bille Larsen and Marjorie Pamintuan
156	1 June 2022	¿Una elección difícil? Comparación de los ingresos fiscales que recaudarán los países en vías de desarrollo a partir de los regímenes del Monto A y del Artículo	Vladimir Starkov y Alexis Jin

		12B de la Convención Modelo de las Naciones Unidas	
143	11 January 2022	Brazilian Competition Law and Access to Health in Brazil: Exploitative Pricing in the Pharmaceutical Sector	Bruno Braz de Castro
164	23 September 2022	Impact of a Minimum Tax Rate under the Pillar Two Solution on Small Island Developing States	Kuldeep Sharma
165	4 October 2022	Evaluating the Impact of Pillars One and Two	Suranjali Tandon and Chetan Rao
166	6 October 2022	Lessons From India's Implementation of Doha Declaration on TRIPS and Public Health	Nanditta Batra
167	27 October 2022	Analysing Intersections between Climate Change and Human Rights	Daniel Uribe Teran and Luis Fernando Rosales
168	28 October 2022	TRIPS Flexibilities and Access to Medicines: An Evaluation of Barriers to Employing Compulsory Licenses for Patented Pharmaceuticals at the WTO	Anna S.Y. Wong, Clarke B. Cole, Jillian C. Kohler
169	8 November 2022	The WTO TRIPS Decision on COVID-19 Vaccines: What is Needed to Implement it?	Carlos M. Correa and Nirmalya Syam
170	17 November 2022	Left on Our Own: COVID-19, TRIPS-Plus Free Trade Agreements, and the Doha Declaration on TRIPS and Public Health	Melissa Omino and Joanna Kahumbu
171	29 November 2022	Pautas para el Examen de Solicitudes de Patentes Relacionadas con Productos Farmacéuticos	Carlos M Correa
162	11 August 2022	El mecanismo multilateral permanente propuesto y su posible relación con el universo existente de solución de controversias entre inversionistas y estados	Danish y Daniel Uribe
162	11 August 2022	Le mécanisme multilatéral permanent proposé et sa relation potentielle avec l'univers existant du règlement des différends entre investisseurs et États	Danish y Daniel Uribe
172	1 December 2022	Illicit Financial Flows and Stolen Asset Recovery: The Global North Must Act	Abdul Muheet Chowdhary and Sebastien Babou Diasso

171	31 January 2022	Directives pour l'examen des demandes de brevet relatives aux produits pharmaceutiques	Carlos M Correa
173	7 February 2023	Analysis of COVID-Related Patents for Antibodies and Vaccines	Kausalya Santhanam
174	13 February 2023	Leading and Coordinating Global Health: Strengthening the World Health Organization	Nirmalya Syam
138	October 2021	Más allá de la responsabilidad social de las empresas: reforzar la diligencia debida en materia de derechos humanos mediante el Instrumento jurídicamente vinculante sobre empresas y derechos humanos	Daniel Uribe Terán
138	October 2021	Au-delà de la responsabilité sociale de l'entreprise : Renforcer le devoir de diligence en matière de droits de l'homme au moyen de l'instrument juridiquement contraignant relatif aux entreprises et aux droits de l'homme	Daniel Uribe Terán
167	27 October 2022	Analyse des Intersections entre le Changement Climatique et les Droits de l'Homme	Daniel Uribe Teran y Luis Fernando Rosales
167	27 October 2022	Análisis de las intersecciones entre cambio climático y derechos humanos	Daniel Uribe Teran y Luis Fernando Rosales
175	22 March 2023	Experiencias internacionales sobre la concesión de licencias obligatorias por razones de salud pública	Catalina de la Puente, Gastón Palopoli, Constanza Silvestrini, Juan Correa
176	29 March 2023	De dónde viene y a dónde va el financiamiento para la salud mundial	Germán Velásquez
177	18 May 2023	Policy Dilemmas for ASEAN Developing Countries Arising from the Tariff Moratorium on Electronically Transmitted Goods	Manuel F. Montes and Peter Lunenborg
178	22 May 2023	A Response to COVID-19 and Beyond: Expanding African Capacity in Vaccine Production	Carlos M. Correa
179	14 July 2023	Reinvigorating the Non-Aligned Movement for the Post-COVID-19 Era	Yuefen Li, Daniel Uribe and Danish
180	9 August 2023	Neglected Dimension of the Inventive Step as Applied to Pharmaceutical and	Ruwan Fernando

		Biotechnological Products: The case of Sri Lanka's patent law	
181	14 August 2023	Trends, Reasons and Prospects of De-dollarization	Yuefen Li
182	7 September 2023	Multistakeholderism: Is it good for developing countries?	Harris Gleckman
183	15 September 2023	Least Developed Countries and Their Progress on the Sustainable Development Goals	Peter Lunenborg
184	15 September 2023	Promoting Jordan's Use of Compulsory Licensing During the Pandemic	Laila Barqawi
185	13 October 2023	Foreign Investment Flows in a Shifting Geoeconomic Landscape	Danish
182	7 September 2023	Multistakeholderismo: ¿Es bueno para los países en desarrollo?	Harris Gleckman
182	7 September 2023	Multipartisme: est-ce bon pour les pays en développement?	Harris Gleckman
186	14 November 2023	Patentamiento de anticuerpos monoclonales. El caso de Argentina	Juan Correa, Catalina de la Puente, Ramiro Picasso y Constanza Silvestrini
187	4 December 2023	The Global Digital Compact: opportunities and challenges for developing countries in a fragmented digital space	Carlos Correa, Danish, Vitor Ido, Jacquelene Mwangi and Daniel Uribe
188	7 December 2023	The Intersection Between Intellectual Property, Public Health and Access to Climate-Related Technologies	Lívia Regina Batista
189	21 December 2023	Status of Permanent Establishments under GloBE Rules	Kuldeep Sharma
190	24 January 2024	Implementing the Doha Declaration in OAPI Legislation: Do Transition Periods Matter?	Patrick Juvet Lowé Gnintedem
191	25 January 2024	TRIPS Waiver Decision for Equitable Access to Medical Countermeasures in the Pandemic: COVID-19 Diagnostics and Therapeutics	Nirmalya Syam and Muhammad Zaheer Abbas, PhD
192	30 January 2024	Pautas para el examen de patentes sobre anticuerpos monoclonales	Juan Correa, Catalina de la Puente, Ramiro Picasso y Constanza Silvestrini
193	2 February 2024	Desafíos actuales y posibles escenarios futuros de la salud mundial	Germán Velásquez

194	15 February 2024	Implementation of TRIPS Flexibilities and Injunctions: A Case Study of India	Shirin Syed
195	6 March 2024	Régimen de licencias obligatorias y uso público no comercial en Argentina	Juan Ignacio Correa
196	19 April 2024	Licencias obligatorias para exportación: operacionalización en el orden jurídico argentino	Valentina Delich
197	28 May 2024	Compulsory Licensing as a Remedy Against Excessive Pricing of Life-Saving Medicines	Behrang Kianzad
198	31 May 2024	What Can Cambodia Learn from Thailand and India as It Prepares to Graduate from Least Developed Country Status?	Brigitte Tenni, Deborah Gleeson, Joel Lexchin, Phin Sovath, and Chalermsak Kittitrakul
199	10 June 2024	A Toss Up? Comparing Tax Revenues from the Amount A and Digital Service Tax Regimes for Developing Countries	Vladimir Starkov and Alexis Jin
200	26 June 2024	Transforming the Non-Military Structures of Global Governance Assessing Priorities for Chapter 5 of the Pact for the Future	Harris Gleckman
201	27 June 2024	Antimicrobial Resistance: Optimizing Antimicrobial Use in Food-Producing Animals	Viviana Munoz Tellez
202	28 June 2024	Constraints to and Prospects for Sustainable Livestock Sector Practices in Argentina with Emphasis on Antimicrobial Usage	David Oseguera Montiel
203	11 July 2024	The Vaccine Industry After the COVID-19 Pandemic: An International Perspective	Felix Lobo

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