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Negotiating health and autonomy: Data exclusivity, healthcare policies and access to pharmaceutical innovations

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Henrique Zeferino De Menezes, Julia Paranhos,
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RESEARCH PAPER

204

NEGOTIATING HEALTH AND AUTONOMY: DATA EXCLUSIVITY, HEALTHCARE POLICIES AND ACCESS TO PHARMACEUTICAL INNOVATIONS¹

Henrique Zeferino De Menezes,² Julia Paranhos,³ Ricardo Lobato
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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.

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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-exclusivity-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

Year	Special 301		Report		
	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.

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