

Sweetening a Bitter Pill: Of Drug Prices, Drug Delays and Data Exclusivity

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Abstract

Commentators and social activists vehemently demonize data exclusivity for increasing the price of essential pharmaceuticals beyond the purchasing power of developing countries' citizens, whereas R&D industries defend it as a necessary instrument for bringing new medicines into the market. The present work adds to the ongoing debate by addressing the topic under the light of the empirical evidence suggesting that low-income countries significantly lag behind Western economies in the introduction of new drugs. Under a policy perspective, the paper reviews in a unitary and comprehensive framework the stance that data exclusivity has a role to play in reducing the international drug lag in developing countries. This paper concludes that empirical evidence does not offer compelling arguments to either uphold or discard drug lag driven data exclusivity claims and there is no room to advocate for data exclusivity as a generalized solution to the international drug lag. In spite of this, developing countries tend to give in to the pressures of their western counterparts and have already accepted data exclusivity in more than 30 bilateral and multilateral free trade agreements. As such, anytime data exclusivity is accepted as a bargaining chip to strike a more favourable trade deal, a health-oriented precautionary approach demands to safeguard those flexibilities that are best fit to strike a balance between intellectual property, affordable medicines and prompt drug introductions. The paper will, therefore, analyse and defend the consistency of six data exclusivity flexibilities with the international intellectual property regime and in particular with the TRIPS Agreement. In doing so, the paper provides developing countries' governments with some legal and policy arguments in support of data exclusivity flexibilities, with the goal of best protecting the health interests of their populations in the process of implementation and/or negotiation of international data exclusivity provisions.

Keywords: Data Exclusivity, Drug Lag, TRIPS, Flexibilities

I. Introduction

In modern legal systems, a pharmaceutical is commercialized only after a drug sponsor has proved its safety, quality and efficacy before a specialized governmental

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agency. The drug features are usually proven through the submission of a dossier illustrating the results of drug experimentation on thousands of human subjects. The development of clinical information absolves important reasons of public safety, but it is still carried out privately by those pharmaceutical companies investing heavily in research and development. Testing represents the most critical and expensive phase of drug development, which according to some estimates, albeit heavily disputed, may overcome the threshold of one billion of capitalized American dollars.¹

Differently than innovative firms, generic companies do not have to submit a full set of clinical trials to medical agencies. It is sufficient that they can show evidence that their generic is “bio-equivalent” to a previously authorized one. Bio-equivalency demonstrates that overall the two drugs have the same chemical composition, comparable drug absorption and therapeutic effects. In the legal jargon, this is called obtaining drug authorization by “relying” on a previous approval or by filing a “me-too application.”

R&D industries look unfavourably at data reliance by generic companies. They claim that it undermines their investment in trials generation and that it may eventually dissuade innovators from embarking in drug testing and experimentation. For these reasons, western-based companies advocate for the necessity to protect newly generated trials through data exclusivity periods. Data exclusivity stands for a limited period of time during which medical agencies are not allowed to rely on first authorizations for the approval of generic applications. By banning generic competition for some years following approval, pioneer companies are able to recoup the investment in trials generation through monopolistic price strategies.

Already in the 80s, pharmaceutical companies successfully lobbied data exclusivity periods in both the U.S. and in the EU. Later on, these two started to push for the adoption of data exclusivity standards in the international forum. At the multilateral level, this was done during the negotiations of the Treaty on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Western pressures led to the adoption of Article 39(3) of the Agreement, which obliges parties to protect clinical data against “unfair commercial use.” The Treaty wording is particularly unclear, and it is still debated

¹ Jorge Mestre-Ferrandiz et al. *The R&D Cost of a New Medicine*. Monograph, Office of Health Economics, 2012.

among scholars if it encompasses any prohibition against data reliance. At the regional and bilateral level, the U.S. and the EU have agreed on data exclusivity rules in ad hoc Free Trade Agreements (FTAs) with targeted commercial partners.²

At a policy level, data exclusivity is ostracised by several developing countries, backed-up by scholars and non-governmental organizations. They claim that, by limiting competition, data exclusivity imposes unsustainable prices on emerging pharmaceutical markets, and that it consequently impedes the distribution of affordable drugs among developing countries' populations. A common rhetoric utilized both by NGOs and the press to warn developing countries against accepting data exclusivity has been the exhortation not to swallow the bitter pill of stringent regulatory protection rules.³

Besides unaffordable medicines, a more overlooked problem affecting developing countries is the lack of authorized medicines in some therapeutic fields. In this sense, relevant literature shows that western drugs often reach developing countries markets with several years of delay. This phenomenon, known as 'international drug lag,' denies the populations of developing countries access to last generation medicines, and it might constitute an even graver danger to public health than high pharmaceutical prices.

The present work reviews the claim that data exclusivity is conducive to faster drug introductions in developing countries. After analysing both empirical studies and governmental reports, the paper first concludes that there is no compelling evidence to either uphold or discard data exclusivity' beneficial effects on fast drug introductions, and thus it does not dare to propose data exclusivity as a generalized solution to the international drug lag. However, no analysis would be complete without taking into account the existing legal and political framework. Several developing countries have already agreed on data exclusivity as a bargaining chip to obtain more favourable trade deals with Western countries and more might follow the same path in the future.⁴

² See Diependaele, Lisa, Julian Cockbain, and Sigrid Sterckx. "Raising the Barriers to Access to Medicines in the Developing World - The Relentless Push for Data Exclusivity." *Developing World Bioethics* 17, no. 1 (2016): 11-21.

³ "Don't Swallow This Pill." Médecins Sans Frontières (MSF) International. Accessed April 25, 2015. <https://www.msf.org/dont-swallow-pill>; Unni Karunakara, *Don't Swallow this Pill*, Times of India <https://timesofindia.indiatimes.com/edit-page/Dont-swallow-this-pill/articleshow/7312903.cms> (accessed October 30, 2018).

⁴ For a list of FTAs currently being negotiated by the EU, see "European Commission Directorate-General for Trade." Accessed January 21, 2019. <http://ec.europa.eu/trade/policy/countries-and-regions/>

Considered the foregoing, the paper advances a simple predicament: countries that are obliged or willing to swallow the bitter pill of data exclusivity should try to sweeten it by tweaking their domestic systems to tackle slow drug introductions and high pharmaceutical prices.⁵ The paper, therefore, advocates for a health-oriented precautionary approach once international data exclusivity obligations have or are being agreed upon. This leverages on the axiom that there is sufficient evidence to support developing countries' drug lag concerns. Although some may object of such evidence having merely conjectural or speculative value, there is enough ground to advocate for a risk-averse public health policy in the implementation of international treaties. This is to mean that, all things being equal, it is preferable to opt for rules that safeguard public health rather than those that do not, especially when the former do not affect the core interests of intellectual property holders.⁶

The goal of striking a balance between intellectual property, affordable medicines and prompt drug introductions can be achieved by wisely exploiting the flexibilities inherent in the TRIPS discipline on regulatory data protection. The expression "flexibilities" describes the leeway left to member states to tailor their TRIPS obligations to meet specific policy goals and objectives, e.g. safeguarding access to medicines or nutrition.⁷ There are two ways to achieve this. The first one is by pushing for the inclusion of health-oriented flexibilities in the text of free trade agreements. This might be done by leveraging on the previous trade practice of the EU and the U.S., which in several occasions in the past have conceded some public health safeguards in some FTAs' data exclusivity provisions.⁸ The second is by interpreting vague treaty expressions in a manner conducive to public health during the process of

negotiations-and-agreements/#_being-negotiated.

⁵ See e.g. Paragraph 4 of the WTO Ministerial Conference, *Declaration on the TRIPS Agreement and Public Health* WT/MIN(01)/DEC/W/2, Doha, November 14, 2001.

⁶ See Li, Phoebe. *Health Technologies and International Intellectual Property: A Precautionary Approach*. London: Routledge, Taylor & Francis Group, 2014; Hung, Phoebe Chienwen. "The Precautionary Approach under the Right to Health Dilemma." *International Review of Law, Computers & Technology* 24, no. 1 (2010): 73.

⁷ See Shaikh, Owais H., *Access to Medicine versus Test Data Exclusivity: Safeguarding Flexibilities under International Law* (Munich: Springer, 2016), 30.

⁸ For information on different flexibilities proposed in the draft text of the Trans-pacific Partnership (2015), see "Submit Documents to WikiLeaks." About. Accessed November 8, 2018. <https://wikileaks.org/tpp-final/>.

domestic implementation of developing countries international obligations. This strategy has been successfully deployed by Chile, who has implemented one of the most public health-oriented data exclusivity laws worldwide, notwithstanding being bound by data exclusivity obligations with both the European Free Trade Association (EFTA) and the United States.⁹

This paper engages in a two-fold analysis of the data exclusivity debate. Firstly, it reviews the policy implications of data exclusivity, taking into account the characteristics of developing countries' markets. Secondly, it defends the TRIPS consistency of the data exclusivity measures implemented by some developing countries to foster prompt drug introductions, reviews the relevant provisions of several free trade agreements on the matter and explains how these measures might prove an important tool to reduce drug lags.

The remainder of this paper is structured as follow. Section two will focus on data exclusivity in the TRIPS Agreement. Section three will describe the health-oriented criticisms towards data exclusivity, as well as their weaknesses. Section four will introduce the phenomenon of international drug lag, and section five will provide three explanations for drug delays in developing countries. Section six will explore how governments may foster domestic drug introductions by customizing their data exclusivity laws. Section seven will conclude with some final considerations.

II. Data Exclusivity: From the TRIPS Agreement to FTAs

At the end of the 80s the United States and the European Union, alongside Switzerland, insistently pushed for the adoption of a five-year data exclusivity period in the TRIPS agreement. In 1990, their positions were unified in a single proposal known as the Brussels Draft. It read:

“4A PARTIES, when requiring, as a condition of approving the marketing of new pharmaceutical products or of a new agricultural chemical product, the submission

⁹ See Article 91 of the Chilean Law 19,039 on Industrial Property, as amended by Law 19,996 vis-à-vis Article 17(10) of the US-Chile FTA and Article 4, Annex XII (2003) EFTA-Chile Free Trade Agreement.

of undisclosed test or other data, the origination of which involves a considerable effort, shall [protect such data against unfair commercial use. Unless the person submitting the information agrees, the data may not be relied upon for the approval of competing products for a reasonable time, generally no less than five years, commensurate with the efforts involved in the origination of the data, their nature, and the expenditure involved in their preparation. In addition, PARTIES shall] protect such data against disclosure, except where necessary to protect the public.”¹⁰

The bracketed text indicated a lack of consensus on the text to be adopted. This was the result of the opposition of a group of developing countries, led by India, which insistently opposed the incorporation of a data exclusivity obligation in the treaty.¹¹ The result of the disagreement between the contracting parties is still carved in the only provision of the TRIPS dealing with clinical trials protection. Article 39.3 reads:

“Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.”

1. State of the Art on Article 39.3: An Unsettled Matter

Already at first glance, the provision does not formulate an explicit data exclusivity obligation, but it reiterates the need to protect the data “against unfair commercial use.”

¹⁰ *Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations*. Geneva: GATT Secretariat, 1991.

¹¹ See e.g. Notes on informal meeting in Intellectual Property Standards, March 7-11 1988, reproduced in Beier, Friedrich-Karl, and Gerhard Schriker. *GATT or WIPO?: New Ways in the International Protection of Intellectual Property: Symposium at Ringberg Castle, July 13-16, 1988* (Weinheim {W. Germany}: VCH, 1989), 345-347.

This wording has divided scholars into two factions each advocating for “opposed, and reciprocally destructing, interpretations.”¹² The positions expressed on the issue are “critical for the actual disagreements existing between policymakers and scholars from developing and developed countries in respect of the level of protection to be granted under Article 39.3 of the TRIPS Agreement.”¹³

According to a group of eminent scholars, Art. 39.3 does not refer to data reliance. It merely tackles unfair commercial conducts such as breach of confidence and data theft or espionage as a background fact for an independent submission for marketing approval. This solution is based on a literal interpretation of the term “unfair” as a concept specific to a given society in a precise time frame. Therefore, if unfairness is inherently relative, member states are free to include data reliance among the array of conducts that they deem contrary to their domestic fair commercial practices.¹⁴ A look at the ordinary meaning of the words “use” and “commercial,” pursuant to Article 31(1) of the Vienna Convention on the Law of Treaties,¹⁵ reinforces this position. As a matter of fact, the data are not “used” by regulatory authorities when assessing me-too applications, since they rely on their previous administrative decision and do not reanalyse the first protocol.¹⁶ Moreover, the use of the data would not qualify as commercial, since it constitutes a legitimate governmental function, carried out by state agencies rather than by competitors.¹⁷ This interpretation is also defended through an

¹² Malbon, Justin, and Charles Lawson. *Interpreting and Implementing the TRIPS Agreement: Is It Fair?* Cheltenham, UK: Edward Elgar, 2008; Carvalho, Nuno Pires De. *The TRIPS Regime of Antitrust and Undisclosed Information* (The Hague: Kluwer Law International, 2008), 264.

¹³ Dinca, Razvan. “The “Bermuda Triangle” of Pharmaceutical Law.” *The Journal of World Intellectual Property* 8, no. 4 (2005): 525.

¹⁴ Correa, Carlos M. (2002) “Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standard of the Trips” [online]. Available at <http://scholar.google.it/scholar_url?hl=it&q=http://www.who.int/entity/medicines/areas/policy/protection_of_data.pdf&sa=X&scisig=AAGBfm3fi9MCwI8J3dc5u_3YQBbUR3zr0g&oi=scholarr&ei=7dWkUIf_CJHAswbwmoGQCQ&ved=0CCEQgAMoADAA> (accessed January 15, 2015), 39; Correa, Carlos María. *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (Oxford: Oxford University Press, 2007), 381; Sharma, Animesh. “Data Exclusivity with Regard to Clinical Data.” *The Indian Journal of Law and Technology*, 3 (2007): 90.

¹⁵ Article 31(1), Vienna Convention on the Law of Treaties: “A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.”

¹⁶ Correa, “Protection of Data Submitted for the Registration of Pharmaceuticals,” 38.

¹⁷ Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries* (The Hague: Kluwer Law International, 2001), 202; Correa, “Protection of Data Submitted for the Registration of

analysis of the preparatory works, which show the refusal of developing countries to accept the European and American proposals containing a data exclusivity obligation.¹⁸

The opposite interpretation rebukes all these arguments to claim that Article 39.3 contains an obligation to protect the data against free riding, at least for a limited period, even if not necessarily through data exclusivity. This opinion is based on the observation that data reliance constitutes at least an indirect utilization of the data, since second applicants refer to a previous authorization that was granted on the basis of the files submitted by a competitor.¹⁹ This utilization is deemed commercial both because it is aimed at favouring a competitor, and because it refers to a preparatory activity related to the legal and administrative compliances needed for drug marketing.²⁰ The ordinary meaning of “unfair” can also be stretched-up to include reliance conducts, so to claim that data free riding is intrinsically dishonest.²¹ Commentators have also claimed that a misappropriation approach would leave the provision devoid of any autonomous legal meaning, since Article 39.1 and 39.2 of the Agreement already deal with conducts such as “data espionage” or “breach of confidence.”²² For what concerns the preparatory works, it has been noted that since the beginning of the negotiations the expression “unfair commercial use” has always designated protection against data reliance.²³ Hence, the choice to retain this expression hinges that the term “unfair

Pharmaceuticals,” 20; Correa, *Trade Related Aspects of Intellectual Property Law*, 383; Biswajit Dhar, “Data Exclusivity in Pharmaceuticals: Little Basis, False Claims,” *Economical and Political Weekly* 41, no. 49 (2006): 5075-5076; Christopher Wadlow, “Regulatory Data Protection under TRIPs Article 39.3 and Article 10bis of the Paris Convention: Is There a Doctor in the House?” *Intellectual Property Quarterly*, 2007, 403.

¹⁸ Correa, “Protection of Data Submitted for the Registration of Pharmaceuticals,” 27; Correa, *Trade Related Aspects of Intellectual Property Law*, 382; Jerome H. Reichman, “The International Legal Status of Undisclosed Clinical Trial Data: From Private to Public Goods?” in Pedro Roffe, Geoff Tansey & David Vivas Eugui (eds.) *Negotiating Health: Intellectual Property and Access to Medicines* (London: Sterling, 2006): 144.

¹⁹ Dinca, “The Bermuda Triangle,” 527.

²⁰ Dinca, “The Bermuda Triangle,” 528; Shamnad Basheer, “Protection of Regulatory Data under Article 39.3 of TRIPS: The Indian Context,” *Intellectual Property Institute* (2006): 29.

²¹ Lee G. Skillington & Eric M. Solovy, “The Protection of Test and Other Data Required by Article 39.3 of the TRIPS Agreement,” *Northwestern Journal of International Law & Business*, 24, no. 1 (2003): 21; Carvalho *Interpreting and Implementing the TRIPS Agreement*, 271.

²² Aaron X. Fellmeth “Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data under the TRIPs Agreement,” *Harvard International Law Journal*, 45, no 2 (2004): 460; Basheer, “The Indian Context,” 21-23.

²³ See Chairman's Report to the GNG, Status of Work in the Negotiating Group: Chairman's Report to

commercial use” does comprise data reliance. By contrast, the deletion of an expressed reference to data exclusivity extricates the will of contracting parties to not be bound to a unique, “one-size fits all” form of protection.²⁴ Consequently, governments may prefer to implement Article 39.3 through licensing systems in which second applicants reimburse a portion of the costs of the trial to developers in order to rely on the data. For instance, compensatory systems are foreseen in the American agrochemical legislation,²⁵ and to a minor extent, in the European one.²⁶ At an international level, liability models were included in the Free Trade Agreements between the European Free Trade Association (EFTA) and Korea, Lebanon and Tunisia.²⁷

It is not the goal of this paper to take a precise a position on the debate over Article 39.3 obligations, but to remark that, whatever those obligations may be, the provision empowers Members States with important flexibilities to achieve their public health goals.

2. Some Article 39.3 Flexibilities

Even if interpreted as prescribing a data exclusivity obligation, the TRIPS parlance contains important flexibilities. For instance, the treaty text does not define the expression “new chemical entities.” The term “new” might be interpreted in a regulatory context, i.e. as a drug which is registered for the first time, or in a patent connotation, as a compound not comprised in the state of the art.²⁸ Similarly, contracting parties may interpret novelty in a domestic connotation, i.e. as a compound

the GNG, MTN.GNG/NG 11/76 (July 23, 1990).

²⁴ Skillington, “The Protection of Test and Other Data” (2003), 32.

²⁵ Federal Insecticide, Fungicide, and Rodenticide Act, 7 *U.S.C. ch. 6 § 136 et seq.*, Section 3 c(1)F(iii) (1908).

²⁶ Council Directive of 15 July 1991 concerning the placing of plant protection products on the market, *91/414EEC*, Art. 13(7) (1991).

²⁷ EFTA-Lebanon Free Trade Agreement, Annex V, Article 4 (2004); EFTA-Tunisia Free Trade Agreement, Annex V, Article 4 (2004); EFTA-Korea Free Trade Agreement, Annex VIII, Article 3 (2005).

²⁸ Sharma, “Data Exclusivity,” 89; Basheer, “The Indian Context,” 32; United Nations-Conference on Trade and Development, *Using Intellectual Property Rights to Stimulate Pharmaceutical Production in Developing Countries: A reference Guide* (New York: United Nations, 2011) 165; Olasupo Owoeye, “Data Exclusivity and Public Health under the Trips Agreement,” *Journal of Law, Information and Science*, 23, no. 2 (2015): 11.

not applied before in the domestic jurisdiction, or internationally, i.e. a drug which was never approved before by any agency in the world.²⁹

Similarly, the TRIPS provision authorises the parties to deny exclusivity to those data that did not involve “considerable effort” in their origination. Even though the expression “considerable,” as opposed to “ordinary,” suggests the need to protect any investment of uncommon extent in the pharmaceutical sector,³⁰ WTO members retain some leeway in defining the exact meaning of the expression.³¹ Other flexibilities, mostly aimed at reducing drug submission lags, will be analysed further in the paper.

3. Data Exclusivity and TRIPS+

The obscurity of Article 39.3 TRIPS has led the United States to drop litigation on the issue against Argentina.³² Having learned their lesson, the EU and the U.S. started to include express data exclusivity periods in bilateral and regional treaties with several economic partners. As of today, more than 30 Free Trade Agreements spell out data exclusivity provisions.³³ These treaties are often concluded under the lure of preferential trade benefits and under the shadow of unilateral sanctions. Indeed, by shifting the negotiating forum from the TRIPS to bilateralism, data exclusivity proponents place themselves in a better bargaining position by being able to customize their economic offers on the needs of their counterparts.³⁴

²⁹ Correa, “Protection of Data Submitted for the Registration of Pharmaceuticals,” 17; Correa, *Trade Related Aspects of Intellectual Property Law*, 378; Shaikh, *Access to Medicines*, 103; Contra, Fellmeth, “Secrecy, Monopoly and Access to Medicines,” 466, interpreting the expression in a domestic regulatory context.

³⁰ See Carvalho, *Interpreting and Implementing the TRIPS Agreement*, 305; Justin Malbon et al., *The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights* (Cheltenham: Edward Elgar Publishing, 2014), 585, according to which “a considerable effort” is something exceeding a normal effort according to industrial and governmental parameters.

³¹ Correa, “Protection of Data Submitted for the Registration of Pharmaceuticals”, 378; Malbon, *The WTO Agreement*, 585.

³² Argentina v. United States, Patent protection for pharmaceuticals and test data protection for agricultural chemicals, WT/DS171/3 and WT/DS196/4, WTO Appellate Body (2002). Note that the US reserved the right to start future litigation on the issue.

³³ Shaikh, *Access to Medicines*. The last of these being the ‘Agreement between the European Union and Japan for an Economic Partnership,’ Intellectual Property Chapter, Article 14(37).

³⁴ See Peter K. Yu, “Currents and Crosscurrents in the International Intellectual Property Regime,” *Loyola Law Review*, 38 (2005); Peter K. Yu, “Five Disharmonizing Trends in the Intellectual Property

Bilateral FTAs often limit countries' abilities to exploit TRIPS flexibilities. For instance, they comprise the prohibition to rely on foreign approvals, data exclusivity terms for follow-on innovations on known chemical entities, and limitations to the possibility to issue compulsory licenses on clinical data.³⁵

III. Data exclusivity: Access to Medicines Concerns

Leaving legal considerations aside, data exclusivity is heavily criticised for its negative impact on access to medicines in developing countries. As well known, the price of pharmaceuticals steeply decreases after generic medicines are allowed into a market. For instance, according to a report of the European Commission, between 2000 and 2007, average pharmaceutical prices fell by 20% in the first year after generic entry and by 25% in the second year. In extreme cases, price drops reached 80 to 90% of the initial market price of the branded drug.³⁶ A study by the IMS Institute for Health Informatics underlines an even greater impact of competition on drug prices in the U.S. market. Generic medicines launched between 2002 and 2014 reduced pharmaceuticals prices by 51% within the first year of launch and by 57% within the second. In the case of oral medicines, price drops reached a peak of 74% after the second year of generic competition.³⁷ Similarly, a study conducted in Colombia outlined price drops between 1% and 10% in the first year after generic entry and between 13% and 59% in the two following years.³⁸

Regime,” *International Intellectual Property Law and Policy*, 4, no. 73 (2007); Brook B. Baker (2008) “Ending Drug Registration Apartheid - Taming Data Exclusivity and Patent/Registration Linkage,” *American Journal of Law & Medicine*, 34 (2008): 25-30; Gabriel J. Michael, (2016) “International Coercion and the Diffusion of Regulatory Data Protection,” *The Journal of World Intellectual Property* 19, no. 1-2 (2016): 1-26.

³⁵ Brian C. Mercurio, “TRIPS-Plus Provisions in FTAs: Recent Trends,” in Bartels, L. & Ortino, F. (eds.) *Regional Trade Agreements and the WTO Legal System* (Oxford: Oxford University Press, 2006); Jerome H. Reichman, “Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach,” *Marquette Intellectual Property Law Review* 13, no. 1 (2009): 1-68.

³⁶ European Commission *Pharmaceutical Sector Enquiry: Final Report* (2009), 78. Available at <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf> (accessed September 20, 2016).

³⁷ IMS Institute for Healthcare Informatics, *Price Declines after Branded Medicines Lose Exclusivity in the U.S.* (2016) [online]. Available at <<http://www.imshealth.com/files/web/IMSH%20Institute/Healthcare%20Briefs/PhRMA%20Generic%20Price%20Brief%20January%202016.pdf>> (accessed September 20, 2016).

When these considerations are applied to developing countries' markets, the conclusions are easy to predict. By delaying competition, data exclusivity favours monopolistic behaviours that increase the price of life-saving pharmaceuticals well beyond the purchasing power of emerging economies' populations. The vast majority of these citizens live below or slightly above the poverty line and can already barely afford generics. Moreover, the lack of medical insurance and the absence of a developed public healthcare system hinder the distribution of expensive western medications.³⁹

Therefore, it does not surprise that besides governments, also NGOs and scholars have openly opposed the adoption of data exclusivity rules in developing countries' pharmaceutical laws.⁴⁰ The dire impact of data exclusivity on public health expenditures has been the target of both theoretical and empirical studies. An illustration of these will follow.

1. Evidence of Data Exclusivity Impact on Prices

Already in 2003, the Australian Institute tried to predict the effects of the data exclusivity measures contained in the draft version of the Australia-U.S. FTA (AUSFTA), which would be signed on 18 May 2004. By analysing five blockbuster drugs, the study concluded that the additional public expenditure of these drugs alone would have amounted to more than 1.12 billion between 2006 and 2009 and that generic introduction would be delayed by 24 months in average.⁴¹

³⁸ Miguel E. C. Gamba et al., *Impacto de 10 Años de Protección de Datos en Medicamentos en Colombia* (IFARMA Institute, 2011) [online]. Available at <http://web.ifarma.org/images/files/buscandoremedio/BuscandoRemedio_2.pdf> (accessed August 3, 2016), 67.

³⁹ Prashant Yadav, *Differential Pricing for Pharmaceuticals: Review of Current Knowledge, New Findings and Ideas for Action* (2010) 24 [online]. Available at: <https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/67672/diff-pricing-pharma.pdf> (accessed October 26, 2015); Rakesh Basant & Shuchi Srinivasan, (2015) "Intellectual Property Protection in India and Implications for Health Innovation: Emerging Perspectives," *Innovation and Entrepreneurship in Health* (2016): 58-9.

⁴⁰ Baker, "Ending Drug Registration Apartheid"; Reichman, "Rethinking the Role of Clinical Trial Data" 1-68; Médecins Sans Frontières, "Don't Swallow this Pill."

⁴¹ Buddhiman Lokuge et al., "A Backdoor to Higher Medicine Prices? Intellectual Property and the Australia-US Free Trade Agreement", *Australia Institute* (2003) [online]. Available at <https://www.google.it/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKewiOgNPTwp3PAhVRv5QKHX0hDA8QFggcMAA&url=http%3A%2F%2Fwww.aph.gov.au%2F~%2Fmedia%2Fwopapub%2Fsenate%2Fcommittee%2Ffretrade_ctte%2Fs>

A theoretical model elaborated in 2006 tried to predict the impact of data exclusivity rules of the U.S.-Peru FTA in the Peruvian market. The study warned that already in the first year after the entry into force of the Agreement the price of medicine would increase by 9.6%. Between the seventh and the thirteenth year, pharmaceutical prices would inflate between 55% and 100%. This was supposed to lead to an overall increased pharmaceutical spending of over 103 million USD per year within seven years from the agreement (up to 130.6 million USD in the thirteenth year). Because of these price hikes, the study predicted that over 900,000 Peruvians would be denied access to critical medicines.⁴²

These forecasts found confirmation in several empirical studies on pharmaceutical markets following the enactment of data exclusivity laws. The first and most famous of these works was conducted by Oxfam in 2007 on the impact of the 2000 U.S.-Jordan FTA. That paper examined 108 medicines distributed in Jordan in the years 2002-2006 and concluded that data exclusivity imposed a heavy toll on Jordanians: additional annual drug expenditures ranged between 6.3 and 22.04 USD millions in the period under review. Some pharmaceuticals in Jordan were 800% more expensive than in Egypt, mainly because 79% of them did not have to face generic competition. The high prices of pharmaceuticals made them unaffordable to ordinary Jordanians.⁴³

Another study on the pharmaceutical market of Guatemala in 2009 assessed the price of some data exclusivity protected drugs in the 2000s. The basket of pharmaceuticals ranged from insulin to antibiotics and HIV/AIDS antiretrovirals. Because of data exclusivity, the price of some of these medicines was significantly higher than comparable drugs on the public domain. For instance, the insulin Lantus was 846% more expensive than Isophane insulin, and the price of the antifungal Vfend was 810% higher than amphotericin B. The negative impact of these high prices on the Guatemalan population was exacerbated by the unwise choice of the Ministry of Health

ubmissions%2Fsub171b_pdf.ashx&usg=AFQjCNEV8E68rjkoFv9bZDv8TL_0oKzOiA&sig2=GKpg_Dg9ShRZMNVYt3J3YQ&bvm=bv.133178914,d.dGo> (accessed September 20, 2016).

⁴² Juan Pichihua-Serna, J. *The FTA and Access to Medicines in Peru: the Economic Impact of Intellectual Property* (2006) [online]. Available at <http://www.iprsonline.org/unctadictsd/dialogue/2006-07-31/Peru_Pichihua.pdf> (accessed September 20, 2016).

⁴³ Oxfam, *All Costs, No Benefits: How TRIPS-plus Intellectual Property Rules in the US-Jordan FTA Affect Access to Medicines* (2007) [online]. Available at <<https://www.oxfam.org/sites/www.oxfam.org/files/all%20costs,%20no%20benefits.pdf>> (accessed June 20, 2016).

to prefer data exclusivity protected drugs during public procurement.⁴⁴

A later study, conducted in 2011 by the IFARMA Institute, tried to calculate the impact of data exclusivity rules on drug prices in Colombia during the years 2003-2011. It concluded that without data exclusivity, expenses in the public sector would have dwindled from 1.3 USD billions to 783 million USD. This would have amounted to public savings for 396 USD millions, corresponding to the value of 146,000 medical insurances for Colombians. Data exclusivity also generated an increment of out-of-pocket spending of 1.56 USD millions in the period. The paper concluded that in around ten years, data exclusivity imposed a burden of 412 million dollars on Colombian citizens.⁴⁵

2. Counter-evidence

The above-mentioned studies raise a dim shadow over the opportunity to introduce data exclusivity in developing countries. However, a closer look reveals several flaws and contradictions. The work on Guatemala fails to emphasize the overall inherent deficiencies of the data exclusivity law enacted in the country. In 2000, the government decided to grant a 15-year exclusivity term on new pharmaceuticals, a protection period probably longer than any other worldwide data exclusivity law to date. As if that would not be enough, the exclusivity period was granted retrospectively: for instance, the drug Kaletra, registered in Guatemala in 2005, was granted a 15-year exclusivity period starting from 2000. The law was eventually repealed, but data exclusivity had to be reinstalled following the signature of the DC-CAFTA, which required a five-year exclusivity period on chemical entities.⁴⁶ Most importantly, the study presents the limitation of not assessing the overall impact of data exclusivity in Guatemala, but it merely compares the price difference between data protected drugs and comparable generics.

In the IFARMA study on the Colombian market, the price difference between

⁴⁴ Ellen R. Shaffer & Joseph E. Brenner, "A Trade Agreement's Impact on Access to Generic Drugs," *Health Affairs* 28, no. 5 (2009): 957-68.

⁴⁵ Gamba, *Impacto de 10 Años* (2011).

⁴⁶ Shaffer, "A Trade Agreement's Impact," 959.

generics and brand drugs was calculated on the only 13 drugs facing generic competition in 2011. The price gap was then multiplied for the 122 branded drugs in the basket. The study failed to consider whether the absence of generic competition in the country depended solely on data exclusivity or if other factors could play a significant role.⁴⁷ In this sense, concerns about delaying generic competition might be credible in a country like Jordan, which possesses a leading pharmaceutical industry among Arab countries, but they cannot be automatically extended to any small and mid-size market.⁴⁸ The absence of generic competition in Central and Latin America countries is in some measure endemic and largely depends on the lack of an established pharmaceutical industry, mainly because of market size.⁴⁹ The cost of conducting bioequivalence studies is also a deterrent of generic competition in those markets and does jeopardise the ability of generics to serve as an affordable alternative to branded drugs. For instance, a study on Colombia has revealed that the cost of bioequivalence studies would raise the price of generics between 46 and 61%.⁵⁰

Two additional factors hinder the installation of generic competition in some emerging markets. Governments have often failed to guarantee an overall level of quality and efficacy between generics and branded products, often by not requiring evidence of strict bio-equivalency. This often leads to a generalised mistrust of consumers toward generics. Lastly, the absence of legal mechanisms favouring the manufacturing and distribution of generics, e.g. Bolar exemptions or the duty of doctors to prescribe generics, has impeded the instalment of a stable generic industry in developing countries. Because of these factors, in Central America, more than 90% of the drugs on the market are branded.⁵¹

Also, two ex-post investigations temper the fears that data exclusivity plays a

⁴⁷ Gamba, *Impacto de 10 Años*, 60.

⁴⁸ Jordan-Kuwait Bank, "Pharmaceutical Industry in Jordan: A Story of Success and Excellence" (2012) [online]. Available at <http://www.jkb.com/sites/default/files/JKB_AnnualReport_En_2012.pdf> (accessed on October 4, 2016).

⁴⁹ Angelina Godoy-Snodgrass, "Market Myths and Assumptions: Examining the Transnational Politics of Access to Medicines Campaigning in Central America," *Studies in Comparative International Development*, 50 (2015): 193-195.

⁵⁰ Peter K. Yu, "The International Enclosure Movement," *Indiana Law Journal*, 82 No 4 (2007): 849.

⁵¹ Godoy-Snodgrass, "Market Myths," 195-196.

negative effect on pharmaceutical prices. Official Australian statistics contradict the 2003 study on the impact of data exclusivity in the country. On the contrary, the data outline that public healthcare spending for pharmaceuticals did not increase following the AUSFTA but remained stable at an average growth of 5.48% per year, well below the 6.9% growth rate in the overall healthcare expenditure.⁵²

These trends have been confirmed in a study assessing the effect of data exclusivity and other FTA provisions in Costa Rica five years after the entry into force of the DC-CAFTA in 2009. The study found that only 30 active ingredients and 39 pharmaceutical specifications were eligible for the five years data exclusivity period granted by the law between 2009 and 2012. This accounts for only 1% of the active ingredient registrations during the period. This low amount was attributable to the fact that the vast majority of drug registrations in the country did not relate to new chemical entities. Moreover, data exclusivity in the country did not impose any toll on the public healthcare drug spending of Costa Rica, which remained stable at an average rate of 8%.⁵³ Most importantly, generic equivalents were not available in Costa Rica even for drugs without data exclusivity protection. The study suggests that low profitability and drug complexity may play a bigger role in deterring generic competition than data exclusivity.⁵⁴

3. Data Exclusivity and Innovation

However, while evidence on the negative impact of data exclusivity in some countries remains contentious, the alleged positive correlation between data exclusivity and innovation is also heavily contested. The related criticisms can be split into three sub-arguments.

First of all, the staggering cost of clinical testing, which is at the very foundation

⁵² Tom Giovanetti, "The Australia-U.S. Free Trade Agreement Did NOT Blow-up Australia's Pharmaceutical Benefits Program" (2015) [online]. Available at <http://www.ipi.org/policy_blog/detail/the-australia-us-free-trade-agreement-did-not-blow-up-australias-pharmaceutical-benefits-program> (accessed September 20, 2016).

⁵³ Alejandra Castro, "Intellectual Property Rights in CAFTA-DR and Pharmaceuticals in Costa Rica," in Koehler-Geib, F. & Sanchez, S. M. (eds.) *Costa Rica Five Years after CAFTA-DR: Assessing Early Results.*, (Washington: World Bank Group, 2015): 93.

⁵⁴ Castro, "Intellectual Property Rights in CAFTA-DR," 97.

of data exclusivity *raison d'être*, has been exaggerated by pharmaceutical companies and has been significantly inflated in several reports.⁵⁵ Not only those studies are often conducted on documentation provided by pharmaceutical companies at their sole discretion, but also the choice of the items included in those budgets appears at least questionable. This is true with respect of the inclusion in the reports of the value of venues and laboratories, and most importantly to account for the cost of capital (i.e., to add the profits that would be gained from investing in the stock market rather than in R&D). Some studies also fail to acknowledge the vital contribution of public institutions in the initial phase of clinical research and to consider that in the U.S. clinical testing receives substantial public subsidies in the form of tax deductions and public grants.⁵⁶ Moreover, brand companies data exclusivity claims start to pale when confronted with the observation that those industries spend significantly more on the marketing and advertisement of their products than in the research and development of new medicines.⁵⁷

Secondly, whatever the precise cost of R&D might be, monopoly prices in developing countries markets play a modest or insignificant role in spurring medical innovation. Pharmaceutical companies rely on two primary markets, Europe and the U.S., as main sources of revenue. The sales in those two territories suffice to recoup the sunk costs of innovation and to guarantee pharmaceutical companies billions of returns on their investments.⁵⁸ By contrast, western companies mostly neglect emerging markets in their strategic management, because they are considered unprofitable and often do not even bother to seek patent protection in those countries.⁵⁹ As a result,

⁵⁵ See e.g. Joseph A. Di Masi et al., "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics* 22, no. 2 (2003): 151-85.

⁵⁶ Donald W. Light & Rebecca Warburtonc, "Demythologizing the High Costs of Pharmaceutical Research," *Biosocieties* (2011): 1-17.

⁵⁷ See Prabodh Malhotra, *Impact of TRIPS in India: An Access to Medicines Perspective* (Basingstoke: Palgrave Macmillan, 2010) 50; European Commission, "Pharmaceutical Sector Enquiry: Final Report" (2009) 30 [online]. Available at <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf> (accessed September 20, 2016).

⁵⁸ United Nations, *Using Intellectual Property Rights to Stimulate Pharmaceutical Production*, 168; Reichman, "Rethinking the Role of Clinical Trial Data" 18; Peter K. Yu, "The Political Economy of Data Protection," *Chicago-Kent Law Review*, 84 (2010): 785; Brian C. Mercurio & Daria Kim, "Patently Lacking: A Call for Systemic Review of Pharmaceutical Law and Policy - A Case Study of Hong Kong," *Asian Journal of WTO & International Health Law and Policy* 9, no. 63 (2014): 106.

⁵⁹ Amir Attaran, A. "How Do Patents and Economic Policies Affect Access To Essential Medicines In

while research on diseases affecting predominantly developing countries such as malaria, tuberculosis and human leishmaniasis is neglected, western lifestyle treatments for baldness and dietary purposes are continually developed.⁶⁰ For instance, it was calculated that in the 90s only 0.2 per cent of the 60 billion dollars spent annually in R&D worldwide was directed to tuberculosis, malaria, and acute respiratory infections. Those three diseases accounted for the 18 per cent of the global deaths from all diseases in the 2000s.⁶¹

Thirdly, even in technologically proficient western markets, data exclusivity has been accused of stimulating repetitive or incremental research rather than leading to breakthrough discoveries. This outlines one of the main differences with the patent system, where the requirement of inventiveness ensures that protection is granted only to pharmaceuticals that represent a significant contribution over the state of the art.⁶²

To recapitulate, any drug unit sold in developing countries represent a net profit for pharmaceutical industries. Monopoly prices in those countries impede access to lifesaving drugs to the vast majority of the population while playing no positive effect on R&D. For instance, only in 2009, the revenues from HIV drugs in the U.S. and Europe accounted for 11.8 billion USD.⁶³ Considering the low price of drug manufacturing and shipment, even the free distribution of antiretrovirals in developing countries populations would have hardly left a scratch on big pharma budgets.⁶⁴

Developing Countries?" *Health Affairs*, 23, no. 3 (2004): 155-66. This was also the case of Guatemala, see Shaffer, "A Trade Agreement's Impact," 958.

⁶⁰ Stuart O. Schweitzer, *Pharmaceutical Economics and Policy* (Oxford: Oxford University Press, 2007) 160; Malhotra, *Impact of TRIPS in India*, 51; James Orbinski, "Health, Equity, and Trade: A Failure in Global Governance" (2010): 232 [online]. Available at <archive.unu.edu/news/wto/ch11.pdf> (accessed July 4 2016); Pinelopi K. Goldberg (2010) "Intellectual Property Rights Protection in Developing Countries: The Case of Pharmaceuticals," *Journal of the European Economic Association* 8, no. 2-3 (2010), 332-333.

⁶¹ Orbinski, "Health, Equity, and Trade," 234.

⁶² Shaikh, *Access to Medicines*, 39.

⁶³ Nikhil Kumar, "Big Pharma and the Business of HIV/AIDS," *The Independent* (2010) [online]. Available at <<https://www.independent.co.uk/news/business/analysis-and-features/big-pharma-and-the-business-of-hiv-aids-2147987.html>> (accessed September 22, 2016).

⁶⁴ To be fair, to some extent pharmaceutical companies have engaged in several drug donations and discount programs for developing countries. However these donations have not been immune to several criticisms. See Malhotra, *Impact of TRIPS in India*, 204-205; Adam R. Green (2013) "Drug Donations Are Great, but Should Big Pharma be Setting the Agenda?" *The Guardian* [online]. Available at <<https://www.theguardian.com/world/2013/apr/29/drug-company-donations-bigpharma>> (accessed September 22, 2016).

IV. Drug Lag in Developing Countries: An Overview

Unfortunately, high prices are not developing countries' sole health concern. Access to life-saving medicines in emerging markets is precluded any time a drug is authorised only after a significant delay from the first worldwide approval. In such an instance, it is meaningless to complain about medical prices, because drugs are not available to patients in the first place. Several empirical studies demonstrate that developing countries lag behind in the approval of medicines. This phenomenon is commonly referred to as "international drug lag." It may depend on slow regulatory pathways, i.e. review lag, or more often on the tendency of western companies to postpone drug launches in unprofitable markets, i.e. submission lag.

The first studies on international drug lag date back to the 1970s, with the pioneering work of Wardell, who first compared drug introductions between the United States and the United Kingdom.⁶⁵ Starting in the '90s, research on the topic widened up to compare drug launches among several western markets.⁶⁶ Most recently, a great number of investigations have focused on drug authorisations in Japan, often mentioned as the government with slowest regulatory assessment among high-income countries.⁶⁷

⁶⁵ See William M. Wardell, "Therapeutic Implications of the Drug Lag," *Clinical Pharmacology and Therapeutics* 15, no. 1 (1974): 73-96; William M. Wardell (1978) "The Drug Lag Revisited: Comparison by Therapeutic Area of Patterns of Drugs Marketed in the United States and Great Britain from 1972 through 1976," *Clinical Pharmacology and Therapeutics* 24, n. 5 (1978): 499-524; Kenneth I. Kaitin et al. (1989) "The Drug Lag: An Update of New Drug Introductions in the United States and in the United Kingdom, 1977 through 1987," *Clinical Pharmacology and Therapeutics* 46, no. 2 (1989): 121-38.

⁶⁶ John Parker, "Who Has a Drug Lag?" *Managerial and Decision Economics* 10, no. 4 (1989): 299-309; Fredrik Andersson, "The Drug Lag Issue: The Debate Seen from an International Perspective," *International Journal of Health Services* 22, no. 1 (1992): 53-72; Kathleen M. Lafrancis Popper & Robert W. Nason, "The Drug Lag: A 20-Year Analysis of Six Country Markets," *Journal of Public Policy & Marketing* 13, no. 2 (1994): 290-299; Kenneth I. Kaitin & Jeffrey S. Brown "A Drug Lag Update," *Therapeutic Innovation and Regulatory Science* 29, no. 2 (1995): 361-73; Stuart O. Schweitzer et al., "Is there a U.S. Drug Lag? The Timing of New Pharmaceutical Approvals in the G-7 Countries and Switzerland," *Medical Care Research Review* 53, no. 2 (1996): 162-78.

⁶⁷ Hashimoto, J., et al. (2009) "The Current Situation of Oncology Drug Lag in Japan and Strategic Approaches for Pharmaceutical Companies," *Therapeutic Innovation and Regulatory Science* 43, no. 6 (2009): 757-65; Gunjan Sinha, "Japan Works To Shorten Drug Lag," *Journal of the National Cancer Institute* 102, no. 3 (2010), 148-51; K. Yonemori et al. (2011) "The Notorious Drug Lag for Oncology Drugs in Japan," *Investigational New Drugs* 29, no. 4 (2011): 706-12; T. Ueno et al. (2014) "Significant Differences in Drug Lag in Clinical Development Among Various Strategies Used for Regulatory Submissions in Japan," *Clinical Pharmacology and Therapeutics* 95, no. 5 (2014): 533-41; Peter K. Honig, "Recent Trends and Success Factors in Reducing the Lag Time to Approval of New Drugs in Japan," *Clinical Pharmacology &*

Several studies have dealt with the issue of drug lag in developing countries. They all underline a severe delay in the authorization of western-developed medicines in those territories. In some cases, western companies delay market entrance in emerging markets to the point that their drugs are launched by domestic firms after independent development. This was the case of Bayer's Ciprofloxacin, which was introduced in India by a domestic firm three years after worldwide launch, while Bayer entered the market only eight years after U.S. authorisation.⁶⁸

In 2010, Wileman and Mishra examined 132 drug launches in BRICS and N-11 countries from 1960 to 2009.⁶⁹ They found out that the average drug lag from the moment of authorisation by the American Food and Drug Administration (FDA), even if it has drastically decreased from the 1960s (7843 days), still amounted to 560 days in the 2000s. In the analysis by these authors, this acceleration of drug launches is attributable to a significant reduction of submission lag in the period, which dwindled from 7754 days in the 1960s to only 190 days in the 2000s.⁷⁰

Sivaramakrishnan and Bhide, in an investigation published in 2013, compared drug approvals in Brazil, India and the U.S. between 1999 and 2012. The research describes a significant delay in drug introduction in India compared to the U.S., which reached its peak in 2011, with 7.79 years of average drug lag. In comparison, Brazilian authorizations lagged behind American ones by only 3.94 to 4.88 years, depending on the therapeutic category. However, the average drug lag was reduced in Brazil by some drugs being approved in the country earlier than in the U.S., especially in the cardiovascular and nervous sectors. More realistically, it took some ten years of delay to approve some western drugs in Brazil.⁷¹

Therapeutics 95, no. 5 (2014): 467-9.

⁶⁸ Jean O. Lanjouw, "Patents, Price Controls and Access to New Drugs: How Policy Affects Global Market Entry," Centre for Global Development, Working Paper no. 61 (2005): 5; Goldberg, "Intellectual Property Rights Protection in Developing Countries," 341.

⁶⁹ The BRICS countries are Brazil, Russia, India, China and South Africa. The N-11 countries include Bangladesh, Egypt, Indonesia, Iran, Mexico, Nigeria, Pakistan, the Philippines, South Korea, Turkey and Vietnam.

⁷⁰ Harriet Wileman & Arun Mishra, "Drug Lag and Key Regulatory Barriers in the Emerging Markets," *Perspectives in Clinical Research* 1, no. 2 (2010): 51-56.

⁷¹ Vaibhav Sivaramakrishnan & Manesh Bhide "A Comparative Analysis of Drug Lag in Emerging Markets," *Regulatory Focus* (2013): 1-9.

India specifically, hosting one of the most developed generic industries in the world, has been the target of several studies on drug lag. In 2002, Karan et al. analysed Indian drug authorizations between 1988 and 1999 and concluded that the average drug lag in India in those years ranged between 2.77 and 4.02 years.⁷² A more recent investigation by Berndt and Cockburn (2014) compared Indian launches with 184 drugs approved by the American FDA between 2000 and 2009. It concluded that more than 50% of those drugs were available in India only after a five-year delay. The median delay in drug approval was between 4.5 and 5 years. To put these numbers into a context, foreign developed drugs are approved in the U.S. with a median drug lag of only two months.⁷³ Between 2012 and 2016, Kataria et al. have published three studies on drug lag in India in three different therapeutic sectors. The first two examined drug introductions in the years 1991-2011. They outline a median drug lag of 44.14 months on 75 cardiovascular drugs,⁷⁴ and of 39.7 months for 70 antimicrobial agents. The delays were counted from the dates of first approval in the U.S. or the EU.⁷⁵ The last research on anti-cancer drugs outlined similar findings. Of the 67 anticancer drugs approved in the U.S. and EU between 2011 and 2015, only 18 had been approved in India before the study was concluded (26.86%). Moreover, those drugs entered the market with 18.36 months median drug lag when compared with the first registration in the U.S. or EU. Once again, the median drug lag was improved by the fact that India was the first country to approve one of the drugs under review.⁷⁶

None of these studies offers a sound explanation of the causes of the international drug lag in developing countries. However, few of them suggest that in the past drug delays might have been due to the absence of patent protection for pharmaceuticals.⁷⁷

⁷² R. Karan et al., “The Drug Lag: New Drug Introductions in India in Comparison to United States,” *Journal of Association of Physicians of India*, 50 (2002): 782-7.

⁷³ Ernst R. Berndt & Iain M. Cockburn, “The Hidden Cost of Low Prices: Limited Access to New Drugs in India,” *Health Affairs* 33, no. 9 (2014): 1567-75.

⁷⁴ Bhaven C. Kataria et al., “Drug Lag for Cardiovascular Drug Approvals in India Compared with the US and EU Approvals,” *Indian Heart Journal* 65 (2013): 24-9.

⁷⁵ Bhaven C. Kataria et al., “Drug Lag for Antimicrobial Agents: Comparison of the US, EU and India Approvals,” *National Journal of Medical Research* 2, no. 3 (2012): 264-8.

⁷⁶ Bhaven C. Kataria et al., (2016) “Drug Lag for Antineoplastic and Immunomodulating Agent Approvals in India Compared with the US and EU approvals,” *International Journal of Basic & Clinical Pharmacology* 5, no. 2 (2016): 335-40.

⁷⁷ Kataria, “Drug Lag for Antimicrobial Agents,” 267; Kataria, “Drug Lag for Cardiovascular Drug

Some even argue that stronger IP standards in emerging economies may work as a remedy to late drug introductions.⁷⁸

V. Drug Lag in Developing Countries: Origins and Explanations

At first glance, the existence of an international drug lag defies common logic. As seen, pharmaceuticals are developed and tested to target western markets, where companies recoup their investments in R&D and earn revenues for hundreds of millions of dollars. Less affluent markets offer more limited revenues, but since R&D sunk costs have already been recouped, they still represent a net profit for pharmaceutical companies.

The answer to this conundrum is rather complex. A first response can be found in the specific characteristics and structure of developing countries markets. A second one depends on market spillovers, such as the fear that drug sales in low-income countries may erode revenues in richer ones. In the pharmaceutical sector, market spillovers take the form of referential pricing and parallel trade.

1. Market Structure and Launching Costs

A pharmaceutical will be introduced into a territory only when at least one undertaking predicts that incremental revenues in the market will overcome ex-ante launch investments. Up-front costs often relate to legal and administrative compliances, such as registration or import licences fees, testing the drug on the local population and commissions for attorneys and representatives. Setting up distribution channels also represents a major financial expenditure. It implicates educating healthcare providers on the drug's appropriate use and persuading them of the drug's higher benefits over similar products in the market. Marketing costs are typically borne by first drug launchers, while future competitors may largely get a free-ride. Consequently, anytime companies predict a rapid generalization of the market, the risk of being unable to

Approvals" 28; Sivaramakrishan, "A Comparative Analysis of Drug Lag," 6-8. See also Brook K. Baker, "A Critical Analysis of India's Probable Data Exclusivity Provisions" (2006) [online]. Available at <<http://www.cptech.org/blogs/ipdisputesinmedicine/2006/10/critical-analysis-of-indias-probable.html>> (accessed April 17, 2015).

⁷⁸ Berndt, "The Hidden Cost of Low Prices," 1573-4.

recoup ex-ante costs might deter them from embarking in launching new drugs.⁷⁹

In addition, in the absence of IP protection, or of any other form of monopoly, blockbuster pharmaceutical companies are unable to exploit the market structure of some developing countries. These are characterised by a significant income gap between the vast majority of the population, who are living below or slightly above the poverty threshold, and a fortunate minority living above average western wealth standards. These markets also lack insurers or well-developed public healthcare institutions as payers for low-income patients and buyers of IP-protected pharmaceuticals.⁸⁰ For instance, in 2004, a World Health Organization report outlined that in developing countries up to 90% of medicines are bought out of pocket,⁸¹ while in India even hospitalized patients had to pay for prescription medication themselves 79.74% of the time.⁸² Evidence from several developing countries, ranging from Mexico to Cambodia, shows that public healthcare providers are incapable of procuring last generation patented medicines and intensively rely on generics, whereas patented drugs are supplied via private distribution channels at high prices.⁸³ In turn, drugs unavailability in the

⁷⁹ Berndt, "The Hidden Cost of Low Prices," 1568; Patricia M. Danzon & Andrew J. Epstein, "Effects of Regulation on Drug Launch and Pricing in Interdependent Markets," *Adv. Health Econ Health Serv. Res.*, 23, (2008): 37; Margaret Kyle & Yi Qian, "Intellectual Property Rights and Access to Innovation: Evidence from the TRIPS," *National Bureau of Economic Research*, (2014): 7-8; Ian M. Cockburn et al., "Patents and the Global Diffusion of New Drugs" 106 no. 1 (2016): 137-8.

⁸⁰ Yadav, *Differential Pricing*, 23; Shankar Prinja et al., "Availability of Medicines in Public Sector Health Facilities of Two Northern India States," *BMC Phamarcol. Toxicol.* No. 16 (2015) showing that anti-cancer drugs were available in India in only the 30% of the public healthcare facilities of two Indian states; Patricia Danzon et al., "Pharmaceutical Pricing in Emerging Markets: Effects of Income, Competition and Procurement," *Health Economics*, 24 (2015): 238.

⁸¹ World Health Organization, "Equitable access to essential medicines: a framework for collective action," Geneva: World Health Organization (2004).

⁸² Sudip Chauduri "Pharmaceutical Prices in India" in Zaheer-Ud-Din Babar (ed.) *Pharmaceutical Prices in the 21st Century* (Springer International: Switzerland 2015), 120.

⁸³ See Heinz Klug, "Pharmaceutical Production and Access to Essential Medicines in South Africa," in Kenneth C. Shadlen et al. (eds), *Intellectual Property Pharmaceuticals and Public Health* (Edward Elgar Publishing: Cheltenham, 2011), 43-5; Alenka Guzman, "The Challenges of Constructing Pharmaceutical Capabilities and Promoting Access to Medicines in Mexico under the TRIPS," in Kenneth C. Shadlen et al. (eds), *Intellectual Property Pharmaceuticals and Public Health* (Edward Elgar Publishing: Cheltenham, 2011): 116-7; N. Lalitha, "Access to Indian Generic Drugs: Emerging Issues," in Kenneth C. Shadlen et al. (eds), *Intellectual Property Pharmaceuticals and Public Health* (Edward Elgar Publishing: Cheltenham, 2011), 225-6; Edith Patouillard, Kara Hanson et al., "Determinants of Price Setting Decisions on Anti-malaria Drugs at Retail Shops in Cambodia," *Malaria Journal* 14 no 224 (2015): 1-12; Alexandra Cameron et al., "Medicine Prices, Availability and Affordability in 36 Developing and Middle Income Countries: A secondary Analysis,"

public sector increases private out-of-pocket pharmaceutical expenditure, often driving developing countries' patients into poverty or forcing them to quit therapy.⁸⁴

In markets with such characteristics, a rational monopolistic operator would exclusively target the richest layers of the population. This implies charging the highest possible price to the most affluent class while renouncing to supply drugs to the middle and lower classes.⁸⁵ For instance, in South Africa, a profit-driven patentee would maximise its revenues by distributing the drug at a monopoly price affordable to only the 10% of the population, creating, therefore, a deadweight loss of 90%.⁸⁶

Empirical evidence corroborates the above theoretical model. According to a 2005 study, patients in Latin America bore higher pharmaceutical prices than in western countries once the prices were adjusted according to the purchasing power of the relevant population. This was at least partly attributable to those countries uneven wealth distribution coupled with the tendency of pharmaceutical companies to target affluent minorities.⁸⁷ In 2015, another study analysed the price determinants of drugs for HIV, tuberculosis and malaria in middle and low-income countries. Again, it concluded that skewed income distribution exacerbated high drug prices relative in per capita income.⁸⁸ These findings are overall consistent with the economic literature

Lancet, 373 (2009): 244-7; Heba Wanis, "Pharmaceutical Pricing in Egypt" in Zaheer-Ud-Din Babar (ed.) *Pharmaceutical Prices in the 21st Century* (Springer International: Switzerland, 2015), 60-1; Eshetu Ali, Anwarul-Hassan Gilani et al., "Pharmaceutical Pricing in Ethiopia," in Zaheer-Ud-Din Babar (ed.) *Pharmaceutical Prices in the 21st Century*, (Springer International: Switzerland, 2015), 83; Mariko Watanabe & Luwen Shi, "Sufficient but Expensive Drugs: A Double-track System that Facilitated Supply Capability in China," in Kenneth C. Shadlen et al. (eds), *Intellectual Property Pharmaceuticals and Public Health* (Edward Elgar Publishing: Cheltenham, 2011), 258.

⁸⁴ Vera Songwe, "Financing Africa Healthcare," *GBC Health* [online]. Available at <http://gbchealth.org/financing-africas-healthcare/> (accessed January 25, 2019); N. Lalitha, "Access to Indian Generic Drugs: Emerging Issues," 225; L. M. Niens & W. B. Brouwer, "Measuring the Affordability of Medicines: Importance and Challenges," *Health Policy*, 112 (2012): 46; Sudip Chaudhuri, "Pharmaceutical Prices in India," 121.

⁸⁵ Yadav, *Differential Pricing*, 33-9; Yu, "The International Enclosure Movement," 844; Margaret Kyle & Yi Qian, "Intellectual Property Rights and Access to Innovation: Evidence from the TRIPS," 21.

⁸⁶ Sean Flynn et al., "An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries," *Journal of Law Medicine and Ethics* 37, no. 2 (2009): 184-208.

⁸⁷ Patricia Danzon & Michael Furukawa, "International Prices and Availability of Pharmaceuticals in 2005," *Health Affairs*, 29 No. 1 (2008), p. 229.

⁸⁸ Patricia Danzon et al., "Pharmaceutical Pricing in Emerging Markets: Effects of Income, Competition and Procurement," *Health Economics*, 24 (2015), 238.

suggesting that developing countries' lower purchasing power plays only a modest role in the determination of pharmaceutical prices, especially compared to factors such as the degree of competition in the market.⁸⁹

Anecdotal evidence points in the same direction. For instance, prior to the Indian government issuing a compulsory license on the compound, the high price of Bayer's anti-cancer drug Nexavar made it affordable to only 2% of Indian patients.⁹⁰ Similarly, the intervention of the South African government was necessary to remedy the high prices fixed by major global pharmaceutical companies for Nevirapine, an HIV antiretroviral that halved the rate of mother-to-child HIV transmission.⁹¹ Besides India and South Africa, the practice of some developing countries to issue compulsory licenses to increase affordability suggests a tendency of patent holders to overprice pharmaceutical drugs and create significant deadweight losses.⁹² In the same vein, according to some studies, the price of branded drugs in countries such as Ethiopia and Morocco makes it unaffordable to ordinary citizens, with some medicines being more expensive than in developed countries such as France.⁹³

To recapitulate, without IP protection companies cannot maximise profits through "high prices - ν volumes" strategies; while poorly funded developing countries' national healthcare are often unable to stockpile patented drugs and generate sufficient demand for IP holders. This situation might discourage firms from entering a market, while wealthy individuals might be targeted by offering them the unauthorised treatment in western or nearby territories.

⁸⁹ See e.g. Rebecca Hellerstein, "What Do Drug Monopolies Cost Consumers in Developing Countries?" *Economics Letters*, 116 (2012): 108-11.

⁹⁰ Hemant Singh et al., "India's IPR Regime: Reconciling Affordable Access with Patent Protection," *Indian Council for Research on International Economic Relations* (2015): 22.

⁹¹ Heinz Klug, "Pharmaceutical Production and Access to Essential Medicines in South Africa," 44-5.

⁹² See e.g. Nicol Dianne & Olasupo Owwoeye, "Using TRIPS Flexibilities to Facilitate Access to Medicines," *Bulletin of the World Health Organization*, 91 no. 7 (2013): 533-9.

⁹³ Gaëlle Krikorian, "Intellectual Property and Access to Medicines: Paradoxes in Moroccan Policy," in Kenneth C. Shadlen et al. (eds), "Intellectual Property Pharmaceuticals and Public Health," Edward Elgar Publishing: Cheltenham, United Kingdom (2011): 72; Eskinder Eshetu Ali, Anwarul-Hassan Gilani et al., "Pharmaceutical Pricing in Ethiopia," 86.

2. Referential Pricing

Submission delays may also arise from the practice of ‘external referential pricing (ERP).’ The expression refers to the strategy of some governments to set price ceilings on pharmaceuticals using as parameter drug prices in selected foreign markets.⁹⁴ Referential pricing systems can use minimum, median or mean price in foreign territories.⁹⁵

To provide an example, Canada has used referential pricing by limiting the price of innovative pharmaceuticals at the median price of some selected countries.⁹⁶ The vast majority of European countries, with the exceptions of Sweden and the United Kingdom, have also used external referential pricing. However, ERP systems in Europe vary significantly from one country to another.⁹⁷ In Latin America ERP has been used by countries as Brazil, Colombia, El Salvador and Mexico.⁹⁸ In Asia and Oceania, by South Korea, Japan, Australia and New Zealand.⁹⁹

Traditionally, geographical proximity and economic comparability have been used as the main criteria to devise a basket of countries to reference. Nowadays, country baskets tend to include larger samples of countries, often by utilising dubious selective criteria.¹⁰⁰ ERP might refrain pharmaceutical companies from charging lower prices in developing countries, because of the fear that the price could be referenced by more affluent countries.¹⁰¹ For the same reason, it may also lead to a delay in drug

⁹⁴ See Goldberg, “Intellectual Property Rights Protection in Developing Countries,” 342.

⁹⁵ See Danzon “Effects of Regulation on Drug Launch,” 36.

⁹⁶ Danzon, “Effects of Regulation on Drug Launch,” 11; Mondher Toumi, et al. (2014) “External Reference Pricing of Medicinal Products: Simulation-based Considerations for Cross-country Coordination,” 17-21. [online]. Available at <ec.europa.eu/health/healthcare/docs/erp_reimbursement_medicinal_products_en.pdf> (accessed July 1 2016).

⁹⁷ See Patricia M. Danzon & Jonathan D. Ketcham, “Reference Pricing of Pharmaceuticals for Medicare: Evidence from Germany, the Netherlands, and New Zealand,” *Forum for Health Economics & Policy* 7. No. 2 (2004): 1-56; Danzon, *ibid* (2008), 11; Toumi, “External Reference Pricing of Medicinal Products,” 17-21; Cecile Rémuzat et al., “Overview of External Reference Pricing Systems in Europe,” *Market Access and Health Policy* 3 (2015): 1-11.

⁹⁸ Tobar, F. & Martich, E. “Economic tools for Ensuring Access to Medicines in Latin American countries,” *Pharmaceuticals Policy and Law*, 16, no. 3, 4 (2014): 214-215.

⁹⁹ Toumi, “External Reference Pricing of Medicinal Products,” 22-5.

¹⁰⁰ Toumi, “External Reference Pricing of Medicinal Products,” 19.

introduction in referenced countries when companies do not have IP means to control the market price of pharmaceuticals.¹⁰² This hypothesis has been confirmed in Europe by research on 375 molecules launched in 15 different countries between 1992 and 2003. The study found evidence that, because of referential pricing, firms delay the launch of pharmaceuticals in low-income European markets until higher prices are fixed in high-income countries.¹⁰³

3. Parallel Trade

While fixed R&D cost for new drugs usually exceeds hundreds of millions of USD, their marginal manufacturing and shipment cost is typically low. Therefore, to maximise their profits, pharmaceutical companies may try to charge different prices in different national markets, according to the ability to pay of different consumers. This entails pricing pharmaceuticals at lower prices in developing and emerging markets.¹⁰⁴ However, ‘market segmentation’ strategies can be fully implemented only when market actors have limited arbitrage opportunities, i.e., they are not in the position to take advantage of price differences between two or more markets.

¹⁰¹ Patricia M. Danzon & Adrian Towse “Theory and Implementation of Differential Pricing for Pharmaceuticals” in K. Maskus & J. Reichman (eds) *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime* (Cambridge University Press, 2005), 425-456; Jonathan J. Darrow, “Essential Medicines: Why International Price Discrimination May Increasingly Be the Wrong Solution to a Global Drug Problem,” *Journal of Law, Medicine & Ethics* 39 (2011): 293; Yadav, *Differential Pricing*, 40-41; Yu, *Five Disharmonizing Trends*, 844; Toumi, “External Reference Pricing of Medicinal Products,” 27-28.

¹⁰² Lanjouw, “Patents, Price Controls and Access to New Drugs,” 3; Abdulkadir Civan & Michael T. Maloney, “Launch Decisions of Pharmaceutical Companies,” *European Journal of Economic and Political Studies* 8, (2015): 38-39.

¹⁰³ Danzon, “Effects of Regulation on Drug Launch,” 36; See Margaret K. Kyle, “Pharmaceutical Price Controls and Entry Strategies,” *The Review of Economics and Statistics* 89, no. 1 (2007): 90. More generally the article describes the behaviour of companies as follow: “[a] preference for entry into markets with free pricing first, reaping profits from high prices for as long as possible, and launching their products in low-price markets as late as possible”; Nebibe Varol, et al., “Does Adoption of Pharmaceutical Innovation Respond to Changes in the Regulatory Environment?” *Economic Perspectives and Policy* 34, no. 3 (2012): 550.

¹⁰⁴ Nick Gallus, “The Mystery of Pharmaceutical Parallel Trade and Developing Countries,” *The Journal of World Intellectual Property* 7, no. 2 (2004): 169; Olasupo Owoeye, “Access to Medicines and Parallel Trade in Patented Pharmaceuticals,” *European Intellectual Property Review* 37, no. 6 (2015): 359-360; Devarshi Mukhopadhyay, “Parallel Trade in Pharmaceuticals: Re-Aligning National Patent Exhaustion and Life-Saving Drugs,” *Business and Law Review* 37, no. 2 (2016): 73.

This is not the case of the pharmaceutical market, characterised by frequent spill-overs of developing countries' drugs into western markets, usually through international drug sales and re-importations. When IP rights are involved, 'parallel trade' is the term used to indicate the trade of pharmaceuticals among segmented markets, typically from unprofitable ones towards wealthier western territories.¹⁰⁵ Parallel trade arises in IP protected pharmaceutical as a consequence of the principle of exhaustion, i.e. the inability of right holders to control patented products once they have been lawfully put on sale in a market.

Unfortunately, drug re-importation and parallel trade fireback against developing countries by reducing price discriminations. This happens anytime companies fear that inexpensive drugs destined for developing countries might be redirected to western territories, thus eroding pharmaceutical revenues in affluent markets where drugs are priced according to the higher spending power of local citizens.¹⁰⁶

The 2009 report of the European Commission on the pharmaceutical sector outlined an overall parallel trade turnover ranging between 3.5 and 5 billion euros per year. This represents between 2 and 3% of the overall market.¹⁰⁷ Because of parallel trade, the UK pharmaceutical industry is deemed to have lost some £1.3 billion in 2015.¹⁰⁸ In 2016, re-imports amounted to some USD 10 billion dollars worldwide and they are predicted to increase at a rate of 3-4% per year.¹⁰⁹

Drug importations and parallel trade usually take the form of drug shipments in developed markets. Drugs are high-value commodities, easy and inexpensive to ship worldwide. Because of this, pharmaceuticals destined to African countries have been redirected to countries such as Belgium and Germany.¹¹⁰ Inside the EU borders, drugs

¹⁰⁵ See Owoeye, "Access to Medicines and Parallel Trade," 360; Mukhopadhyay, "Parallel Trade in Pharmaceuticals," 72.

¹⁰⁶ See Gallus, "The Mystery of Pharmaceutical Parallel Trade," 169; Owoeye, "Access to Medicines and Parallel Trade," 360.

¹⁰⁷ European Commission (2009) "Pharmaceutical Sector Enquiry: Final Report" [online]. Available at <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf> (accessed September 20, 2016).

¹⁰⁸ Owoeye, "Access to Medicines and Parallel Trade," 360.

¹⁰⁹ Mukhopadhyay, "Parallel Trade in Pharmaceuticals," 73.

¹¹⁰ Malhotra, *Impact of TRIPS in India*, 202.

are often redirected from low to high-income countries, e.g. from Greece to Germany, Holland or Denmark.¹¹¹ Nowadays drugs may even be ordered online directly from developing countries' web-stores. Hence, it does not surprise that some have described the advent of the Internet as the biggest challenge to international pharmaceutical price discrimination.¹¹²

Market spill-overs are also attributable to on-site purchases by patients travelling abroad to buy cheaper drugs. Medical tourism, i.e., travelling made with the goal of receiving medical treatment, is a growing business, which according to some sources involves some 5 million individuals per year.¹¹³

European citizens often take advantage of the price differences among nearby member states to purchase drugs.¹¹⁴ In the EU this is also facilitated because prescriptions delivered by a doctor in a member state are valid throughout all EU countries.¹¹⁵ Similarly, hundreds of thousands of U.S. citizens travel every year to Central America and Canada to get cheaper health products and treatments.¹¹⁶ As a response, companies such as AstraZeneca, Pfizer and GlaxoSmithKline have threatened to withhold their drugs from those Canadian companies that resell their products to American customers.¹¹⁷ Similarly, the U.S. FDA has threatened legal action against

¹¹¹ Panos Kanavos & Joan Costa-Font, "Pharmaceutical Parallel Trade in Europe: Stakeholder and Competition Effects," *Economic Policy* (2005): 751-98; Oliver Morgan, "Parallel Trade in Drugs Puts EU Patients at Risk" *The Guardian* (2008) [online]. Available at <<https://www.theguardian.com/business/2008/jun/29/pharmaceuticals>> (accessed September 26, 2016).

¹¹² Darrow, "Essential Medicines," 291.

¹¹³ Neil Lunt, N. & Percivil Carrera, "Medical Tourism: Assessing the Evidence on Treatment Abroad," *Maturitas* 66, (2010): 27-32; Tricia Johnson & Andy N. Garman, "Impact of Medical Travel on Imports and Exports of Medical Services," *Health Policy* 98, (2010): 171.

¹¹⁴ Patricia Danzon et al., "The Impact of Price Regulation on the Launch Delay of New Drugs: Evidence from Twenty Major Markets in the 1990s," *Health Economics* 14 (2005): 286-290.

¹¹⁵ European Commission, "Presenting a Prescription Abroad" [online]. Available at <http://europa.eu/youreurope/citizens/health/help-from-the-pharmacy/prescription/index_en.htm> (accessed September 26, 2016).

¹¹⁶ See Thomas M. Fullerton & Osvaldo Mirandab, "Borderplex Brand Name Medicine Price Differences," *Applied Economics* 43 (2011): 929-39; Devon M. Herrick "Medical Tourism: Global Competition in Health Care," National Center for Policy Analysis (2007): 3; Darrow, "Essential Medicines," 292; Monali J. Bhosle & Rajesh Balkrishnan "Drug Reimportation Practices in the United States," *Therapeutics and Clinical Risk Management* 3, no. 1 (2007): 41-6; Mukhopadhyay, "Parallel Trade in Pharmaceuticals," 75.

¹¹⁷ See M. Arnold & J. G. Dickinson, "Cracking Down on Cross-Border Drug Sales," *Medical Marketing and Media* 38, no. 6 (2003): 34; Lanjouw, "Patents, Price Controls and Access to New Drugs," 5; Mukhopadhyay, "Parallel Trade in Pharmaceuticals," 75.

websites and storefront operators helping U.S. citizens to receive imported drugs.¹¹⁸

In these respects, many FTAs containing data exclusivity standards were concluded with countries that are popular destinations for health tourism or that possess proficient generic industries. This is not only the case of the North America FTA (NAFTA), concluded between the U.S. and its neighbours Canada and Mexico, but also the case of Jordan, a leading destination for medical tourism in the Middle East, or countries such as Tunisia, Singapore, and Malaysia.¹¹⁹

To avoid the erosions of profits in affluent markets, pharmaceutical companies may adopt three strategies. The first one is to differentiate pharmaceutical products internationally. This can be done by registering the same drug in different countries with different dosage regimes or route of administrations. This deters parallel trade because developing countries versions could not be legally imported in western markets, at least till the moment they are registered in there.¹²⁰ A second option is to raise the price of pharmaceuticals to deter parallel importers. This amply reduces arbitrage and the profit to be gained from drug exportation.¹²¹ The last strategy, the most threatening on a public health perspective, is to neglect, or at least delay, market entrance in small or unprofitable markets.¹²² This last hypothesis was confirmed by a 2004 study, on the launch of 85 new drugs in 25 major markets during the years 1994-1998. The findings of the research were largely consistent with the hypothesis that parallel trade and external referencing pricing negatively affect the launch of new drugs. Without price spill-overs, firms would have no reason to delay distribution in low-price countries, as

¹¹⁸ See Arnold, "Cracking Down on Cross-Border Drug Sales," 34.

¹¹⁹ John Connell, "Contemporary Medical Tourism: Conceptualisation, Culture and Commodification," *Tourism Management* 34 (2013): 8.

¹²⁰ See Margaret K. Kyle, "Strategic Responses to Parallel Trade," *The B.E. Journal of Economic Analysis & Policy* 11, no. 2 (2011): 1-32.

¹²¹ Brian C. Mercurio, "Resolving the Public Health Crisis in the Developing World: Problems and Barriers of Access to Essential Medicines," *Northwestern Journal of International Human Rights* 5, no. 1 (2006): 37-40. Schweitzer, *Pharmaceutical Economics and Policy*, 171; Saba Danawala & Zoe Zhang, "Implications of TRIPS Flexibilities for Access to Non-communicable Disease Medicines in Lower and Middle Income Countries," *International Journal of Nursing and Health Care* 1, no. 1 (2013): 3-4, 9; Om V. Singh, & Thomas Colonna "Friend or Foe: Prescription Drug Reimportation in the US," *Pharmaceutical Technology* (2011): 96-7; Yadav, *Differential Pricing*, 40.

¹²² Lanjouw, "Patents, Price Controls and Access to New Drugs," 4; Civan, "Launch Decisions of Pharmaceutical Companies," 38-39.

long as the prices offered exceed marginal cost plus fixed costs of launch.¹²³ Similarly, a 2017 study on the international price differences of insulin medicines concluded that because of market spillovers the degree of price discrimination among countries remained suboptimal. The study even revealed that, once the price of the drugs was adjusted per capita income, developing countries' patients paid a higher price compared to high-income countries.¹²⁴

VI. Drug Launches and IP Protection

To recapitulate, access to drugs in developing countries can be described as a tension between ensuring affordable prices and promoting timely drug launches. If drugs are priced at western standards they remain unaffordable by the local populations. Conversely, because of market spill-overs, low prices may deter market introduction and impede drug distribution. Ultimately, a long-term solution to the drug lag problem will depend on the social and economic development of developing countries into full-grown economies.

On their turn, researchers have only begun analysing the relationship between intellectual property and drug launches, even though they mostly outline a positive correlation between the two. For instance, according to a first study on the topic, analysing 68 countries between 1982 and 2002, IP protection is usually associated with faster drug launches.¹²⁵ Likewise, a 2015 study comparing drug launches between 1982 and 2008 in Organisation for Economic Co-operation and Development (OECD) countries found a significant linkage between indexes of IP protection and launch approvals.¹²⁶ Other studies provide even stronger evidence. A 2014 investigation on the effects of the TRIPS Agreement on drug launches concluded that stronger IPRs led to faster drug launches both in developed and developing countries.¹²⁷ In 2016, some

¹²³ Patricia Danzon et al. "The Impact of Price Regulation on the Launch Delay of New Drugs: Evidence from Twenty Major Markets in the 1990s," *Health Economics* 14 (2005): 290.

¹²⁴ Matthias Helble & Toshiaki Aizawa, "International Trade and Price Determinants of Price Differentials of Insulin Medicines," *Health Policy and Planning* 32 (2015): 1-10.

¹²⁵ Lanjouw, "Patents, Price Controls and Access to New Drugs," 24.

¹²⁶ Civan, "Launch Decisions of Pharmaceutical Companies," 48.

¹²⁷ Margaret Kyle & Yi Qian, "Intellectual Property Rights and Access to Innovation: Evidence from the

researchers published a study which analysed the time of launch of 642 new molecules in 76 countries between the years 1983-2002. They concluded that, all things being equal, longer patent terms accelerated drug launches by 55%, thus suggesting a strong correlation between patents and drug introductions.¹²⁸

However, it is unclear whether the same conclusions reached for patents can be extended to data exclusivity. In particular, the aforementioned 2016 study pointed out that that short patent protection was not correlated with a positive effect on drug launches. This finding was explained by noticing that companies need longer monopolies to recoup the costs of long clinical development, while regulatory lags might end up eating a big portion of the patent term and thus making short protection periods unappealing. This is all the more relevant considering that patents are filed at a very early stage of clinical research, when firms are incapable of anticipating with precision the compound's future financial returns.¹²⁹

As such, no definitive conclusion can be reached in favour of data exclusivity as a remedy to a country's drug lag, especially considering its potentially detrimental effect on pharmaceutical prices. Nevertheless, data exclusivity systems may and are often adopted as a result of developing countries' international obligations with western counterparts. The necessity to provide adequate data exclusivity safeguards to pursue faster drug introductions arises in these occasions, as a response to international pressures, when the case for trying to counterbalance the negative effects of data exclusivity becomes the strongest. The negotiating history of the Trans-Pacific Partnership perhaps best epitomizes the above. It was indeed the United States that pushed for the inclusion of data exclusivity provisions in the agreement, with the remaining parties almost unanimously opposing the U.S. proposal.¹³⁰ As an alternative, they fought for the inclusion of a provision safeguarding the right to "adopt or maintain measures to encourage the timely entry of pharmaceutical products",¹³¹ and

TRIPS," 1-26.

¹²⁸ Ian M. Cockburn et al., "Patents and the Global Diffusion of New Drugs," 162.

¹²⁹ Ian M. Cockburn et al., "Patents and the Global Diffusion of New Drugs," 152.

¹³⁰ See Article QQ.E.16, Trans-Pacific Partnership, Bracketed Negotiating Text (2013).

¹³¹ See Article QQ.E.XX.1, Trans-Pacific Partnership, Bracketed Negotiating Text (2013) [online]. Available at <<https://wikileaks.org/tpp/#sdfnote111anc>> (last accessed January 22, 2019).

even proposed specific measures to pursue the above goal.¹³²

Premised that, there are two reasons not to discard to hastily the role that data exclusivity might play in promoting timely drug introductions. First of all, data exclusivity has some characteristics that, under a certain vantage, might make it even more attractive to companies than patents. Secondly, international provisions on data exclusivity, including the TRIPS Agreement, allow for important flexibilities. By exploiting these, governments might be able to customize data exclusivity laws with the explicit policy goal of fostering prompt drug introductions.

1. Data Exclusivity Characteristics

Patents and data exclusivity confer to IP holders rights that are characterized by differences in scope, length and exceptions, but both entail the same factual result of ensuring a period of market monopoly over new drugs. From the standpoint of pharmaceutical firms, the main advantage of patents over data exclusivity essentially resides in a longer term of protection. Patent protection lasts for 20 years from the date of filing, in addition to which several countries provide patent extensions for the time wasted in obtaining regulatory review.¹³³ As seen earlier on, a long term of monopoly might indeed be essential to push firms to launch a drug into a market.¹³⁴ By contrast, data exclusivity normally expires after five years after the issuance of marketing authorization, even though longer periods of protection are foreseen in some jurisdictions, e.g. the EU,¹³⁵ or for biological drugs.¹³⁶

On the other side, data exclusivity presents some significant advantages over patents. To begin with, it is not obtained after expensive and unpredictable prosecution but granted automatically altogether with marketing authorization. This avoids regulatory lags

¹³² See Article QQ.E.17 and QQ.E.17, Trans-Pacific Partnership, Bracketed Negotiating Text (2013).

¹³³ For the US see 21 U.S.C. 355(b), (j), (l) of the Drug Price Competition and Patent Term Restoration Act (1984); for the EU Article 4 of Council Regulation (EEC) No. 1768/92.

¹³⁴ Ian M. Cockburn et al., “Patents and the Global Diffusion of New Drugs,” 152.

¹³⁵ For instance, Article 14(11) of Regulation (EC) No 726/2004 provides for up to 11 years of protection.

¹³⁶ For instance, The Biologics Price Competition and Innovation Act (2009), awards 12 years of data protection on biologics.

eating a substantial portion of the term of protection, especially in countries that do not provide for patent extension terms.¹³⁷ Also, data exclusivity does not oblige companies to engage in sophisticated and risky patenting strategies related to time and jurisdiction of filing, or the drafting and the specifications of the patent application. Firms seek out regulatory approval only after clinical development is completed and the main drug features are known, as such data exclusivity does not require firms to undertake all those cost/benefits analyses related to seeking protection in the early stage of R&D.

Data exclusivity also does not involve examination or attorney's fees. Lack of examination also eliminates the risk that protection could be denied on substantial grounds. Hence, data exclusivity might be an incentive to stimulate drug launches in low revenues countries where patents are not filed because they are considered unprofitable.¹³⁸ This is the case in most African countries,¹³⁹ as well as small countries such as Guatemala¹⁴⁰ and Jordan.¹⁴¹

Similar savings derive from data exclusivity being less likely to be invalidated during opposition procedures or litigation.¹⁴² This makes data exclusivity more reliable than patents because it cannot be revoked after granting on substantive grounds, like hidden prior art pieces.¹⁴³

Most importantly, data exclusivity enforcement operates upstream, through the denial of the medical authority to authorize generic applications. Therefore, right holders

¹³⁷ There are few exceptions. Colombia for instance conducts an assessment of the application entitlement to data exclusivity. Between 2002 and 2012, 122 new chemical entities were registered in Colombia and all elicited data exclusivity protection. However, 4.1% of the applications were denied protection, mainly because they were not undisclosed at the moment of submission. See Gamba, *Impacto de 10 Años*, 8. Overall, even when medical agencies carry a formal examination of data exclusivity requirements, this is done on much less stringent grounds than patents.

¹³⁸ Oxfam, *All Costs, No Benefits*, 7.

¹³⁹ Attaran, "How Do Patents And Economic Policies Affect Access to Essential Medicines," 155-66. This was also the case of Guatemala, see Shaffer, "A Trade Agreement's Impact," 958.

¹⁴⁰ Shaffer, "A Trade Agreement's Impact," 958.

¹⁴¹ Oxfam, *All Costs, No Benefits*, 7-8. Among the 108 medicines approved in Jordan between 2001 and 2007 only five received patent protection.

¹⁴² Carlos M. Correa, "A Model Law for the Protection of Undisclosed Data," in Ricardo Meléndez-Ortiz, A. & Pedro Roffé (eds.) *Intellectual Property and Sustainable Development* (Cheltenham: Edward Elgar Publishing, 2009) advocates for a generalization of data exclusivity prosecution and proposes the adoption of opposition proceedings to challenge undeserving data exclusivity grants.

¹⁴³ Shaikh, *Access to Medicines*, 133.

can protect their IP without identifying infringers or bringing them to court. This not only reduces firms' litigation expenses, but it overcomes the unpredictability and the limits of private enforcement. This advantage might acquire particular importance in countries where the national judicial system is considered slow, understaffed or unreliable.¹⁴⁴ There is, therefore, sufficient ground to conclude that at least two of the reasons deemed responsible for the inability of short patents to stimulate drug introductions - i.e. regulatory lags and the necessity for early patent filing - do not to hold up for data exclusivity.

In the context of the U.S.-Jordan FTA, different parties have drawn different conclusions on the ability of data exclusivity to quicken drug launches. A U.S. representative emphasized that Jordan benefitted from 65 new drug launches in the years following the agreement. Oxfam has noted that these still amount to only a fraction of the drugs available in the U.S., with, only 9 of the 26 top-selling drugs in the U.S. market being available in Jordan at the time the study was finished.¹⁴⁵ Then, it would appear that, without the inclusion of specific flexibilities, data exclusivity alone is not sufficient to promote early drug launches.¹⁴⁶ For this reason, developing countries may consider fostering drug introductions through specific clauses in their pharmaceutical laws.

2. TRIPS and FTAs Flexibilities: Articles 7 and 8

Even when interpreted as imposing a strict data exclusivity obligation, Article 39.3 TRIPS contains important flexibilities that allow WTO members to customize their data exclusivity laws to pursue public goal objectives. These find a compelling justification in Article 7 and 8 of the Agreement, which deal respectively with the Treaty's "Objectives" and "Principles." The Vienna Convention explicitly recognizes that interpreters have to clarify the legal meaning of a treaty text in the "light of the treaty

¹⁴⁴ Lanjouw, "Patents, Price Controls and Access to New Drugs," 24; Lee G. Branstetter, "Volume 2: Innovations in Trading Rules," in Schott, J. J. & Cimino-Isaacs, C. (eds.) *Assessing the Trans-Pacific Partnership* (Peterson Institute for International Economics, 2016), 26; Margaret Kyle & Yi Qian, "Intellectual Property Rights and Access to Innovation: Evidence from the TRIPS," 26.

¹⁴⁵ Oxfam, *All Costs, No Benefits*, 17.

¹⁴⁶ It is worth noticing that the Jordan government did not implement none of the flexibilities that will be discussed below.

objective and purpose.”¹⁴⁷ Teleological means avoid over-formalistic interpretations of a text, which could “emasculate the policies and the interests that it embodies.”¹⁴⁸ In particular, interpreters may use a teleological approach to decide between two alternative readings, which are both plausible from the point of view of the text ordinary meaning.¹⁴⁹ Under this perspective, Article 7 and 8 constitute a legal basis to defend the TRIPS consistency of those public health-oriented measures that do not openly contradict the text of the Agreement.

WTO panels have never invoked Article 7 and 8, which “still await proper interpretation.”¹⁵⁰ Nevertheless, they retain primary importance in the interpretation of the TRIPS agreement, especially under the light of Article 31 of the Vienna Convention on the Laws of Treaties.¹⁵¹

According to Article 7: “The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.”¹⁵² The provision reminds the interpreter to take into account conflicting interests underlying TRIPS provisions and in particular dynamic vis-à-vis static efficacy. This is to mean striking a balance between access to medicines and innovation in the process of interpretation.¹⁵³

An even more solid justification to these measures comes from Article 8 TRIPS, which reads: “Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the

¹⁴⁷ Article 31 Vienna Convention (1969): “A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.”

¹⁴⁸ United States - Standards for Reformulated and Conventional Gasoline [1996], WT/DS2/AB/R, p18 [online]. Available at <http://www.wto.org/english/tratop_e/dispu_e/2-9.pdf> (accessed June 17, 2015).

¹⁴⁹ Ulf Linderfalk, *On the Interpretation of Treaties* (Dordrecht: Springer 2007), 206.

¹⁵⁰ Canada v. European Communities, Patent protection of pharmaceutical products, WT/DS114/R (2000).

¹⁵¹ Canada v. European Communities (2000).

¹⁵² Article 7, TRIPS Agreement.

¹⁵³ Shaikh, *Access to Medicines*, 70; Alison Slade, “The Objectives and the Principles of the WTO TRIPS Agreement: A Detailed Anatomy,” *Osgoode Hall Law Journal* 53, no. 3 (2016): 948-97.

public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.”¹⁵⁴ The provision allows members to introduce measures to safeguard public health as long as those are necessary and TRIPS-consistent. The expression “necessary” is precisely defined in the WTO case law. It mandates a least-restrictive approach, i.e., it allows invoking an exception to a WTO rule only when no other less restrictive measure could be reasonably utilised to safeguard the public goal at stake.¹⁵⁵ For what concerns the requirement of “TRIPS consistency,” it is still disputed in the academia whether Article 8 asks for specific measures to be consistent with a specific TRIPS provision or with the Agreement as a whole.¹⁵⁶

The present paper leverages on Article 8 TRIPS to argue that the proposed data exclusivity flexibilities are TRIPS compliant. These measures: a) do not contradict the parlance of Article 39.3, or of any other provision of the TRIPS Agreement, and b) can be deemed necessary for reducing drug delays. This appears evident in light of developing countries not having reasonable control over other means to remedy the drug lag problem. Other solutions, such as increasing the market power of their citizens, or impeding drug spill-overs towards wealthier markets stand well beyond their reach or abilities.

Article 39.3 provides legislators with a very high number of different legal options and implementations,¹⁵⁷ but this paper will focus exclusively on six flexibilities related to achieving the best possible balance between launching new drugs and price control. The first four safeguards aim at fostering prompt drug launches, while the remaining two prevent abusing data exclusivity rules once an authorization has been issued.

1) Reliance on Foreign Approvals

Under a public health perspective, the most important flexibility in the treaty text is

¹⁵⁴ Article 8, TRIPS Agreement.

¹⁵⁵ Panagiotis Delimatsis “The Principle of Necessity in the WTO – Lessons for the GATT Negotiations On Domestic Regulation,” Tilburg Law School Legal Studies Research Paper Series 4 (2014): 7-9; Malbon, *The WTO Agreement*, 591-592.

¹⁵⁶ Shaikh, *Access to Medicines* 72.

¹⁵⁷ For instance see all the different draft proposals discussed in Correa, *ibid* (2009).

the possibility to authorise pharmaceuticals by referencing foreign authorizations. Even though some commentators argue that foreign reliance is not consistent with the TRIPS because members are “requiring submission of otherwise protectable data for approval, albeit indirectly,”¹⁵⁸ this conclusion has to be rebuked. The freedom of governments to utilize foreign authorizations is double-locked in the treaty text by two expressions. The first one is the word “require.” Indeed, parties are not requiring any data when utilizing foreign decisions.¹⁵⁹ The second one leverages on the expression “submission,” which can be defined as the “action of presenting a proposal, application, or other document for consideration or judgment.”¹⁶⁰ Evidently, no documentation is presented to the domestic agency in case of foreign reliance, nor an activity or consideration or judgment is at stake. Allowing generic companies to rely on foreign authorisations is nowadays a preferential route for drug introduction in important generic markets like India¹⁶¹ and Argentina.¹⁶²

Reliance on foreign approvals obeys the important policy function of securing drugs availability even when the data originator did not file an application in the domestic market.¹⁶³ In this sense, foreign reliance finds a strong justification in Article 8 TRIPS, providing that member states may amend their IP laws to protect public health and nutrition.¹⁶⁴

However, relying on foreign approvals alone does not guarantee timely drug

¹⁵⁸ Skillington, “The Protection of Test and Other Data,” 25.

¹⁵⁹ See Basheer, “The Indian Context,” 35; Baker, “Ending Drug Registration Apartheid,” 13; Fleur J. Claessens, *Intellectual Property and Developing Countries: Balancing Rights and Obligations* (Nijmegen: Wolf Legal Publisher, 2009) 193-194; D. Acquah, “Extending the Limits of Protection of Pharmaceutical Patents and Data Outside the EU - Is There a Need to Rebalance?” *International Review of Intellectual Property and Competition Law* 45, no. 3 (2014): 256-86.

¹⁶⁰ *Oxford Dictionaries, British and International English: Submission* [online]. Available at <<http://www.oxforddictionaries.com/it/definizione/inglese/submission>> (accessed May 23, 2016).

¹⁶¹ See Schedule Y, Drugs & Cosmetics Rule, 1945; Prashant Reddy “The Data Exclusivity Debate in India: Time for a Rethink?” *Indian Journal of Law and Technology* 10 (2014): 16-7.

¹⁶² See Articles 4 and 5 Law on the Confidentiality of Information and Products, No. 24,766 (Argentina).

¹⁶³ See Shaikh, *Access to Medicines*, 226.

¹⁶⁴ Article 8.1 TRIPS: “Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.”

approvals. The inherent limitation of this safeguard is that it depends on an earlier foreign authorization. After that, a domestic actor needs to develop a generic and conduct bioequivalence studies.¹⁶⁵ A specialized agency has to review the generic application and issue a marketing authorization, a process that can take years. The time passing between these three phases - .e. foreign authorization, bio-equivalence and review - inevitably results in international drug lag.¹⁶⁶ This explains why even India, a country systematically relying on foreign approvals, has experienced significant drug lag over the years.¹⁶⁷

The FTAs concluded by the European Union do not take a precise position on reliance on foreign approvals.¹⁶⁸ Therefore, the issue will have to be decided by interpreters by investigating the ordinary meaning of each treaty. For instance, the FTA between the EU and Canada seems to allow foreign reliance because it reiterates the wording of the TRIPS Agreement.¹⁶⁹ The same conclusion can be reached on the FTAs between Europe, Singapore,¹⁷⁰ and Ukraine,¹⁷¹ which utilize expressions as “requiring” and “submission” of regulatory data.

The question is more complicated in relation to the FTA between the EU and Moldova. The treaty states that no person should be allowed to rely “directly or indirectly” on the data, but on the other, it reminds that only the person who has submitted the data is allowed to utilize them. The ordinary meaning of the word “submit” hints that the government of Moldova is allowed to rely on foreign authorizations, at least until the moment an applicant has submitted a full dataset.¹⁷² The same argument can be used in the EU FTAs with Korea¹⁷³ and Georgia.¹⁷⁴

¹⁶⁵ However, Shaikh, *Access to Medicines*, 226, argues that in some cases generic companies can conduct bioequivalence studies even before a drug is authorised. This might be done by monitoring scientific publication to detect promising medical innovations.

¹⁶⁶ In addition, some governments may allow foreign reliance only after several years have passed from the first authorisation abroad, to have further evidence of the safety of the drug on patients.

¹⁶⁷ Lanjouw, “Patents, Price Controls and Access to New Drugs,” 5; Goldberg, “Intellectual Property Rights Protection in Developing Countries,” 341.

¹⁶⁸ See Shaikh, *Access to Medicines*, 227.

¹⁶⁹ Article 20.29 of EU Canada FTA.

¹⁷⁰ Article 11.33 of EU Singapore FTA.

¹⁷¹ Article 222 of EU Ukraine FTA.

¹⁷² Article 315 of EU Moldova FTA.

By contrast, most U.S. FTAs do limit reliance on foreign authorizations. This is done in the context of provisions regulating the starting date of exclusivity periods. For reasons of convenience, they will be analysed in the next section.

2) Early Elapsing

The second safeguard consists of starting to count the period of exclusivity from the day of the first worldwide authorisation. Early computing of exclusivity periods aims at luring companies into filing early marketing applications in developing countries. This would be done in order to exploit the full length of the exclusivity periods already running abroad. Ideally, this measure could even lead to simultaneous submissions of marketing applications in multiple jurisdictions.

Under a legal perspective, the lawfulness of this safeguard might be justified on two grounds. A weaker argument relies on the concept of “considerable efforts” and “of protection against unfair commercial use.” Since trials developers have already been partially compensated for their efforts from a monopoly period abroad, it might be argued that the period of protection can be proportionally reduced in the domestic jurisdiction. However, the flaws in this position are that Art. 39.3 TRIPS relates ‘considerable efforts’ to the origination of the trials, and not to the moment of submission; and that IP rights are intrinsically territorial.

A more persuading argument notices that, unlike for patents and copyright, the TRIPS Agreement does not specify the length of data protection nor its starting moment.¹⁷⁵ In this sense, the choice of contracting parties not to specify the starting point and the length of protection indicates the will to leave governments free to decide on the issue. This solution might appear the most consonant with the interpretative principle that the silence of a treaty text should be interpreted in the

¹⁷³ Article 10.36 of EU-Korea FTA.

¹⁷⁴ Article 187.3 of EU-Georgia FTA.

¹⁷⁵ See Article 12 TRIPS: “Whenever the term of protection of a work, other than a photographic work or a work of applied art, is calculated on a basis other than the life of a natural person, such term shall be no less than 50 years *from the end of the calendar year of authorized publication*, or, failing such authorized publication within 50 years *from the making of the work*, 50 years *from the end of the calendar year of making*” and Article 33: “The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.”

manner less restrictive for the sovereignty of contracting parties.¹⁷⁶ As such, in light of Article 8 TRIPS, early elapsing has to be considered TRIPS-consistent, because it does not specifically contradict the parlance of the Agreement and it is aimed at pursuing a public health goal.

Both scholars and legislators have been looking favourably at this safeguard.¹⁷⁷ For instance, Malaysian law calculates the exclusivity period from “the date the product is first registered or granted marketing authorisation and granted Data Exclusivity/Test Data Protection in the country of origin or in any country recognised and deemed appropriate by the Director of Pharmaceutical Services.”¹⁷⁸ Turkish pharmaceutical law limits the territorial scope of early counting: it prescribes a six years exclusivity period starting from the date of initial authorisation in the territory of the Customs Union (i.e. Turkey or European Union).¹⁷⁹ Similar clauses were included in the pharmaceutical laws of several eastern European countries before joining the European Union. They allowed registration on the basis of complete similarity to a medicinal product, which had been registered domestically or in at least one member state of the EU for at least 6 years.¹⁸⁰

Similarly, the 2007 Indian report on steps to be taken in India in the context of Art. 39.3 TRIPS Agreement (Reddy’s Report) suggested that any future period of exclusivity for pharmaceuticals “should be counted from the date of the first marketing

¹⁷⁶ Robert Weissman, “Data Protection: Options for Implementation,” in Pedro Roffe, Geoff Tansey & David Vivas Eugui (eds.) *Negotiating Health: Intellectual Property and Access to Medicines* (London: Earthscan, 2006), 177.

¹⁷⁷ Weissman, “Data Protection: Options for Implementation,” 175-176; Baker, “Ending Drug Registration Apartheid,” 38; United Nations, *Using Intellectual Property Rights to Stimulate Pharmaceutical Production*, 182.

¹⁷⁸ Article 4.6 of Regulation 29 of the Control of Drugs and Cosmetics Regulations 1984 (Malaysia).

¹⁷⁹ Article 9, Regulations on Licensing the Human Medical Products, 25705/2005 (Turkey).

¹⁸⁰ Article 2.11(c) of the Estonian law on Submission of Application for Marketing; Article 19.3 of the superseded Latvian Regulation for Registration of Medicinal Products; §21(6) of Act No. 140/1998 Coll. on Pharmaceuticals (Slovakia) and Article 15 of the Slovenian Act on Medicinal Products and Medical Devices; in IFPMA (2004) *A Review of Existing Data Exclusivity Legislation in Selected Countries* [online]. Available at <<https://www.google.de/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwjD3NiD8MrNAhVkoPKHZ9NCisQFggmMAA&url=http%3A%2F%2Fwww.who.int%2Fintellectualproperty%2Ftopics%2Fip%2Fen%2FData.exclusivity.review.doc&usq=AFQjCNHA9gFafPdZuKA9-LhWWdep4UnKgA>> (accessed June 28, 2016) and IFPMA (2011) *Data Exclusivity: Encouraging Development of New Medicines* [online]. Available at <http://www.ifpma.org/fileadmin/content/Publication/IFPMA_2011_Data_Exclusivity__En_Web.pdf> (accessed January 15, 2015).

approval granted anywhere in the world so that the drug companies market the new drug in India at the earliest.”¹⁸¹

The United States and the EU have demonstrated an unsteady trend regarding early elapsing clauses in their international relations. In the NAFTA, the first of a long series of FTAs dealing with data exclusivity, early computing was specifically allowed: “Where a Party relies on a marketing approval granted by another Party, the reasonable period of exclusive use of the data submitted in connection with obtaining the approval relied on shall begin with the date of the first marketing approval relied on.”¹⁸² This clause encouraged signatories to rely on foreign authorisations and American applicants to seek simultaneous approval in Mexico and Canada.¹⁸³

Later on, the U.S. started to introduce progressively stricter limitations to clauses of this kind in bilateral agreements. The U.S. Free Trade Agreements with Colombia, Panama, and Peru establish that a party might compute the period of data exclusivity from the moment of American authorisation,¹⁸⁴ but only if domestic approval is granted within six months from the moment of registration in the Party.¹⁸⁵ According to some commentators, these provisions allow the two periods of exclusivity to run concurrently, meaning that exclusivity ends in both countries at the moment of expiration in the U.S..¹⁸⁶ It has also been held that the clause incentivises accelerated regulatory reviews, to be concluded within a timespan of six months.¹⁸⁷ Others criticize the six months requirement for being too short to be met by the regulatory authorities of most

¹⁸¹ Satwant Reddy & Gurdial S. Sandhu, *Report on Steps to be Taken by Government of India in the Context of Data Protection Provisions of Article 39.3 of TRIPS Agreement* (2007), 33; Tahir Amin et al, *The Impact of Article 39.3 in India: A Practical Perspective* (2006) [online]. Available at <<http://www.iilj.org/research/documents/TheImpactofArticle39.3inIndiaAPracticalPerspective.pdf>> (accessed September 15, 2016), 4.

¹⁸² Article 1711(7) NAFTA.

¹⁸³ See Shaikh, *Access to Medicines*, 227-8.

¹⁸⁴ These agreements are silent on reliance on different jurisdictions. Shaikh, *Access to Medicines*, 228.

¹⁸⁵ See Article 16.10.2(c) US Colombia FTA: “Where a Party relies on a marketing approval granted by the other Party, and grants approval within six months of the filing of a complete application for marketing approval filed in the Party, the reasonable period of exclusive use of the data submitted in connection with obtaining the approval relied on shall begin with the date of the first marketing approval relied on.”; Article 15.10.2(c) US Panama FTA and Article 16.10.2(c) US-Peru FTA.

¹⁸⁶ See Brian C. Mercurio & Michael Handler ‘Intellectual Property,’ in Mercurio, B. C. & Lester, S. (eds.) *Bilateral and Regional Trade Agreements* (Cambridge University Press, 2009), 21.

¹⁸⁷ See Shaikh, *Access to Medicines*, 228.

countries, including the United States. This makes de facto impossible to start counting the exclusivity period from earlier U.S. authorizations.¹⁸⁸

Most of American FTAs stipulate even more stringent rules. They provide that the period of exclusivity starts from the date of approval in the territory of the party or in the other country, whichever is later.¹⁸⁹ The U.S.-DC CAFTA adds on that, in order to qualify for data exclusivity, a party may require registration within five years from the first foreign authorization.¹⁹⁰ Mechanisms of this kind allow applicants to prolong the monopoly period by utilising sequential filing strategies. These consist of registering drugs abroad shortly before the expiry of the exclusivity in the United States.¹⁹¹ Therefore, they incentive submission lags instead of trying to reduce it and should be avoided by developing countries.¹⁹²

As anticipated, EU FTAs mostly allow relying on foreign approvals. Some of them explicitly allow calculating the data exclusivity period from “the date of the first authorisation in one of the Parties.”¹⁹³ By contrast, others clarify that the period of data protection should start from “the date of the first marketing authorisation in the respective parties.”¹⁹⁴ This last position is reiterated in most EFTA FTAs.¹⁹⁵

3) Time Windows

A similar safeguard consists in granting data exclusivity only when marketing authorisation is sought in the domestic jurisdiction within a specific time window (e.g.

¹⁸⁸ Baker, “Ending Drug Registration Apartheid,” 34-8.

¹⁸⁹ See Art. 16.8.2 of the US-Singapore FTA; Art 14.9.1(b) Bahrain FTA and Art 15.9.1(b) Oman FTA; Art 15.10.1 Morocco FTA; See Art 4.22 Jordan – US FTA and footnote 11; Art 17.10.1(c) Australia – US FTA; Art 18.9.1(b); Korea – US FTA; Art 16.8.2 US-Singapore FTA.

¹⁹⁰ Art 15.10.1(b) CAFTA-DR

¹⁹¹ For an in depth analysis of the topic see Shaikh, *Access to Medicines*, chapter 7.

¹⁹² Mercurio, “Resolving the Public Health Crisis in the Developing World,” 227.

¹⁹³ Article 187(3) EU-Georgia FTA.

¹⁹⁴ Article 10.36 EU-South Korea FTA; See also Article 315(2) EU-Moldova Association Agreement; Article 231 FTA between the EU, Colombia and Peru; Article 11.3 EU-Singapore FTA; Article 222 EU-Ukraine Association Agreement.

¹⁹⁵ Article 4, Annex V, EFTA-Lebanon FTA; Article 6.11 EFTA-Colombia FTA; Article 6.11 EFTA-Peru FTA.

one year) counted from the first worldwide authorisation. Once the drug is registered within the prescribed time limit, the exclusivity period can either elapse normally or be computed from the first authorisation. Evidently, time windows provide a “countdown incentive” to register drugs before the deadline to gain data exclusivity expires.

The TRIPS consistency of time windows might be justified on the vagueness of the expression “new chemical entity” in Article 39.3. As seen, according to some scholars, the expression leaves member states free to opt between a patent-like worldwide connotation of novelty, and a domestic one, where chemical entities are considered novel only when approved for the first time by the domestic medical agency.¹⁹⁶ Member states might stretch this flexibility to consider a chemical entity lacking novelty after a reasonable period of time has passed since regulatory approval worldwide. Grace periods of such a kind are well known in several patent systems, including the one used by the U.S..¹⁹⁷

In addition, the possibility to rely on foreign authorizations allows WTO parties to devise TRIPS compliant mandatory submission periods. Governments may start relying on foreign approvals only after a reasonable period of time has passed from the first world authorization; while in case trials are submitted within the prescribed time window, companies are awarded an ordinary data exclusivity period.¹⁹⁸

Time windows have been proposed by several scholars and adopted in some pharmaceutical laws.¹⁹⁹ For instance, Chilean law requires data developers to register drugs within one year from foreign approval in order to enjoy data exclusivity in the country.²⁰⁰ Similarly, Taiwanese law prescribes a three-year mandatory registration

¹⁹⁶ See Correa, “Protection of Data Submitted for the Registration of Pharmaceuticals,” 17; Correa, *Trade Related Aspects of Intellectual Property Law*, 378; Basheer, “The Indian Context,” 32; Sharma, “Data Exclusivity,” 89; Owoye, “Data Exclusivity and Public Health,” 11.

¹⁹⁷ Slingsby Partners, *Patent Grace Periods Around the World* [online]. Available at <<http://www.slingsbypartners.com/news/patent-grace-periods/>> (accessed on September 28, 2016).

¹⁹⁸ See Article 91 of the Chilean Law 19,039 on Industrial Property, as amended by Law 19,996 (implemented in part by Decree No. 153 by the Ministry of Health, 2005).

¹⁹⁹ Carlos M. Correa, “A Model Law for the Protection of Undisclosed Data,” in Ricardo Meléndez-Ortiz & Pedro Roffe (eds.) *Intellectual Property and Sustainable Development* (Cheltenham: Edward Elgar Publishing, 2009) 375; United Nations, *Using Intellectual Property Rights to Stimulate Pharmaceutical Production*, 182; Mercurio, “Patently Lacking,” 106.

²⁰⁰ See Article 91, Law 19,039 on Industrial Property (as amended by Law 19,996) (Chile). Interestingly, Chile obtained to maintain this domestic flexibility during the Trans Pacific Partnership (TPP)

period.²⁰¹ Also the Indian Reddy Report on the opportunity to adopt data exclusivity suggested to condition data exclusivity upon the submission of a marketing application in India within 24 months from the first worldwide authorisation.²⁰²

4) Short Protection Period

Article 39.3 TRIPS allows States to modulate the data exclusivity term to promote early generic launches. Even though the vast majority of free trade agreements provide for an exclusivity period of at least five years for new chemical entities, this is not a TRIPS requirement. Best-selling drugs, like Lipitor or Kaletra, do not need five years of exclusivity to recoup the investment in clinical data generation. Shorter exclusivity periods are necessary to reduce the price of pharmaceuticals through generic competition. On these premises, India for example, which has been considering in several stages the adoption of data exclusivity for pharmaceuticals, has nowadays a three-year data exclusivity period on agrochemicals.²⁰³

When Article 39.3 is read as imposing a data exclusivity obligation, two instances have to be taken account in setting a minimum period of protection. The first one is that, according to Article 7 TRIPS, intellectual property rights are conducive to innovation, and they are not awarded to protect financial investments per se. Thus, not only does the TRIPS Agreement not mandate a minimum period of protection of five years, but it does not even oblige member states to measure the period of protection to the average time needed to recoup the entire cost of clinical experimentation (i.e. the break-even point). The second one is that the length of protection should necessarily mirror the requirement that data protection in the TRIPS is to be granted only for experimentations that did involve considerable efforts in their origination. Evidently, this is explained by the observation that if the efforts in trials generation are “ordinary,” i.e. affordable by any company in the market, no real incentive is needed to persuade companies in embarking in trials experimentation. Logically, what triggers the protection

negotiations (see Annex 18-B TPP). A similar concession was given to Malaysia (See Annex 18-C TPP).

²⁰¹ See Article 40.2 Taiwanese Pharmaceutical Affairs Law, February 5, 2005.

²⁰² See Reddy, *ibid* (2007), 33. See also See Malhotra, *Impact of TRIPS in India*, 102.

²⁰³ Reddy, “The Data Exclusivity Debate in India,” 20.

in Article 39.3 should also limit its length: i.e., if there is no need to protect trials which did not involve considerable efforts, for the same reason companies should be compensated only for the portion of trials costs exceeding those efforts. Under this perspective, Article 39.3 does not guarantee to data originators the right to be compensated till break-even point is reached, but it simply requires that the efforts in data origination are reduced from “considerable” to “ordinary.”

5) Revocation

Incentives to drug registrations through data exclusivity are useless if companies do not start supplying the market after registration. To avoid companies from keeping generic competition at bay while neglecting patients, parties may provide for data exclusivity revocation measures in case companies do not start distributing the drug within a time limit from authorisation.

Unlike for other IP rights, the TRIPS Agreement is silent on the legal discipline of exceptions to data protection.²⁰⁴ However, this does not entail that the treaty prevents parties from enacting appropriate exceptions in their domestic laws. On the contrary, the silence of the treaty is consistent with the freedom granted to Member States in implementing the provision. Since Article 39.3 does not require exclusive rights, it appeared superfluous to expressly state the exception to the rights granted to data holders. This appears evident when the provision is implemented through a compensatory liability model. In this case, the data are systematically “used without the authorization of the data holder” so that it has little sense to list specific exceptions.²⁰⁵

Premised that, the TRIPS consistency of providing revocation for failure to work the authorized medicine can rely on several arguments. As already seen, the silence of a treaty has to be interpreted in the least restrictive manner for the freedom of the parties to legislate on the matter. This is to mean that, being international treaties a limitation of state sovereignty, interpreters need to be cautious to not impose unwanted obligations on states, especially when these were not accepted through a clear legislative utterance. Again, under Article 8 TRIPS, a measure has to be considered

²⁰⁴ See for instance Article 13, 17, 30 and 31 of the TRIPS Agreement.

²⁰⁵ See the heading of Article 31 TRIPS on Patents.

TRIPS-consistent, whenever it does not contradict the parlance of the Agreement and it is necessary to achieve a public goal. In addition, once the provision is interpreted in its context, it appears reasonable to grant member states the same freedom that was granted for patents, as stated in Article 32 of the Treaty.²⁰⁶

Eminent scholars have advocated for the revocation of data exclusivity rights in specific circumstances.²⁰⁷ Revocation is also expressly stated in some national laws. For instance, Chilean law provides that data exclusivity shall not proceed when: “The owner of the test data referred to in article 89 has incurred in conducts or practices declared contrary to free competition in direct relation to the utilization or exploitation of this information, according to a final decision of the Court of Defence of Free Competition,”²⁰⁸ or “The pharmaceutical or chemical-agricultural product has not been commercialized in the national territory after 12 months, counted as from the registration or sanitary permit obtained in Chile.”²⁰⁹ Similar provisions are included in the pharmaceutical laws of Colombia²¹⁰ and Saudi Arabia.²¹¹

In other laws, data exclusivity simply follows the revocation of the authorization in case the drug sponsor forfeits to distribute the medicine within a given period. This is the case of Article 14(4) of EC Regulation 726/2004, which reads: “Any authorisation which is not followed by the actual placing of the medicinal product for human use on the community market within three years after authorization shall cease to be valid.”

²⁰⁶ Article 32 TRIPS: “An opportunity for judicial review of any decision to revoke or forfeit a patent shall be available.”

²⁰⁷ Correa, “A Model Law,” 383-4.

²⁰⁸ Article 91(2), Law 19,039 on Industrial Property (as amended by Law 19,996), Articles 89 through 91 (implemented in part by Decree No. 153 by the Ministry of Health (2005).

²⁰⁹ Article 91 (4), Article 91(2), Law 19,039 on Industrial Property (as amended by Law 19,996), Articles 89 through 91 (implemented in part by Decree No. 153 by the Ministry of Health (2005).

²¹⁰ Article 4(4), Data Protection Decree No. 2085 – September 19, 2002 (Colombia): “The protection referred to in this decree does not apply in the following cases: When the new chemical entity that is the object of the sanitary registration has not been commercialized in the country one year after the issuance of said commercialization authorization.”

²¹¹ Article 6(1) Decision No. 3218: Regulations for the protection of Confidential Commercial Information, later amended by Decision No. 4319 of 2005 (Saudi Arabia): “The competent registration authority – during the protection term of commercial secrets – may permit third parties to use the undisclosed data of secret tests submitted by another application in the following cases: (1) If the product first registered in the Kingdom has not been subject of trading within a reasonable period of time determined by the registration authority, after approving its marketing.”

However, as clarified by the European Court of Justice in the Astra/Zeneca case, the voluntary withdrawal or the revocation of marketing authorization still allows generic competitors to rely on the originator's files. This is because the medical agency remains in possession of all the relevant documentation to assess the generic application.²¹²

6) Compulsory Licensing and Post-introduction Controls

A last safeguard consists of controlling excessive prices through ex-post measures as compulsory licensing.²¹³ As seen for revocation, Article 39.3 TRIPS does not prevent the compulsory licensing of regulatory data. Again, the silence of the treaty has to be interpreted in the manner least restrictive for state sovereignty. This solution is corroborated by two additional arguments: a) limitation to compulsory licensing in the Agreement are always expressly stated, like in Article 21 TRIPS,²¹⁴ and that is not the case of data exclusivity;²¹⁵ and b) there is no "unfair commercial use of the data" anytime a fair remuneration is paid for their use, like in the case of compulsory licenses.²¹⁶

Some FTAs limit the possibility of compulsory licensing regulatory data through "necessity tests." More in detail, they specify that data exclusivity might be waived only for "reasons of public interest, situations of national emergency or extreme urgency, when it is necessary to allow access to those data to third parties."²¹⁷ The concept of necessity is narrowly defined in the international legal system to limit the operability of an exception only to those cases where any reasonable alternative to pursue the public interest at stake is not viable.²¹⁸ However, out of 35 FTAs

²¹² AstraZeneca A/S v Lægemedelstyrelsen, C-223/01 European Court of Justice (2003).

²¹³ Basheer, S. (2006) "The 'Glivec' Patent Saga: A 3-D Perspective on Indian Patent Policy and TRIPS Compliance" [online]. Available at <<http://webcache.googleusercontent.com/search?q=cache:ZMpn0RtI3dQJ:www.atrip.org/Content/Essays/Shamnad%2520Basheer%2520Glivec%2520Patent%2520Saga.doc+&cd=1&hl=it&ct=clnk&gl=it&client=safari>> (accessed May 5, 2016), 3; Weissman, *ibid* (2006); Rius Sanjuan and Weissman, *ibid* (2006), Correa, *ibid* (2009), 382.

²¹⁴ Article 21 TRIPS: "The compulsory licensing of trademarks shall not be permitted."

²¹⁵ Carvalho, *Interpreting and Implementing the TRIPS Agreement*, 309.

²¹⁶ Carvalho, *Interpreting and Implementing the TRIPS Agreement*, 309; Owoeye, "Access to Medicines and Parallel Trade," 1-24.

²¹⁷ See Article 231.4(a) of the FTA between the EU, Colombia and Peru.

²¹⁸ Delimatsis, "The Principle of Necessity in the WTO," 1-22.

containing data exclusivity obligations, only five contain necessity tests. The remaining agreements either expressly recognize the possibility to offset data exclusivity through compulsory licenses or remain silent on the issue.²¹⁹

Likewise, several domestic legislations expressly admit compulsory licenses on regulatory data. These include the laws of Chile,²²⁰ Costa Rica,²²¹ and Malaysia.²²² Other laws simply state (or add-on) that data exclusivity might be waived in order to protect the public.²²³

VII. Conclusions and Public Adjustments

In conclusion, TRIPS flexibilities, when not unfairly limited in bilateral agreements, can help mitigate the adverse effects of data exclusivity on access to medicine and

²¹⁹ The author has analysed this issue more in depth in a previous paper. See more recently, Article 14(37). Of the ‘Agreement between the European Union and Japan for an Economic Partnership,’ Intellectual Property Chapter.

²²⁰ Article 91(3), Law 19,039 on Industrial Property (as amended by Law 19,996): “The protection of this Paragraph will not proceed, when: The pharmaceutical or chemical-agricultural product is subjected to a compulsory license, in conformity with that established in this law.”

²²¹ Article 10, Law no. 7975 (2000) Regulations for the Undisclosed Information Law Costa Rica: “A health authority may provide for the granting of non-exclusive mandatory licenses that make it possible to obtain authorizations for the sale of pharmaceutical preparations without the need to comply with the five year data protection period. A mandatory licensee shall be exempt from compliance with the five years period provided by the foregoing Article, but it shall not be authorized to access the sale authorization documentation for the reference pharmaceutical preparation.”

²²² Article 5(1) Regulation 29 of the Control of Drugs and Cosmetics Regulations 1984: “Nothing in the Data Exclusivity shall: i) apply to situations where compulsory licenses have been issued or the implantation of any other measures consistent with the need to protect public health and ensure access to medicines for all.”

²²³ Article 5(2) Regulation 29 of the Control of Drugs and Cosmetics Regulations 1984 (Malaysia): “Nothing in the Data Exclusivity shall: prevent the Government from taking any necessary action to protect public health, national security, non-commercial public use, national emergency, public health crisis or other extremely urgent circumstances declared by the government”; Article 4(3), Data Protection Decree No. 2085 – September 19, 2002: “protection referred to in this decree does not apply in the following cases: When it is necessary to protect the public, as qualified by the Ministry of Health”; Chile Article 91(3), Law 19,039 on Industrial Property (as amended by Law 19,996): “The protection of this Paragraph will not proceed, for: For reasons of public health, national security, non-commercial public use, national emergency or other circumstances of extreme urgency declared by the competent authority, it is justified to put an end to the protection referred to in article 89”; Article 6(2), Decision No. 3218/2005 (Saudi Arabia): “The competent registration authority – during the protection term of commercial secrets – may permit third parties to use the undisclosed data of secret tests submitted by another application in the following cases: If this is required by a pressing necessity determined by the competent authority to protect the public.”

might help to reduce the drug lag afflicting developing countries. In this way, those developing countries who are incapable of escaping the data exclusivity pressures of western economies can make the best out of their IP obligations in the pursuit of their public health goals. This paper concludes with two final remarks.

The first one is that the described flexibilities should be necessarily adjusted to take into account entry delays not attributable to pharmaceutical companies. This might be the case of excessively long regulatory review periods in developing countries, which could be attributed to a lack of manpower or flaws in administrative procedures. In other cases, western companies have to delay submission in some foreign countries because of additional regulatory requirements. For instance, Russia and India require local testing of western medicines in at least 100 local citizens. This is to prove that the drug has a comparable efficacy in the population of those countries, notwithstanding ample differences in their lifestyles, genetics and metabolism.²²⁴

For our concerns, the time needed to meet domestic requirements should be taken into account when designing data exclusivity flexibilities. For instance, companies might miss time window deadlines to develop local trials. To avoid this, time windows might be prolonged to include a reasonable period of time necessary to test the drug in the local population after the first approval. Another solution might be to accept provisional applications lacking local testing to accelerate regulatory review, while the final authorization would be issued after the submission of a full set of trials on the local population. Similarly, when exclusivity is computed from the first worldwide authorization, local testing might unduly erode the exclusivity period and hinder the efficacy of data exclusivity as a solution to submission lags. Governments may remedy to this inconvenient by providing data exclusivity restoration to applicants, similarly to what is done for patents in the EU and U.S. legal systems.

The second reflection draws attention to the circumstance that quickening drug launches does not depend exclusively on intellectual property. Providing an efficient and reliable and regulatory environment is a key element in increasing the appeal of

²²⁴ See Shivam Vashisth, Govind Singh & Arun Nanda “A Comparative Study of Regulatory Trends of Pharmaceuticals in Brazil, Russia, India and China (BRIC) Countries,” *Journal of Generic Medicines* 9, no. 3 (2012): 128-43; Reddy, “The Data Exclusivity Debate in India,” advocating that data exclusivity has a role to play in spurring companies to conduct local tests.

low-income markets. Appropriate regulatory measures might include reducing regulatory fees for drugs not authorised abroad. Most importantly, harmonising regulatory requirements to allow a single application to be submitted in multiple jurisdictions creates incentives for timely submissions. This has already been accomplished between Europe, the United States, and Japan through the International Conference on Harmonization, allowing the same English dossier to be approved in the three jurisdictions.²²⁵

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²²⁵ Jatinder Singh, “International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use,” *Journal of Pharmacology and Pharmacotherapeutics* 6, no. 3 (2015): 186.