

Patent linkage, data exclusivity and public health: approaches for reform

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Abstract

- The COVID-19 Pandemic exposed the fragility of the global public health regime (N Jensen et al, 'The COVID-19 pandemic underscores the need for an equity-focused global health agenda' (2021) 8 *Humanit Soc Sci Commun* 15.). Never before in history, we had a vaccine for an ongoing pandemic which the majority had no access to. Even prior to the pandemic, the global public health regime was showing signs of vulnerability manifested by the rising costs of medicines and public health expenditure levels, increased levels of legal monopolies exasperated by originator drug manufacturers activities and the widening gap between those who can afford medicines and therapeutic treatments, and those who can't, even for those residing in developed countries (M El Said, 'The Global IP Response to COVID-19 Pandemic: A Tale of Several Ironies?' (2022) 19 *MJIEL* 79–91.). In fact, global spending on pharmaceuticals is forecast to exceed pre-pandemic outlook to \$1.2 trillion by 2028 (IQVIA, *The Global Use of Medicines 2024: Outlook to 2028* (2024). Available at <https://www.iqvia.com/-/media/iqvia/pdfs/china/viewpoints/iqvia-institute-general-use-of-medicines-2024-for-print.pdf> (accessed 22 July 2024)). At a time when the world started to recover from the negative impact of the COVID-19 Pandemic, fears about the potential arrival of a new pandemic arising from the outbreak of Mpx in Africa started to emerge thus putting more strain on public health providers everywhere.
- Many reasons may be attributed to the failure of addressing the public health needs of the majority at the global level; however, one of the main factors related to this is the role patent protection and regulatory approvals play in imposing market barriers and monopoly exclusivities on drugs and medicines. In more recent years, the role of data exclusivity restrictions and patent linkage mechanisms became apparent and a vital component of this debate.
- The significance of this paper is demonstrated by the policy reform options it is advancing. This paper provides a review of the challenges posed by data exclusivity restrictions and patent linkage mechanisms and will propose policy recommendations and approaches in order to mitigate the negative impact on public health and access to medicines arising from patent linkage and data exclusivity protection. The paper will rely on specifically selected country case studies to demonstrate the feasibility of achieving such objectives.

I. Background: patents, data exclusivity and pharmaceuticals

Generally speaking, there are two regimes that regulate the pharmaceutical production market. These are (i) traditional intellectual property rules and the (ii) the laws and regulations related to the process of drug registration and approval (non-traditional in that sense). These two sets of regimes serve specific purposes and are administered by different government agencies.¹

¹ As the International Federation of Pharmaceutical Manufacturers and Associations explains, 'Patents and data exclusivity are different concepts, protect different subject matter, arise from different efforts and have different legal effects over different time periods'. International Federation of Pharmaceutical Manufacturers & Associations, 'Data Exclusivity: Encouraging Development of New Medicines' (2011), 5. Available at <https://www.ifpma.org/publications/data-exclusivity-encouraging-development-of-new-medicines/> (accessed 23 July 2024).

With relation to patent protection, national patent offices are the designated authorities dealing with the process of granting patents in any country. Their role is to ensure that the patent application meets the requirements of the national law set for a patent grant. Although intellectual property in general and patent laws more specifically are territorial in nature, international agreements play a big role in shaping and forming these laws and legislations.

With the creation of the TRIPS Agreement toward the end of the Uruguay Round, which resulted in the creation of the World Trade Organization (hereinafter the WTO) in 1995,² the world witnessed a new era in the regulation of intellectual property

² The Agreement on Trade-Related Aspects of Intellectual Property Rights, April 15 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

at the international level. This new global regime had a direct impact on public health and access to medicines nationally. In consequence, the TRIPS Agreement made it obligatory for the first time in history for all member states to grant patent protection for pharmaceutical products and processes.³ Prior to that, countries had considerable freedom and discretion in determining what to protect, or otherwise. The TRIPS Agreement was followed by various initiatives and agreements aimed toward increasing the levels of intellectual property rights protection at the national and regional levels including bilateral and regional free trade agreements (FTAs).⁴

On the other hand, and in order to ensure the safety and efficacy of medicines,⁵ countries tend to regulate the sale and marketing of medicines through designated national drug regulatory agencies dedicated to this matter such as the US Food and Drug Administration (the FDA), the European Medicines Agency and the Japan Pharmaceuticals and Medical Devices Agency.⁶ As such, these agencies undertake the needed measures to verify that the submitted test data meets the efficacy, safety and quality requirements of any medicines prior to its launch nationally.

National drug regulatory authorities often operate independently from national patent offices, as the latter are more concerned with ensuring that the application for obtaining a patent meets the requirements of patentability as set under the national patent law (such as novelty, inventiveness and industrial applicability), as opposed to the role of national drug regulatory authorities, which are more concerned with the quality and safety of the drug. Moreover, most of national drug regulatory authorities are affiliated with or have linkages with national health strategies and ministries while patent offices are often affiliated with ministries of trade or commerce.

Nevertheless, the role of national drug regulatory authorities has been impacted in a number of ways in recent years. The aim was to introduce additional requirements on these authorities in order for them to provide protection terms (data exclusivity protection) and to link the status of clinical trial applications with that of patent protection (patent linkage).⁷ These developments have huge public health impact upon the accessibility and affordability of medicines as will be explained in the ensuing sections of this paper.

II. Data exclusivity and patent linkage under the TRIPS Agreement

Undisclosed information, as referred to under the WTO's TRIPS Agreement, 'has never been the subject of any multilateral agreement until the adoption of TRIPS'.⁸ The TRIPS Agreement itself does not oblige member states to provide exclusive protection specifically to the originator of data but rather calls more broadly and generally for the protection of 'undisclosed data' against 'unfair' and 'non-commercial use' of such data.⁹ In addition, the TRIPS Agreement states that countries have the discretion to require the submission of undisclosed tests or any other data in accordance with their needs and priorities.¹⁰

Despite the above, developed countries such as the USA and the European Union have been advocating the inclusion of stronger market and data exclusivity provisions¹¹ and patent linkage regimes through FTAs.¹² Accordingly, data exclusivity provisions refer to a practice whereby, for a fixed period of time, national drug regulatory authorities prevent and block the registration files of an originator from being used to register a therapeutically equivalent generic version of that medicine without obtaining the consent of the patent holder unless the generic manufacturer actually reconducts the clinical trials. As highlighted, such conditions are referred to as TRIPS-Plus conditions because they go beyond those standards required under the TRIPS Agreement.¹³

The consequences for providing data exclusivity protection are far-reaching and potentially life-threatening to those patients who need access to generic medicines. Because producing test data independently can be costly and time-consuming, most generic producers would not have the resources nor the incentive to produce them independently. Requiring 'data exclusivity' protection creates a problem for generic and biosimilar companies, who would no longer be able to rely on originator test data to obtain marketing approval for generic products.¹⁴ In consequence, data exclusivity periods can delay the entry of lower-cost treatments into the market. Furthermore, if data exclusivity protection is awarded when an existing medicine obtains marketing authorization (or registration) for a second/new indication or for a new form, data exclusivity could potentially extend the period of exclusivity of the originator product further, thus delaying entry

⁸ J Watal (ed) *Intellectual Property Rights in the WTO and Developing Countries* (London, Kluwer Law International, 2001), 4.

⁹ The TRIPS Agreement, Art 39.3.

¹⁰ Accordingly, Art 39.3 of TRIPS stipulates: Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize NCEs, 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.

¹¹ As De Menezes et al explains, there is a technical distinction between market and data exclusivity. They explain that with relation to market exclusivity, '... the agencies can receive and authorize the marketing of a generic medicine, but it can only enter the market after the exclusivity period has expired. In the case of data exclusivity, the agencies are prohibited from receiving and evaluating applications for the duration of the exclusivity period. Thus, data exclusivity provides an additional period of de facto exclusivity equal to the time it takes the regulatory agency to evaluate the application and grant authorization'. See, H Dr Menezes et al, 'Negotiating Health and Autonomy: Data Exclusivity, Healthcare Policies and Access to Pharmaceutical Innovations' (South Centre, Research Paper 204, 2024, at 12). Available at https://www.southcentre.int/wp-content/uploads/2024/07/RP204_Negotiating-Health-and-Autonomy_EN.pdf (accessed 28 July 2024).

¹² M El Said, 'The Road From TRIPS-Minus to TRIPS to TRIPS-Plus: Implications of IPRs for the Arab World' (2005) 8 *Journal of World Intellectual Property* 53-66.

¹³ See, P Drahos, 'BITS and BIPS: bilateralism in intellectual property' (2001) 4 *Journal of World Intellectual Property* 6, 791-808.

¹⁴ Of course, they can produce their own test data; however, this would be costly and ethically contentious.

³ For more see, C Deere, *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* (Oxford University Press, 2008).

⁴ M El Said, *Public Health Related TRIPS-PLUS Provisions in Bilateral Trade Agreements, A Policy Guide for Negotiators and Implementers in the WHO Eastern Mediterranean Region*, (WHO-EMRO 2010). Available at <https://applications.emro.who.int/dsaf/dsa1081.pdf> (accessed 23 June 2024).

⁵ This is also in line with Goal 3 (3.8) of the 17 United Nations Sustainable Development Goals which aims to achieve 'access to safe, effective, quality and affordable essential medicines and vaccines for all'. See the 2030 Agenda for Sustainable Development of the United Nations Available at <https://sdgs.un.org/2030agenda>.

⁶ Prior to 1984 in the USA, and prior to 1987 in the European Union, pharmaceutical test data was protected as a trade secret. The 1984 Drug Price Competition and Patent Term Restoration Act ('Hatch-Waxman Act') in the USA and the 1987 87/21/EEC Directive in the European Union further clarified the rules of clinical test data protection and related procedures. For more see, S Wagner, 'Patents, Data Exclusivity, and the Development of New Drugs' (MPI-IC Munich), (2019). Available at https://rationality-and-competition.de/wp-content/uploads/discussion_paper/176.pdf (accessed 3 November 2024).

⁷ Linkage in this context refer to the practice of linking the patent status with the generic registration process, meaning that the regulatory authority may not register generic versions of a pharmaceutical that is under patent.

of generic medicines into the market.¹⁵ Also, in the case where the remaining patent term at market approval is shorter than the period of data exclusivity, the latter would result in an additional protection term that goes beyond that of the patent term.

Recent technological developments are also playing an important role in shaping how the pharmaceutical industry is moving in the future. In particular, the increased reliance on the use of artificial intelligence (AI) technology, biomarkers and new communications technologies has drastically reduced both the time taken and the associated cost for conducting clinical trials. Moreover, recent developments have seen the increased use of AI in the drug discovery process resulting in reduced the risks and minimized the development time too.¹⁶ As such, AI usage in this process is saving time and leading to higher levels of accuracy in the clinical trial process. As BenchSci reports, there are at least 33 pharmaceutical companies that are currently heavily engaged in AI.¹⁷ What is notable in this regard is that these developments have not yet attracted the attention of policymakers. In other words, reduction in time and lower risk did not result in reduction of data exclusivity protection terms yet. Those developments should trigger an open debate about the granted duration of exclusivity terms since the basis for which such terms were justified are no longer in place, as will be explained.¹⁸

There is also the strong argument that data exclusivity protection has an unethical dimension resulting in the violation of medical ethics because clinical trial methodologies would require some patients to be given placebos.¹⁹ Giving placebos when the safety and clinical validity of the medicine being tested is already established as unethical.²⁰

On the other hand, linkage of the generic approval with the patent term also has repercussions, resulting in delaying the entry of generic products into the market until the expiration or invalidation of the related patent. A 2020 White Paper by Medicines for Europe—a group representing the generic medicines developers and manufacturers in Europe—affirmed that by verifying ‘The artificial linkage of patent status to these processes is readily exploited as a tactic designed to hinder market entry for generic or biosimilar products. In practice, this tactic is effective and is particularly problematic where the patent being relied upon is ultimately found to be invalid’.²¹ Patent

linkage has been found to contribute to increased litigation costs.²²

Patent linkage opponents further claim that linkage between patent status and generic registration is problematic, as the regulatory authority would probably lack the human and other resources to check the patent status of each product, thus resulting in delay or erroneous outcomes. It has been argued that ‘in case there is a patent, regulators may not have the expertise to assess whether the patent is valid and would be infringed. As a result, it is likely that they will enforce all patents, even invalid ones—and thus create additional and unnecessary hurdles for generic competition’.²³ For those reasons, several organizations including WHO, WIPO and WTO took the view that open access to test data is desirable to ‘avoid duplication of clinical trials, encourage innovative activities to develop new medicines and allow researchers to evaluate clinical trial data’.²⁴

On the other hand, proponents of patent linkage requirements say that patent linkage provides transparency, it would encourage R&D and it would in fact reduce patent infringement litigation, ‘since generic companies will be able to assess in advance if they are infringing upon the originator’s product, which serves the dual purpose of safeguarding the patent holder by preventing patent violation’.²⁵ Such claim does not seem to have been adequately substantiated by credible evidence so far.

Other arguments advanced by proponents of data exclusivity protection evolve around the notion that originator companies should be granted protection to reward their investment and efforts in conducting the test trials, which in result would protect their R&D. This argument, however, should be balanced with the public health interest and increasingly acknowledged negative impact arising from such protection. Moreover, the patent protection term provided is the means by which such investments are rewarded.

III. TRIPS—Plus, patent linkage and data exclusivity

Patent linkage and data exclusivity protection regimes found their way under national regimes through two routes, either through national regulation, as in the case of the EU and US systems, or through bilateral FTAs such as the USA–Jordan FTA, the USA–Singapore FTA and US–Oman FTA. These types of agreements include explicit reference to patent linkage and protection of data exclusivity through obliging their member states to provide a regime of *exclusive rights* in test data. Moreover, unlike the TRIPS Agreement, these FTAs also stipulate a minimum period of protection during which data exclusivity protection must be granted for.²⁶

²² A 2009 European Commission Report found that the estimated total cost of patent litigations in the EU between 2000 and 2007 was in excess of €420 million. European Commission, ‘Final Report: Pharmaceutical Sector Inquiry’ (8 July 2009), para. 660. Available at https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf (accessed 16 July 2023).

²³ World Health Organization. Regional Office for South-East Asia. ‘Data exclusivity and other “trips-plus” measures. World Health Organization. Regional Office for South-East Asia’ (2017), 3. Available at <https://apps.who.int/iris/handle/10665/272979> (accessed 16 July 2024).

²⁴ See World Health Organization, the World Intellectual Property Organization and the World Trade Organization, *Promoting Access to Medical Technologies and Innovation* (2020), p. 83.

²⁵ W Armouti, ‘Evolution of Data Exclusivity for Pharmaceuticals in Free Trade Agreements’ (2020) The South Centre, Policy Brief, 76 Available at <https://www.southcentre.int/policy-brief-76-april-2020/> (accessed 18 July 2024).

²⁶ For example, the US FTA with Morocco stipulates that: If a Party requires, as a condition of approving the marketing of a new pharmaceutical and agricultural chemical product, (i) the submission of safety and efficacy data, or

¹⁵ As Greg Perry, from the European Generic Medicines Association, explains, ‘[T]he expansion of data exclusivity provisions has become one of the main ways of extending market protection and blocking generic competition. Data exclusivity is seen now as the principal means of extending market protection for new indications, pharmaceutical forms and other variations, especially where these are not innovative enough to gain patent protection’. G Perry, ‘Data Exclusivity—A Major Threat to Access to Affordable Medicines. Business Briefing’ (2002) 16 *Pharmagenetics*. Cited in L Diependaele et al, ‘Raising the Barriers to Access to Medicines in the Developing World—The Relentless Push for Data Exclusivity’ (2017) 17 *Dev World Bioeth.* 16, 11–21.

¹⁶ See, J Kimball and S Ragavan, ‘AI (Re) Defining Pharmaceutical Exclusivities’ (2022) 41 *Biotechnology Law Report* 1, 23–29.

¹⁷ See Deep Pharma Tech, ‘AI for Drug Discovery, Biomarker Development and Advanced R&D Landscape Overview Q4 2021. Available at <https://analytics.deep-pharma.tech/AI-for-DD-Q4-2021/Full-Report.pdf> (accessed 16 May 2024).

¹⁸ See more generally M Sulaiman, *The Coming Wave: Technology, Power, and the Twenty-First Century’s Greatest Dilemma*, (The Bodley Head, London, 2023).

¹⁹ See, E t’ Hoen, ‘Protection of Clinical Test Data and Public Health: A Proposal to End the Stronghold of Data Exclusivity’ in C Correa and R Hilty (eds) *Access to Medicines and Vaccines* (Springer, Cham, 2022) Available at https://doi.org/10.1007/978-3-030-83114-1_7 (accessed 16 May 2024).

²⁰ Oxfam, ‘All Costs, No Benefits: How TRIPS-Plus Intellectual Property Rules in the US–Jordan FTA Affect Access to Medicines’ (2007) 7 Oxfam Int’l, Briefing Paper No. 102.

²¹ R Vidal et al, ‘Legal Affairs Committee of Medicines for Europe. Anatomy of a failure to launch: a review of barriers to generic and biosimilar market entry and the use of competition law as a remedy. Medicines for Europe’ (November 5 2020), 18. Available at <https://www.medicinesforeurope.com/docs/2020.11.04-Medicines-for-Europe-Whitepaper.pdf> (accessed 16 May 2024).

In brief, these FTAs restrict the period under which national drug regulatory authorities can recognize foreign marketing approval decisions (referred to as the ‘non-reliance obligations’). In addition, some of these agreements take an even more stringent approach by also prohibiting national regulatory authorities from relying on ‘safety or efficacy information submitted in support of the prior marketing approval in the other territory, for at least five years for pharmaceutical products from the date of marketing approval of the new product in the Party’.²⁷

As highlighted, the negative impact of data exclusivity can be manifested by delaying the entry of affordable medicines into the market. More worryingly, the existence of a data exclusivity regime would also effectively prevent the use of compulsory licences by preventing the registration of medicines produced under a compulsory licence where data exclusivity protection remains in place. Other problematic scenarios may also arise such as the case when a patent is invalidated and data exclusivity is granted, the latter would become the sole source of market exclusivity.

The following section will provide some examples and emerging evidence about the negative impact of data exclusivity and patent linkage based on the experience of several countries.

IV. Assessing the damage

Data exclusivity has been a controversial issue in recent years due to the negative impact it has on the prices of medicines and the impact it has upon delaying the entry of generic medicines into the markets. Data exclusivity may even apply even if no patent protection exists and may also curb the exercise of compulsory licensing, as highlighted.

There has been mounting evidence about the above claims. One of the earliest case studies reviewed in this context was that of the case of Jordan. A 2007 Oxfam study on the impact of the USA–Jordan FTA found that ‘most pharmaceutical companies have not bothered to apply for patent protection for medicines launched onto the Jordanian market’ but rather relied on data exclusivity.²⁸ Notably, the FTA includes 5 years of data protection plus 3 years for new uses of known compounds and patent linkage notification condition.²⁹ The Oxfam study found that since 2001 medicine prices in Jordan have increased by 20 per cent (this led to price increases between two and ten-fold for key medicines to treat cardiovascular disease and cancer), and data protection has delayed generic entry for 79 per cent of medicines newly launched between 2002 and 2006. The study estimates that the availability of generic equivalents would have reduced Jordan’s expenditure on medicines by between \$6.3 and \$22 million between mid-2002 and 2006.³⁰

(ii) evidence of prior approval of the product in another territory that requires such information, the Party shall not permit third parties not having the consent of the person providing the information to market a product on the basis of the approval granted to the person submitting such information for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of approval in the Party. For purposes of this paragraph, a new product is one that contains a NCE that has not been previously approved in the Party [emphasis added].

²⁷ For example, see US–Bahrain FTA, Art 14.9.1(b)(i). Also see US–Oman FTA, Art 15.9.1(b)(i).

²⁸ Oxfam, ‘All Costs, No Benefits: How TRIPS-Plus Intellectual Property Rules in the US–Jordan FTA Affect Access to Medicines’ (2007) 7 (Oxfam Int’l, Briefing Paper No. 102).

²⁹ Oxfam, ‘All Costs, No Benefits: How TRIPS-Plus Intellectual Property Rules in the US–Jordan FTA Affect Access to Medicines’ (2007) 7 Oxfam Int’l, Briefing Paper No. 102, 28.

³⁰ Compared to the Oxfam study, Abbott et al. found a loss of \$18 million in 2004—larger than the additional outlays of between \$6 and \$22 million between 2002 and 2006 found in the Oxfam study. Abbott et al. concluded that the provisions for data protection arising from the FTA had the most significant effect on the price of medicines on Jordan. R Abbott et al, ‘The Price of Medicines

There are several other studies documenting the negative impact of data exclusivity across the globe.³¹ For example, the price of a drug called Colchicine—which is mainly used for the treatment of gout conditions—in the USA has increased by more than 5000 per cent upon the introduction of data exclusivity protection in 2009.³² This caused some uproar since the drug has been widely known for decades and costs almost nothing to produce locally; hence, it is neither new nor inventive and therefore should not be allowed to be patented or granted legal protection. As a result of data exclusivity protection, however, the US FDA started to accept ‘clinical data from a one-week trial of the drug and granted data exclusivity to URL Pharma, which led to the gigantic price increase of Colchicine. As Chakrabarti explains, “URL Pharma subsequently sued to force their manufactures off the market and raised prices from US\$ 0.09 to 4.85 per pill.”³³

In addition, Kesselheim et al. found that protection of data exclusivity resulted in a delay in availability, elevated drug prices and slowed the uptake of generic alternatives which cost Medicaid \$1.5 billion over 4 years.³⁴ Another study examining the availability of certain drugs in Guatemala found that as a result of the signing of the Central American FTA (‘CAFTA’),³⁵ intellectual property rules reduced access to some generic drugs already on the market and delayed new entry of other generics.³⁶ Even worse, the study found that some drugs protected from competition in Guatemala will become available in the US market for generic competition even before generic versions will be legally available in Guatemala.³⁷

Another perspective study on the impact of the EU–Colombia FTA by IFARMA commissioned by Health Action International Europe projects that by 2030, data exclusivity rules could result in an increase of more than \$340 million.³⁸ Another perspective study on the impact of the USA–Thailand FTA conducted by a team at the University of Bangkok adopting a macroeconomic model measuring the impact of data exclusivity and patent extension proposals forecasted that all scenarios demonstrated a negative impact on the pharmaceutical market and access to medicines. In consequence, medicine prices would increase by 32 per cent and the domestic pharmaceutical market is expected to contract by \$3.3 million by 2027.³⁹

in Jordan: The Cost of Trade-Based Intellectual Property’ (2012), 9 *J. Generic Med.* 75, 79.

³¹ For more see, M El Said, ‘The Impact of “TRIPS-Plus” Rules on the Use of TRIPS Flexibilities: Dealing with the Implementation Challenges’ (2022) in Correa, CM Hilty and RM (eds) *Access to Medicines and Vaccines*. (Springer, Cham, 2022) Available at https://doi.org/10.1007/978-3-030-83114-1_11 (accessed 18 July 2024).

³² G Chakrabarti, ‘Need of Data Exclusivity: Impact on Access to Medicine’ 19 (2014) *J. Intell. Prop. Rights* 325 at 332.

³³ G Chakrabarti, ‘Need of Data Exclusivity: Impact on Access to Medicine’ (2014) 19 *J. Intell. Prop. Rights* 325 at 332.

³⁴ A Kesselheim et al, ‘Extensions of intellectual property rights and delayed adoption of generic drugs: effects on Medicaid spending’ (2006) 25 *Health Aff (Project Hope)* 6:1637–47.

³⁵ See, B Tenni et al, ‘What is the impact of intellectual property rules on access to medicines? A systematic review’ (2022) 15 *Global Health*. 18: 40.

³⁶ E Shaffer & J Brenner, ‘A Trade Agreement’s Impact on Access to Generic Drugs’ (2009) 28 *Health Affairs* 5, 957.

³⁷ A 2009 study commissioned by ICTSD concluded that the CAFTA-DR would lead to an annual price increase for active ingredients in Costa Rica of between 18 per cent and 40 per cent by 2030, requiring increased public spending in the range of US\$2 million to US\$3.357 million. The strongest impact was expected to arise from standards on patentability criteria and standards on test data exclusivity. H Georg Bartels et al, *Promoting Access to Medical Technologies and Innovation: Interceptions Between Public Health, Intellectual Property and Trade*, 183 (2012).

³⁸ IFARMA, ‘Impact of the EU–Andean Trade Agreement on Access to Medicines in Peru’ (2009) Health Action International Europe and IFARMA Foundation.

³⁹ N Kessomboon et al, ‘Impact on Access to Medicines from Trips-Plus: A Case Study of Thai-US FTA’ (2010) 41 *Southeast Asian J. Tropical Med. & Pub. Health* 667, 674, at 667.

The claims that data exclusivity protection is important for the stimulation of innovation has also been challenged. A publication by Dutch research group Technopolis, prepared upon request of the Dutch government, looked at pharmaceutical exclusivity incentives available to the industry in the EU. The study concluded that there is no conclusive evidence on the positive impact of data exclusivity.⁴⁰

Public health advocates are indeed calling for a more balanced approach in dealing with patent regulation in general and data exclusivity protection in particular. Their calls are based on the need to explore further the flexibilities of the patent regime to ensure increased levels of access to medicines and availability of cheaper prices of medicines. In addition, the increasing reliance on AI and the reduction in time and costs resulting from such use call for revisiting the current approach.

The next part will highlight some policy options for countries which may be used to mitigate the negative impact of data exclusivity protection. Some of these recommendations are based on examples from countries which have already reformed their regimes in such a direction.

V. Lessons and policy recommendations

The global challenge to cater for the health needs of citizens everywhere is mounting. It is not an exaggeration to say that many governments and public health providers are at a breaking point in terms of their ability to provide the needed public health support. The COVID-19 pandemic exposed decades of policy failures and led to the breaking down of established public health regimes even within developed countries.

The urgent need to reform patent and data exclusivity regimes is essential. Incorporating the patent related flexibilities of the TRIPS Agreement under national law and exploring the widest possible policy space available to countries in this regard is paramount and should be a priority.⁴¹

The same applies to dealing with the challenges posed by patent linkage and the protection awarded to data exclusivity. Although data protection is often treated outside the intellectual property regime and is viewed more as a quasi-IP right, reforming its regime is seen as an important step for achieving a balanced national pharmaceutical patents regime. Keeping this in mind, we can observe that several countries have already taken some positive steps toward reforming their national laws and policies in order to mitigate the negative impact of extended TRIPS-Plus and data exclusivity rules following the signing of an FTA. This part will look at a couple of cases which may provide useful lessons in this context. Both countries signed similar FTAs with the USA.

The first case is that of Chile. This case provides a good example for a country that signed an FTA which includes data exclusivity obligations of a TRIPS-Plus nature. The country signed an FTA with the USA in 2006 (the USA–Chile FTA). Following a rigorous national debate with relation to the negative effect of data exclusivity and patent linkage commitments included under the FTA, the Chilean government amended its patent law by limiting the availability of data protection under its national law to those pharmaceutical

products that have been marketed in the national territory only within the year after the grant of marketing approval otherwise the test data submitted for approval purposes will not be protected.⁴² The rationale behind such a requirement is to encourage early registration of drugs after first registration abroad, so that the period of protection for the pharmaceutical test data starts early. In addition, the law excluded several elements from the scope of protection.⁴³

Furthermore, Chile implemented the linkage obligation established by the USA–Chile FTA through the provision of information (mere notification without needing approval) to the patent owner about a third party intending to commercialize a product with similar characteristics to one already patented. Once again, the aim of these measures was to limit the implementation thus making use of whatever wiggle room there may be in order to restrict the application of data exclusivity.⁴⁴

On the other hand, and in order to deal directly with the impact data exclusivity protection may have on the issuance of compulsory licences, several countries—such as Malaysia and Columbia—proceeded through the inclusion of waivers to data exclusivity under their national law which would apply in case the of issuance of a compulsory licence.⁴⁵

The second is the case of Jordan. Jordan was the first Arab country to sign an FTA with the USA back in 2002.⁴⁶ The FTA was also one of the first to attract attention due to the TRIPS-plus conditions stated within. Data exclusivity clauses included under the agreement resulted in a negative impact on access to medicines in the country as documented by an Oxfam study in 2007.⁴⁷

⁴² See the Law No. 19 039 Art. 90, September 30 1991 (modified on December 1 2005, by Law 19996, which classifies active ingredients as NCEs if they have not been marketed in the country prior to the health registration or authorization application).

⁴³ Accordingly, Art 91 of the Chilean law states: The protection of this paragraph shall not apply when: (a) The owner of the test data referred to in Article 89 has engaged in forms of conduct or practices declared as contrary to free competition in direct relation to the use or exploitation of that information, according to the final decision of the free competition court. (b) For reasons of public health, national security, non-commercial public use, national emergency or other circumstances of extreme urgency declared by the competent authority, ending the protection referred to in Article 89 shall be justified. (c) The pharmaceutical or chemical-agricultural product is the subject of a compulsory licence, according to what is established in this Law. (d) The pharmaceutical or chemical-agricultural product has not been marketed in the national territory after 12 months from the health certificate or clearance granted in Chile. (e) The pharmaceutical or chemical-agricultural product has a health certificate

⁴⁴ Canada and the EU also include under their legislations a data protection waiver in relation to products produced under compulsory licences for export (but not for domestic use) under the Special Compulsory Licensing System. See Article 18 of EC Regulation No 816/2006 of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.

⁴⁵ For example, Section 5 of the Malaysia 2011 Directive of Data Exclusivity, titled Non-Application of Data Exclusivity, provides that: Nothing in the Data Exclusivity shall: (i) apply to situations where compulsory licences have been issued or the implementation of any other measures consistent with the need to protect public health and ensure access for all; or (ii) 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. See also Cambodia Law on Compulsory Licensing for Public Health (Cambodia). Art 18.

⁴⁶ Art 4.22 of the FTA states: Measures Related to Certain Regulated Products 22. Pursuant to Article 39.3 of TRIPS, each Party, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products that utilize NCEs, the submission of undisclosed test or other data, or evidence of approval in another country, the origination of which involves a considerable effort, shall protect such information against unfair commercial use. In addition, each Party shall protect such information against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the information is protected against unfair commercial use.

⁴⁷ See, Oxfam, 'All Costs, No Benefits: How TRIPS-Plus Intellectual Property Rules in the US-Jordan FTA Affect Access to Medicines' (2007) 7 Oxfam Int'l, Briefing Paper No. 102

⁴⁰ See, T de Jong et al, 'Effects of supplementary protection mechanisms for pharmaceutical products' (2018) *Technopolis Group*, at 156. Available at <https://www.technopolis-group.com/wp-content/uploads/2020/02/Effects-of-supplementary-protection-mechanisms-for-pharmaceutical-products.pdf> (accessed 23 July 2024).

⁴¹ For more, see C Correa, 'Interpreting the Flexibilities Under the TRIPS Agreement' (2022) in C Correa and R Hilty, (eds) *Access to Medicines and Vaccines* (Springer, Cham, 2022). Available at https://doi.org/10.1007/978-3-030-83114-1_1 (accessed 23 July 2024).

The USA–Jordan FTA’s data exclusivity requirements are relatively milder than those stated under other FTA such as the US–Chile and the US–Morocco FTAs. For instance, while the USA–Morocco FTA requires protection of data exclusivity for 5 years exclusivity over test data and a further 3 years exclusivity for ‘new clinical information’, the USA–Jordan FTA requires only 3 years protection for ‘new chemical entities’ (NCEs) only.

Following an active public discourse between various stakeholders in Jordan, the laws were amended in 2015 in order to reduce the negative impact of the FTA on the pharmaceutical sector with relation to data exclusivity requirements. Some of these reforms followed those justifications explained in the Chilean case above. As such, several amendments were introduced in 2015 to address the following issues:

A. Narrowly defining new chemical entities for registration purposes

The USA–Jordan FTA stipulates that the protection for ‘NCEs’ shall include (i) protection for new uses for old chemical entities, (ii) for a period of 3 years. However, beyond this, the FTA does not define what NCEs are for the purpose of the law or registration. A new definition was introduced into the 2015 Registration of Medicines Conditions (hereinafter the Registration Conditions) which limits protection to those NCEs which have not been registered for more than 18 months in the first country of registration anywhere in the world. Based on this, to be granted data exclusivity protection, originators should register the medicines in Jordan within a maximum period of 18 months from the registration in their origin country. If they go beyond this period, they would not be granted any protection.

B. Registration conditions

The 2015 Registration Conditions introduces some important limitations on data exclusivity protection including the stipulation that data exclusivity applies only to ‘NCEs’. Based on this, new medicines which are available in the market which represent modifications of known substances would be excluded from registration.

Moreover, the 2015 Registration Conditions also state that generic manufacturers can now apply for registration of their generics during the last year of data exclusivity protection (ie the 4th year) as the process of approval may take up to 12 months in certain cases. This has the impact of reducing the time of entry of generics into the market. This will almost have the same impact as the Bolar exemption whereby generic producers can start the process of preparing their generics to enter the market on the date which the patent expires.

Lastly, the 2015 Registration Conditions contain some situations where the importation, distribution, suspension, cancellation or recollection of the medicines may take place. Examples of these situations would be applicable in cases of proven non-efficiency/efficacy of the medicine, its suspension in its country of origin, if registration was made based on incorrect information.

VI. Recommendations for policy reform

Generally speaking, countries should design their policies in line with the following recommendations to ensure that patent linkage and data exclusivity protection do not burden their national health regimes through exploring the following various options.

Firstly: the ideal situation would be to refrain from granting data exclusivity protection for long terms and to broadly comply the TRIPS Agreements obligations’ in this regard.⁴⁸ This may be achieved through:⁴⁹

- The best position would be to refrain from granting data exclusivity and linkage requirements per se.
- Legislators should explore the available policy space of Article 39 of the TRIPS Agreement to the maximum through defining what is meant by ‘new’, ‘considerable effect’ and ‘chemical entity’ keeping in mind their socio-economic needs and stage of development. For example, exclusivity for clinical test data for new indications should be avoided.
- Link the expiry term of data exclusivity with that of the expiry of the patent term.
- Calculation of the period of national data exclusivity can be made to not exceed the period in country of origin or exporting country. The start date for exclusivity may be possibly counted from the date of first registration of the medicine anywhere in the world.
- Consider the introduction of limitations and reductions of the duration of data exclusivity protection whereby the medicines was generated through reliance on AI technologies which justifies lower levels of investment and risk taking by the applicants.
- In the case of an anti-competitive behavior related to the exploitation of test data arises, no data exclusivity protection should be granted. Anticompetition law should have remedies for these situations.
- Procedures allowing opposition actions against grant of exclusivity should be included under the national legal framework.
- Public health exceptions such as compulsory licensing and Bolar exemptions⁵⁰ on data exclusivity can be permitted in emergency situations or in public interest. These should be broadly defined under national law.
- Patent linkage should be avoided under national law. Where it is obligatory to do so due to an FTA, then an attempt to comply with this by the mere notification (not linking this to approval) should suffice.

On the other hand, several recommendations could be made to those countries which have already committed to some form of TRIPS-Plus data exclusivity provisions depending on the level of their commitments. These include:

- Not to grant protection unless a specific application is made (within a specific period—no more than 6 months—of time after the first approval in the world of a medicine) and where certain conditions are met.
- Countries may apply a charge for these applications and require annual maintenance fee (such as those applicable to

⁴⁸ M El Said, *Public Health Related TRIPS-PLUS Provisions in Bilateral Trade Agreements, A Policy Guide for Negotiators and Implementers in the WHO Eastern Mediterranean Region*, (WHO-EMRO 2010). Available at <https://applications.emro.who.int/dsaf/dsa1081.pdf> (accessed 23 June 2024).

⁴⁹ Some of these suggestions are based on the evaluation undertaken by Shaikh. For more details see, O Shaikh, ‘Conclusions and Recommendations’ (2018) in *Access to Medicine Versus Test Data Exclusivity. Munich Studies on Innovation and Competition* (Springer, Berlin, Heidelberg, 2018). Available at https://doi.org/10.1007/978-3-662-49655-8_8 (accessed 5 June 2024).

⁵⁰ The early working exception, or the so-called ‘Bolar exception’, is a flexibility exception which facilitates the production and introduction of generic medicines into the market on the date of patent expiry. Accordingly, this exception permits the use of an invention for the purpose of obtaining approval of a generic product before the patent actually expires and without having to obtain the patentee’s approval.

trademarks). In addition, stipulating in detail when protection will terminate is recommended.⁵¹

- When the right-holder or a person authorized by him does not commercialize the approved product in a manner sufficient to supply the demand within a period (eg 12 months) from the date of approval for commercialisation or when the commercialisation is interrupted, for more than specific number of consecutive months (eg 6 months), then no protection should be granted except in cases of force majeure or government's acts that prevent such commercialisation.⁵²
- When, as a result of administrative or judicial procedures, it is determined that the right-holder has abused his/her rights, ie through practices declared as anticompetitive, no protection should be granted.
- Inclusion of waivers against the application of data exclusivity protection in case of issuance of compulsory licence and Bolar exemption.
- Allowing generic competitors to enter the market if their products are approved by health regulators elsewhere if there are no restrictions imposed on this under national law.
- Data exclusivity expiry could also be linked to the pharmaceutical patent protection terms. By doing so, national authorities would ensure that data protection term would not extend beyond the patent protection term hence creating unwarranted further monopolistic term.⁵³
- Proposing alternative models, as T Heon recommends that countries should consider replacing data exclusivity regimes with data protection regimes that acknowledge the investment made to generate data but do not allow the investor to exclude others from using the data. She states suggests that 'Under a data compensation regime, the registration of a generic medicine or biosimilar medicine is considered fair commercial use. The originator company that made the investment that was needed to generate the data will receive adequate remuneration for the use of the data but cannot

prevent its necessary use by the medicines agency to perform its public health duties. The data compensation regime could be proposed as an alternative to data exclusivity demands in trade negotiations'.⁵⁴

The above discussion shows examples of how several countries were able to reform their policies around data exclusivity rules arising from FTAs. The discussion also provided some recommendation about how countries can tailor their national data exclusivity regimes to be more public health friendly. Countries should conduct their national cost-benefit analysis about which model suits their stage of development and what international commitments they have at the same time. Of course, this does not completely eliminate the negative impact of such rules but rather mitigates it.

VII. Conclusions

While patent linkage and data exclusivity protection provisions are obligatory under the rules of the WTO as explained, countries such as the USA and the European Union pushed their stronger data exclusivity provisions and patent linkage requirements on other countries through FTAs. Such regimes have grave repercussions for public health and access to medicines. However, the COVID-19 Pandemic provided momentum for the calls to reform the patent regime.⁵⁵

The debate surrounding this issue is likely to continue and may even take a more aggressive turn in light of recent technological developments if not addressed collectively and globally. As highlighted by Yu, recent developments in the fields of AI and big-data analytics' use in drug development and the rise of investments in biologics and personalized medicines are likely to complicate matters more if left unaddressed.⁵⁶ Humanity should not wait until the next pandemic to address this.

⁵¹ See, C Carlos. Mitigating the regulatory constraints imposed by intellectual property rule under free trade agreements. (Research Paper No. 74, South Centre, Geneva 2017). (Accessed August 1, 2023) Available at https://www.southcentre.int/wp-content/uploads/2017/02/RP74_Mitigating-the-Regulatory-Constraints-Imposed-by-Intellectual-Property-Rules-under-Free-Trade-Agreements_EN-1.pdf (accessed 3 August 2023).

⁵² C Carlos. Mitigating the regulatory constraints imposed by intellectual property rule under free trade agreements. (Research Paper No. 74, South Centre, Geneva 2017). (Accessed August 1, 2023) Available at https://www.southcentre.int/wp-content/uploads/2017/02/RP74_Mitigating-the-Regulatory-Constraints-Imposed-by-Intellectual-Property-Rules-under-Free-Trade-Agreements_EN-1.pdf (accessed 3 August 2023).

⁵³ For more on this see proposal see, T Henriksen and S Henriksen, 'Data exclusivity and patent monopoly extension: A view from Australia' (2024) 27 *The Journal of World Intellectual Property* 314–338.

⁵⁴ See, E t' Hoen, 'Protection of Clinical Test Data and Public Health: A Proposal to End the Stronghold of Data Exclusivity' (2022) in CM Correa and RM Hilty (eds) *Access to Medicines and Vaccines*. (Springer, Cham, 2022) Available at https://doi.org/10.1007/978-3-030-83114-1_7 (accessed 16 May 2024).

⁵⁵ M El Said, 'Radical Approaches During Unusual Circumstances: Intellectual Property Regulation and the COVID-19 Dilemma' (2020) 63 *Development* 209–218.

⁵⁶ P Yu. 'Data Exclusivities and the Limits to Trips Harmonization' (2022) 46 *Fla. St. U. L. Rev.* 415.