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Essay

The Drug Debate: Data Exclusivity is the New Way to Delay Generics

SRIVIDHYA RAGAVAN

The article discusses the protection regime for clinical trial data internationally and outlines the applicable protection regime. In doing so, this article outlines how the data exclusivity regime can operate in parallel with the patent regime to add a layer of protection for the data. Such protection operates at a regulatory level to delay the entry of generic medications. Internationally, the data exclusivity regime, which has become an important contemporary tool in trade negotiations with poorer nations, works to detrimentally affect access to medication.



The Drug Debate: Data Exclusivity is the New Way to Delay Generics

PROFESSOR SRIVIDHYA RAGAVAN*

Suppose that the morning edition of the British Broadcasting Corporation (BBC) reported about “Company A’s” new miracle medication, “Drug A,” to cure acne. Clinical trials conducted on over 3,000 patients showed that Drug A was generally safe, although teenagers with higher than normal blood sugar levels may suffer from mild to severe depression as a side effect. In reality, it might be good for the reader to appreciate that independent drug information journals repeatedly assert that the rate of “truly innovative” new medicines range as low as approximately two percent.¹ A vast majority of so-called new medicines, including those that are protected by patents, typically represent minor improvements over existing standards.² That information aside, any drug, including the exemplar Drug A, would be subject to regulatory approvals. Thus, in this scenario, Company A submitted the clinical trial information as part of the

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¹ See Brian Godman, et al., *Are New Models Needed to Optimize the Utilization of New Medicines to Sustain Healthcare Systems?*, 8 (1) EXPERT REV. CLINICAL PHARMACOLOGY 77, 78 (2015) (highlighting that “Prescrire, a critical independent drug information journal, believed only 2% of new medicines or new indications for existing medicines in France were innovative and/or offered a real therapeutic advantage over existing treatments despite the hype”) (citation omitted).

² See Editorial, *New Drugs, New Indications in 2015: Little Progress, and Threats to Access to Quality Healthcare for All*, 36 (388) PRESCRIRE INT’L 136, 136 (2016), english.prescrire.org/en/3D3B93E1C3DE20A599FBA073C5442463/Download.aspx; see also Editorial, *New Products and New Indications in 2016: A System that Favours Imitation Over the Pursuit of Real Progress*, 37 (400) PRESCRIRE INT’L 136, 136 (2017), english.prescrire.org/en/955912A2E87C92B676874FA2C1354846/Download.aspx [hereinafter *New Products*, 2016] (“[L]ittle therapeutic progress was made in 2016, yet many medicines with no clinical value, uncertain efficacy or an unfavourable harm-benefit balance were authorised. This is due at least in part to the current system that drives pharmaceutical research and development. The primary focus is neither on patients’ needs nor on delivering genuine therapeutic advances at affordable prices.”).

statutory requirements for getting marketing approval for Drug A.

Clinical trial data submitted to federal agencies in support of the application to approve the marketing of the compound is critical to prove important elements such as safety and side effects information of the concerned drug. This article discusses the protection regime for clinical trial data and the applicable protection regime. In doing so, this article outlines how the data exclusivity regime can operate in parallel with the patent regime to add a layer of protection for the clinical trial data. Such protection operates at a regulatory level to detrimentally affect access to medication by delaying the entry of generic medications. Furthermore, the data exclusivity regime, which has become an important contemporary tool in trade negotiations with poorer nations, works internationally to detrimentally affect access to medication.

The historic origin of the requirement that protects the exclusivity of Company A's clinical trial data arose from unfair competition concerns originally outlined in Article 10*bis* of the Paris Convention for the Protection of Industrial Property.³ In essence, Article 10*bis* establishes "honest practices in industrial or commercial matters,"⁴ and prevents actions such as dishonest manufacturing and other practices that mislead the public as to the nature and quality of the goods.⁵ When the World Trade Organization (WTO)⁶ was established, the TRIPS Agreement⁷ incorporated the Paris Convention. Thus, Article 39 (3) of the

³ Paris Convention for the Protection of Industrial Property art. 10*bis*, Mar. 20, 1883, last revised July 14, 1967, 21 U.S.T. 1583, 1648 [hereinafter Paris Convention].

⁴ *Id.*

⁵ *Id.*

⁶ General Agreement on Tariffs and Trade – Multilateral Trade Negotiations (The Uruguay Round): Agreement Establishing the Multilateral Trade Organization [World Trade Organization], 33 I.L.M. 13 (1994) [hereinafter Marrakesh Agreement]; *see also The WTO*, WORLD TRADE ORG. (2018), https://www.wto.org/english/thewto_e/thewto_e.htm (providing an overview of the WTO).

⁷ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, vol. 31, 33 I.L.M. 81 (1994), *reprinted in* WORLD TRADE ORGANIZATION, THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 365 (1995) [hereinafter TRIPS Agreement]; *see also* Overview: the TRIPS Agreement, WORLD TRADE ORGANIZATION, http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm; Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 19 U.S.C. § 4201 [hereinafter TRIPS].

TRIPS Agreement provides protection for “undisclosed test or other data” submitted to governments or “governmental agencies” as part of the approval process for marketing of pharmaceutical or agricultural chemical products which utilize new chemical entities.⁸ The protection is envisaged against unfair commercial use of “undisclosed test or other data” involving *new chemical* entities generated using “considerable effort” and submitted to government regulators such as the US Food and Drug Administration (FDA) or its equivalent in other countries.⁹ There is one exception, however, and it applies where the disclosure of the data is deemed necessary to “protect the public.”¹⁰

Operationally, the data exclusivity regime provides a layer of protection for the data gathered by innovator drug companies. This protection regime for data operates outside the realm of patent protection. Thus, the exemplar Company A above will have two distinct, parallel layers of protection. First, subject to fulfilling the necessary statutory requirements, Company A will benefit from patent protection which, if successful, will allow the company to charge monopoly prices during the patent term of 20 years.¹¹ Second, Company A will get protection over the clinical trial data preventing the disclosure of the clinical trial information during the data exclusivity term.

For innovator pharmaceutical companies like Company A, protecting the clinical trial data provides an economic opportunity by creating a new market for the information relating to the safety of the drug. It also helps provide market exclusivity for compounds that fail patent scrutiny. Critics point out, correctly, that pharmaceutical companies prefer to make general trial information available at the earliest opportunity with a view to boosting share prices. For example, with Drug A it would be common for Company A to highlight general trial information about the drug, such as its ability to cure acne with few side effects, while omitting severe side effects on segments of the population, such as minors using asthma medication or children with diabetes.¹² The general amount of clinical trial information

⁸ TRIPS Agreement, *supra* note 7, at art. 39.

⁹ *Id.*

¹⁰ *Id.*

¹¹ *See generally* 35 U.S.C. §101–130.

¹² *But see New Products*, 2016, *supra* note 2, at 138–39 (asserting how new products in the year 2016 represented no or limited therapeutic advancement and discussing how pharmaceuticals are approved for applications without demanding adequate supporting data of clinical trials).

about drugs is increasing and is pro-actively tracked by health authorities and venture capitalists for market related reasons, such as to determine potential funding models.¹³ Release of limited but early trial information can allow pharmaceutical companies to seek more funding for the launch of their new medicines. However, general disclosures by pharmaceutical companies aimed at securing funding should be carefully distinguished from patient data that includes side-effects and success information, which will remain protected under data protection laws.

Justification for the protection of clinical trial data is owed to the success of innovator pharmaceuticals in asserting that the costs of undertaking clinical trials are considerable, and can run up to four separate phases involving several patients, their confidential information, and varying treatment regimes that can include information on side effects and safety regimens of the medication. That is, innovator pharmaceutical companies assert that Company A's investment to ensure that Drug A is safe by conducting clinical trials must include the protection of the generated data. This logic, of course, stands on shaky ground considering that Company A would typically seek patent protection, which, if successful, leads to monopoly profits during the patent term meant to recoup "research and development" expenses.¹⁴ Clinical trials are part of the development process to

¹³ There is an increasing level of pro-activity among health authorities in Europe to track new medicines early and feed this information into their potential funding models. See, e.g., Irene Eriksson et al., *The Early Awareness and Alert System in Sweden: History and Current Status*, FRONTIERS IN PHARMACOLOGY 8:674, at 1, Oct. 5, 2017, <https://doi.org/10.3389/fphar.2017.00674>; see also Rickard Malmström et al., *Dabigatran - A Case History Demonstrating the Need for Comprehensive Approaches to Optimize the Use of New Drugs*, FRONTIERS IN PHARMACOLOGY 4:39 at 2, May 14, 2013, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3653065/> (discussing the sharing of data between European countries).

¹⁴ The role of patent protection in minor innovation and how it detrimentally affects the cost of medication has become a matter of debate. Researchers and international organizations have highlighted the importance of access to medication. See, e.g., Camille Abboud et al., *The Price of Drugs for Chronic Myeloid Leukemia (CML) is a Reflection of the Unsustainable Prices of Cancer Drugs: From the Perspective of a Large Group of CML Experts*, 121 BLOOD JOURNAL 4439, 4441 (2013), <http://www.bloodjournal.org/content/121/22/4439?sso-checked=true> (noting that "[u]naffordable CML drug prices may be preventing many patients from accessing these lifesaving drugs."); see also Report of the United Nations Secretary-General's High Level Panel on Access to Medicines, at 15 (Sep.

ensure the safety of a chemical compound. That is, clinical trials determine whether the innovated New Chemical Entity, for which a patent is filed, is safe to be marketed as a medication. Conducting clinical trials should therefore be a natural part of the risk that innovator companies undertake in order to gain the enormous market benefits that come with patent protection.

Nevertheless, most governments award a drug company that undertakes clinical trials, typically the innovator drug company, with a period of “exclusivity” which can range anywhere from three to eight years.¹⁵ In the United States, for example, the FDA grants New Chemical Entities a total data exclusivity period of up to five years.¹⁶ That is, during the term when data exclusivity prevails, competing drug companies cannot get access to the clinical trial data. Importantly, such access to data is unavailable even when the patent application fails. Taking the example above, even if Company A’s compound is found to be unpatentable for whatever reasons, and hence falls in the public domain, the data from the clinical trial will remain protected, thus indirectly awarding Company A market exclusivity. In stock market parlance, this is a situation where even though the pharmaceutical company has taken a bad risk in the form of a patent application, data exclusivity provides adequate insurance for a few years of market exclusivity. Even

2016), <http://www.unsgaccessmeds.org/final-report/> (noting that “[c]ost is one of the key determinants of access.”); Ed Silverman, *Hepatitis C Drugs Remain Unaffordable in Many Countries, Says WHO Study*, STATNEWS, May 31, 2016, <https://www.statnews.com/pharmalot/2016/05/31/gilead-hepatitis-drug-prices-who/> (noting that, for diseases like hepatitis C, in some countries where drug prices are high, “the total cost of treating everyone would be more than the cost of all other medicines combined.”); Press Release, World Health Organization, *Over 1 Million Treated With Highly Effective Hepatitis C Medicines* (Oct. 27, 2016), <http://www.who.int/mediacentre/news/releases/2016/hepatitis-c-medicines/en/> (noting “huge differences between what countries are paying” for hepatitis C drugs); Narcyz Ghinea et al., *If We Don’t Talk About Value, Cancer Drugs Will Become Terminal for Health Systems*, THE CONVERSATION, July 26, 2015, <http://theconversation.com/if-we-dont-talk-about-value-cancer-drugs-will-become-terminal-for-healthsystems-44072> (discussing a group of oncologists urging patients to talk about the price of medications).

¹⁵ See 21 U.S.C. § 355(b)(1)–(2) under which applications for a new chemical entity can receive five years of exclusivity; U.S. FOOD AND DRUG ADMINISTRATION, FREQUENTLY ASKED QUESTIONS ON PATENTS AND EXCLUSIVITY (2018), <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079031.htm#howlongexclusivity> (noting a range of exclusivity terms depending on the nature of the drug).

¹⁶ *Id.*

though patent protection has failed, which means that a generic version can be manufactured legally, the clinical trial data remains protected, thus indirectly providing Company A market exclusivity on a product which does not enjoy patent protection. Therefore, generic drug applications of the drug will be delayed, not because there is a patent on the drug, but because the clinical trial information is protected by data exclusivity. In this scenario, generic drug companies are not allowed to access the information related to a chemical that is in the public domain. For consumers, Company A's market exclusivity comes at a financial cost, as well as at the cost of access to the medication. Of course, generic drug companies are free to conduct their own clinical trials, considering that the drug is not a subject of patent protection. However, such duplication of clinical trials will result in subjecting a new set of patients to the same clinical trials and involves additional cost to conduct the trials and delays in manufacturing the generic drug while trials are being conducted. Thus, generic drug companies duplicating a clinical trial already conducted elsewhere will result in duplicative burdens in terms of time and cost. While the cost of the trial will be added to the cost of the drug and passed onto consumers by raising the cost of generic drugs unnecessarily, the delay from duplicating the clinical trial will result in delaying access to the consumers.

Under circumstances where a chemical gets patent protection, data exclusivity regimes have slowly morphed into a weapon resulting in a slow increase in the period of data exclusivity. For example, in the United States, along with the original exclusivity awarded for New Chemical Entities, a six month paediatric exclusivity is added to any existing drug. This extension attaches at the end of the term if the sponsor submits paediatric studies on the active moiety in response to a Written Request from the FDA.¹⁷ Similarly, a separate period of seven years of exclusivity can be awarded under the Orphan Drugs Act for each use of the drug to treat an orphan condition.¹⁸ Recent

¹⁷ See 42 U.S.C. § 284m21(c) (2012) (describing that the Commissioner of Food and Drugs can issue written requests for paediatric studies); 21 U.S.C. § 355a(b)(1) (2012) (stating that “the period during which an application may not be approved . . . shall be extended by a period of six months after the date the patent expires[.]”).

¹⁸ *Frequently Asked Questions on Patents and Exclusivity*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079031.htm>; *Orphan Drug Act - Relevant Excerpts*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesCondi>

research has suggested rampant misuse of this enactment by companies. National Public Radio reported that more than seventy drugs approved as Orphan Drugs were in fact “familiar brand names.”¹⁹ Such examples include popular mass market drugs, such as “the cholesterol blockbuster Crestor, Abilify for psychiatric conditions, cancer drug Herceptin, and rheumatoid arthritis drug Humira, the best-selling medicine in the world.”²⁰ Each of these represented the re-approval of a mass market drug as an orphan drug when its patent was about to expire. Similarly, there have been instances where the same drug received multiple “orphan approvals.”²² The approval of drugs with a new orphan status has caused manufacturers to receive millions of dollars in government incentives.²³ The problem with this is that the seven additional years of data exclusivity creates a monopoly over a drug which already benefitted from patent protection, as well as one layer of data exclusivity, for treating another disease.²⁴

As patents and high drug prices have become increasingly unpopular,²⁶ pharmaceutical companies and interest groups have

ons/HowtoapplyforOrphanProductDesignation/ucm364750.htm (last updated Aug. 2013).

¹⁹ Sarah Jane Tribble & Sydney Lupkin, *Drugs For Rare Diseases Have Become Uncommonly Rich Monopolies*, NAT’L PUBLIC RADIO (Jan. 17, 2017, 4:59 AM), <http://www.npr.org/sections/health-shots/2017/01/17/509506836/drugs-for-rare-diseases-have-become-uncommonly-rich-monopolies>.

²⁰ *Id.*

²² *Id.*

²³ *Id.*

²⁴ *Id.*

²⁶ See, e.g., Alan Haycox et al., *Patent expiry and costs for anti-cancer medicines for clinical use : expiry and costs anti-cancer medicines*. 6 GENERICS & BIOSIMILARS INITIATIVE J. 105 (2017), <http://gabi-journal.net/patent-expiry-and-costs-for-anticancer-medicines-for-clinical-use.html> (finding drastically increased prices for cancer drugs to have only “marginal health gains” compared with lower priced drugs developed previously); Donald W. Light & Hagop Kantarjian, *Market Spiral Pricing of Cancer Drugs*, 119 CANCER 3900, 3900 (2013), <http://onlinelibrary.wiley.com/doi/10.1002/cncr.28321/> (arguing that “cancer drugs should be priced lower” because there is no data to support the position that higher prices correlate with added value in new cancer drugs); Ayalew Tefferi et al., *In Support of a Patient-Driven Initiative and Petition to Lower the High Price of Cancer Drugs*, 90 MAYO CLINIC PROC. 996, 997 (2015), <http://dx.doi.org/10.1016/j.mayocp.2015.06.001> (warning that high drug prices “ultimately harm[] patients with cancer and our health care system”); Narcyz Ghinea et al., *If We Don’t Talk About Value, Cancer Drugs Will Become Terminal for Health Systems*, THE CONVERSATION (July 26, 2015, 4:12 PM), <http://theconversation.com/if-we-dont-talk-about-value-cancer-drugs-will-become-terminal-for-healthsystems-44072> (giving examples of

helped morph data exclusivity into a more potent weapon more often than not, to the detriment of cost of medication and access to medication.²⁷ The much higher standard of data exclusivity sought under the now-failed Trans-Pacific Partnership is a great example.²⁸ In both trade negotiations and free trade agreements with other countries, the US tends to prefer definitions that interpret Article 39 of TRIPS more stringently, in a manner requiring a much higher data protection requirement. The important aspect to remember is that such compromises need not be emulated in every market, especially in countries that have a policy focus on enabling access to medication.²⁹

prominent oncologists in the US and Australia criticizing the rising cost of cancer medications).

²⁷ E.g., Srividhya Ragavan, *Data Exclusivity: A Tool to Sustain Market Monopoly*, 3(5) JINDAL L. REV. 1 (2017); see also Srividhya Ragavan, *The Significance of the Data Exclusivity Debate and its Impact on Generic Drugs*, 1 J. INTELL. PROP. STUD. 131, 133–34 (2017) (“Data submitted for marketing of pharmaceutical . . . products is treated differently partly because of the powerful lobbies of pharmaceutical corporations and interests they represent worldwide.”).

²⁸ See Kristina Lybecker, *When Patents Aren’t Enough: The Case for Data Exclusivity for Biologic Medicines*, IPWATCHDOG (July 9, 2014), <http://www.ipwatchdog.com/2014/07/09/patents-arent-enough-data-exclusivity-for-biologic-medicines/id=50318/> (“Protecting the intellectual property of biologics is . . . one of the remaining hurdles in the Trans-Pacific Partnership (TPP) Trade Agreement negotiations.”); *What Does the TPP Say About Data Exclusivity and Biosimilars?*, MANAGED CARE, <https://www.managedcaremag.com/focus/what-does-tpp-say-about-data-exclusivity-and-biosimilars> (last visited Apr. 5, 2018) (providing a contemporaneous account of the TPP negotiations with respect to data exclusivity).

²⁹ See, e.g., Winnie de Bruijn et al., *Introduction and Utilization of High Priced HCV Medicines across Europe; Implications for the Future*, FRONTIERS IN PHARMACOLOGY, July 2016, at 7, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4964878/> (explaining that “risk sharing agreements and discounts are used by health authorities to control budgets, enabling patients to have access to new high priced medicines”); Maria Phelan & Catherine Cook, *A Treatment Revolution for Those Who Can Afford It? Hepatitis C treatment: New Medications, Profits and Patients*, 14 BMC INFECTIOUS DISEASES S5 (Supp. 6 2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4178584/> (discussing how a pharmaceutical company allowed some countries to make these new medicines available at cost for their populations or appreciable discounts); Srividhya Ragavan, Comment, *Patients Win Over Patents*, HINDU, Mar. 7, 2013, <http://www.thehindu.com/opinion/op-ed/patients-win-over-patents/article4482469.ece> (last updated July 21, 2016) (summarizing an example of Indian government authorities

The question of implementing Article 39 of TRIPS has current significance for WTO members that are developing countries. While WTO members have an obligation to protect data submitted to regulatory bodies, the main objective of Article 39.3's prescription is to provide members the freedom to define the terms flexibly.³⁰ Thus, WTO members that are developing countries should carefully define elements of the article such as "undisclosed test data," or, constituents of "unfair commercial use" in a manner facilitating access to medication.³¹ For instance, under the Article 39.3 while members are required to protect data "against disclosure," there is nothing to suggest that disclosing the data to a government regulator should be construed as "unfair commercial use." Similarly, WTO members should carve out clear public interest exceptions to allow for the use of the data. Developing countries should also follow the pre-TRIPS position under which most countries allowed reliance on innovator test data to approve generic products.³² Generic manufacturers had to prove bioequivalence, which is that their product was chemically identical to the brand-name, original product.³³ This approach was consumer-friendly in that it enabled introduction of generics into the market as soon as the patent expired. The importance of preserving this traditional approach is underscored by the recent UN High Level Panel Report on Access to Medicines,³⁴ the WIPO Development Agenda,³⁵ and the WHO

compelling a multinational pharmaceutical company to license one of its patented drugs to a local generic manufacturer to ensure reasonable pricing); Srividhya Ragavan & Raj Dave, Opinion, *The Right Prescription to the IPR Debate*, HINDUSTAN TIMES, Sep. 29, 2014, <http://www.hindustantimes.com/ht-view/the-right-prescription-in-the-ipr-debate/story-aEvB8EGLIsoweSdpozDwBI.html> (summarizing the Indian government's program of voluntary and compulsory licensing of high-cost patented drugs).

³⁰ Wael Armouti & Mohammad F.A. Nsour, *Data Exclusivity for Pharmaceuticals: Was It the Best Choice for Jordan Under the U.S.-Jordan Free Trade Agreement?*, 17 OR. REV. INT'L L. 259, 260 (2016).

³¹ *Id.*; see also *WTO & the Trips Agreement*, WORLD TRADE ORGANIZATION, http://www.who.int/medicines/areas/policy/wto_trips/en/.

³² TRIPS Agreement, *supra* note 7.

³³ See Ragavan, *Data Exclusivity*, *supra* note 27, at 16–17.

³⁴ See *Report of the United Nations High Level Panel Report on Access to Medicines*, UNITED NATIONS, (Sept. 2016), <http://www.unsgaccessmeds.org/final-report/>.

³⁵ See generally *Development Agenda for WIPO*, WORLD INTELLECTUAL PROPERTY ORGANIZATION, <http://www.wipo.int/ip-development/en/agenda/>.

studies,³⁶ all of which also highlight the importance of access to medicines. It is a documented fact that generics have not only been able to save costs, but also enable access to medication in several parts of the world.³⁷

Lastly, developing countries should avoid instituting “patent linkage,” the tying-in of patent information with data exclusivity.³⁸ Countries such as the United States provide for patent linkage, which essentially prevents regulators such as the FDA from approving a competing product during the patent term.³⁹ When a generic drug company submits an application to get marketing approval, the FDA will process the application only if there is no valid patent on the application material. When

³⁶ See Ed Silverman, *Hepatitis C Drugs Remain Unaffordable in Many Countries, Says WHO Study*, STAT: PHARMALOT (May 31, 2016), <https://www.statnews.com/pharmalot/2016/05/31/gilead-hepatitis-drug-prices-who/> (discussing a WHO study that examined the 2015 prices for certain drugs in over 30 countries); *Over 1 Million Treated with Highly Effective Hepatitis C Medicines*, WORLD HEALTH ORG. (Oct. 27, 2016), <http://www.who.int/mediacentre/news/releases/2016/hepatitis-c-medicines/en/> (discussing a WHO report on access to Hepatitis C treatments).

³⁷ See, e.g., Alexandra Cameron et al., *Switching from Originator Brand Medicines to Generic Equivalents in Selected Developing Countries: How Much Could Be Saved?*, 15 VALUE IN HEALTH 664, 671 (2012) (explaining the results of a study demonstrating the cost-effectiveness of generics and urging governments to “consider intervening . . . to improve access to affordable medicines”); Brian Godman et al., *Multiple Policies to Enhance Prescribing Efficiency for Established Medicines in Europe with a Particular Focus on Demand Side Measures: Findings and Future Implications*, 5 FRONTIERS IN PHARMACOLOGY 1, 5–6 (2014) (highlighting some of the policies that Europe pursued to maintain universal health care); Brian Godman et al., *Payers Endorse Generics to Enhance Prescribing Efficiency: Impact and Future Implications, a Case History Approach*, 1 GENERICS & BIOSIMILARS INITIATIVE J. 69, 75 (2012) (asserting that the savings from generics when compared with the originator are considerable); *Generics Could Cut Costs of Cancer Drugs by Over 99%*, GENERICS & BIOSIMILARS INITIATIVE (Apr. 4, 2017), <http://www.gabionline.net/Generics/Research/Generics-could-cut-costs-of-cancer-drugs-by-over-99> (describing a study that suggested “significant price reductions” for cancer drugs through the use of generics).

³⁸ Ravikant Bhardwaj et al., *The Impact of Patent Linkage on Marketing of Generic Drugs*, 18 J. INTELL. PROP. RTS. 316, 316 (2013); G. Lee Skillington & Eric M. Solovy, *The Protection of Test and Other Data Required by Article 39.3 of the TRIPS Agreement*, 24 NW. J. INT’L L. & BUS. 1, 34 (2003).

³⁹ See 21 U.S.C. §§ 355(c)(3)(E), (j)(5)(F) (2012) (providing limited protection from competition for new drug applications); see also *Small Business Assistance: Frequently Asked Questions for New Drug Product Exclusivity*, U.S. FOOD & DRUG ADMIN. (Feb. 11, 2016), <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm069962.htm> (explaining 21 U.S.C. §§ 355(c)(3)(E), (j)(5)(F), also known as “new drug product exclusivity”).

the Hatch-Waxman Act was enacted in the United States in 1984, innovator pharmaceutical companies realized that they could not deny generic drugs market access for much longer and hence, patent linkage was proposed as an alternative to delay the entry of generic competition.⁴⁰

Developing countries should appreciate that patent linkage results in delaying the entry of generic competition because marketing approval cannot be obtained for manufacturing the product until the patent expires. Thus, from the time the patent expires and until the generic drug is cleared for the market, the innovator will indirectly enjoy a market monopoly even after the patent expires. Therefore, countries such as India, which predominantly houses a generic drug industry, and other countries such as Brazil and Chile, which provide Universal Health Coverage, would be disadvantaged by patent linkage because it largely serves to delay generic drug companies from entering into the market. One of the best examples for determining the question of patent linkage is India where the question arose in relation to the approval of a generic version of “sorafenib tosylate” used to treat renal cell cancer.⁴¹ Bayer, the patent owner, wanted India to prevent Cipla from being granted marketing approval.⁴² Bayer asserted that the TRIPS Agreement necessitated the establishment of patent linkage to prevent the Drug Controller from approving the marketing of drugs whose patent was not owned by the applicant, Cipla. The Delhi High Court was persuaded by the presence of a Bolar Provision under Section 107A of the Indian Patents Act of 1970, which specifically exempted the use of data for regulatory approval from infringement with a view to permit immediate availability of generic drugs in the market when the patent expires.⁴³ On appeal, the Supreme Court sustained the judgment of the Delhi High Court and rejected the applicability of patent linkage in India. Nevertheless, the United States has repeatedly sought to

⁴⁰ D. Christopher Ohly & Sailesh K. Patel, *There is No Orange Book: The Coming Wave of Biological Therapeutics*, 6 J. INTELL. PROP. L. & PRAC. 464, 476–77 (2011) (explaining that innovator companies sought data exclusivity as a “*quid pro quo*” for permitting more generic access).

⁴¹ Bayer Corp. v. Union of India, WP(C) No.7833/2008 (Delhi H.C. Aug. 18, 2009),

<http://www.manupatra.com/manufeed/contents/PDF/633862911775465000.pdf>.

⁴² *Id.* at 2.

⁴³ *Id.* at 12.

pressure India under the Special 301 process to recognize patent linkage on the grounds that Article 39 of TRIPS requires it.⁴⁴

In reality, patent linkage also affects the operation of compulsory licenses, which remains an important tool to tackle public health crises in developing countries. When there is a public health crisis, the presence of patent linkage can operate to prevent a regulator from approving drugs that may be necessary to resolve the crisis. Considering that data exclusivity, as a tool, detrimentally affects generic competition, it is no coincidence that the Office of the United States Trade Representative (USTR) continually pressures developing countries to either extend or increase existing data exclusivity periods.⁴⁵ Hence, it is especially critical that countries appreciate the limits of the flexibilities involved in the international obligations relating to protection of test data. The bottom line is Article 39.3 of the TRIPS Agreement is certainly not worded to impose restrictions such that data exclusivity becomes a hurdle to public health. In any case, considering that the access-to-medication question has become a burden that TRIPS continues to bear poorly, it is critical for countries that either focus on access to medication or house a robust generic drug industry to chart their own courses under Article 39.3.

The End

⁴⁴ Sean M. Flynn, *Special 301 of the Trade Act of 1974 and Global Access to Medicine*, J. GENERIC MEDICINES (forthcoming Jan. 2010) (manuscript at 29), http://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1000&context=pjip_facsch.

⁴⁵ Xavier Seuba, *Pharmaceutical Test Data Protection & Human Rights*, in *RESHAPING INTELLECTUAL PROPERTY LAW THROUGH A HUMAN RIGHTS LENS* (P. K. Yu ed., forthcoming 2017) (extensively discussing access to medication issues arising from data exclusivity).