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Beyond Traditional IP

Addressing Regulatory Barriers

Cynthia M. Ho

The COVID pandemic has underscored that intellectual property (IP) can limit the ability to address public health crises because IP owners have the legal right to bar others from making needed supplies. However, what is less well understood yet critical to making medical treatments available are IP-related barriers existing in regulatory laws that complement traditional IP protection. In other words, even if a potential manufacturer of a needed treatment can obviate patent and trade secret hurdles, that manufacturer could be thwarted due to less well understood regulatory barriers.

There are two key barriers to treatments for which regulatory authorities are involved in review, such as drugs and vaccines. The most dominant is "data exclusivity," which can prevent approval of follow-on treatments (a generic or biosimilar)[1] by barring reliance on previously submitted clinical data of the comparator original that is used to expedite regulatory approval of these lower-cost treatments.[2] In addition, in some countries "patent linkage" can bar regulatory approval of a safe and effective drug solely due to alleged infringement of patent (s) associated with making that drug.

The chapter begins with the genesis of these regulatory protections and their general parameters before discussing their prevalence among countries. It then turns to discussion of proposed and actual modification of Trade Related Agreement on Intellectual Property Rights (TRIPS) requirements for COVID and how that intersects with these regulatory barriers. The chapter concludes with recommendations.

[1] A generic drug has the same active ingredient as the original drug and is what most people consider as drugs that come in pill or tablet form. A biosimilar is a biologic drug that is injected or infused. But, like a generic, it is a lower cost version of an original drug.

[2] This is sometimes referred to as "test data exclusivity" in reference to the clinical tests that provide a measure of exclusivity, or alternatively as "data protection" or "regulatory data protection."

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1 BACKGROUND

A *Genesis*

Data exclusivity and patent linkage were both introduced in the United States in 1984 as part of a legislative compromise intended to promote development of new drugs and expedite generic entry, along with other amendments to patent laws to similarly promote the same balance.[3] Although some aspects of these laws create regulatory barriers, they have also helped to promote more generics.[4]

The new law promoted generic entry by permitting proposed manufacturers of generics to rely on clinical data of the originator drug companies to help infer the generic is safe and effective with a limited showing of bioequivalence to the original; this essentially provided an expedited approval process that avoided unnecessarily duplicating all the same clinical tests of the original approved drugs.[5] This reliance was only possible after a newly established term of data exclusivity from the date of approval of the originator. Permitting subsequent companies to rely on this clinical data to obtain regulatory approval was a major improvement. Previously, the Food and Drug Administration (FDA) considered this data to be an indefinite trade secret.[6] As a result, there were few generic drugs approved even after patents on the original drugs expired since potential generic companies needed to create their own clinical data, but could not recoup costs to do so.[7] Whereas the manufacturer of a new drug can easily recoup the costs of its clinical data by charging a premium enabled by a patent, a generic is by definition a copy of another's drug and so would not meet the patent requirement of being "new." To address pioneer companies' concerns about the ability of generic companies to "free ride" on the time and expense of their data, data exclusivity was created.

[3] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, 1585–1605 (codified as amended at 21 U.S.C. § 355). The balance was required after modern standards of safety and efficacy for drugs to be sold were established in 1962. This resulted in a longer regulatory review of new drugs, which limited the effective patent term. At the same time, the new standards were hard to meet for generic companies which needed to create their own clinical data for generics approved after 1962. *See, e.g.*, Hatch–Waxman Act: A Primer, Congressional Research Service 8–9 (2016).

[4] Before this legislation, only two of the top thirteen drugs had generic competition within a year of patent expiration, whereas a decade after the legislation was enacted, eleven drugs had generic competitors within two years of patent expiration. David Reifin & Michael Ward, *Generic Drug Industry Dynamics* 6 (FTC Working Paper No. 248, 2002), www.ftc.gov/reports/generic-drug-industry-dynamics (last visited Feb. 23, 2023).

[5] 21 U.S.C. § 355(j)(2)(A)(iv).

[6] *E.g.*, Henry G. Grabowski & John M. Vernon, *Effective Patent Life in Pharmaceuticals*, 19 Int'l J. Tech. Mgmt. 98, 104 (2000).

[7] *E.g.*, Gerard J. Mossinghoff, *Overview of the Hatch–Waxman Act and Its Impact on the Drug Development Process*, 54 Food & Drug L.J. 187, 187 (1999) (noting 150 drugs whose patents had expired, but for which there were no generics).

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In addition, generic companies obtained an exception from patent infringement for making a patented drug as part of clinical tests needed to create its proposed equivalent to conduct bioequivalence testing and obtain regulatory approval. This patent exception promoted generic approval and avoided undue extension of the patent term that would otherwise occur, since it typically takes years for regulatory authorities to review data. Although new at the time, most countries today have similar laws and the patent exception is also consistent with international IP rules.[8]

Creators of new drugs also obtained benefits from this new law. First, they obtained an extension of the patent term to compensate for the fact that review of drug applications usually reduces the effective term of a patent since a patented drug has no market power without regulatory approval.[9] Moreover, these creators obtained patent linkage, a powerful new way to bar competitors from the marketplace by delaying regulatory approval to address alleged patent infringement. As a result of this law, applicants of new drugs submit a list of patents that would allegedly be infringed by manufacturing the drug when seeking regulatory approval. When drugs are approved, the patents covering the drugs, as well as their expiration dates, are published in conjunction with the drugs so that potential generic applicants are aware of these patents.[10] Generic applicants need to certify as part of their regulatory approval that there are no unexpired patents, thus creating a link between patent status and regulatory approval.[11] Although the United States created a mechanism for a generic to potentially challenge whether linked patent(s) were invalid or not infringed, the system still generally resulted in an undue delay of two or more years while the patent issues were litigated.[12]

In 1987, the EU created a similar abbreviated pathway for approving generics by permitting them to rely on earlier clinical data after a newly created period of data exclusivity expired.[13] Data exclusivity was granted for different reasons in the European Union than in the United States. Not all EU member states at the time

[8] Cynthia M. Ho, Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights 260 (2011); WTO Panel Report, Canada – Patent Protection of Pharmaceutical Products, WT/DS114/R (Mar. 17, 2000) [hereinafter WTO, Canada-Generics].

[9] 35 U.S.C § 156 (extension of up to fourteen years maximum).

[10] *E.g.*, Fish & Richardson, Orange Book 101 (Mar. 8, 2022), www.fr.com/orange-book-101/ (last visited Feb. 23, 2023).

[11] 21 U.S.C. § 355(j)(II). Generic applicant can also certify no patent(s) listed, or expired. 21 U.S.C § 355(j)(I–IV).

[12] Regulatory approval for a generic is stayed for thirty months, or until a court finds the patent invalid/not infringed, whichever comes first. 21 U.S.C. § 355(j)(5)(B)(iii).

[13] Council Directive 87/21/EEC of Dec. 22, 1986, art. 1(1), 1986 O.J. (L. 015) (amending art. 4 of Council Directive 65/65/EEC of Jan. 26, 1965 on the Approximation of Provisions Laid Down by Law, Regulation or Administrative Action Relating to Proprietary Medicinal Products) (creating minimum six-year period of exclusivity). This legislation is now superseded by a harmonized period in all EU countries. Directive 2004/27/EC of the European Parliament and of the Council of Mar. 31, 2004, O.J. (L. 136) 34–57.

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provided the scope of patent protection desired by the pharmaceutical industry; Spain and Portugal did not provide product patents to pharmaceuticals and instead only patented *methods* of making drugs.[14] The European Union, however, has thus far not adopted patent linkage; the EU considers patents irrelevant to the function of a regulatory agency that is intended to protect public health.[15]

B *Parameters of Regulatory Barriers*

Data Exclusivity

Data exclusivity essentially bars a subsequent applicant from relying on the clinical data of the original manufacturer for the period of the exclusivity to seek expedited approval of new treatment without creating its own clinical data.[16] During the term of data exclusivity, no reliance is possible and applications for follow-on versions will not be approved.[17] Some countries extend the term of exclusivity based on submission of additional clinical data relating to new use of an existing drug, or pediatric use.[18] Also, some countries provide a separate type of exclusivity to promote "orphan drugs" to treat rare conditions even if there is no reliance on any clinical data.[19]

DATA EXCLUSIVITY RATIONALE? Proponents of data exclusivity argue that it protects and encourages investment in producing clinical data that supports new

[14] *E.g.*, Valerie Junod, *Drug Marketing Exclusivity under United States and European Law*, 59 FOOD & DRUG L.J. 479, 503 (2004) (noting they did not provide patent protection until 1992).

[15] EUROPEAN COMMISSION, PHARMA SECTOR INQUIRY: FINAL REPORT 130 (2009). However, some member states have implemented, or are considering implementing, patent linkage tied to reimbursement of drugs.; K. D. Raju, *Patent Linkages and Its Impact on Access to Medicines: Challenges, Opportunities for Developing Countries*, in ACCESS TO MEDICINES AND VACCINES 329, 336–337 (C. M. Correa & R. M. Hilty eds., 2022).

[16] Data exclusivity generally only applies for drugs that have a new chemical entity, but not mirror images of existing drugs. Junod, *supra* note 14, at 494; *See also* 21 C.F.R. § 314.108(b)(1985) (amended 2021) (clarifying that new chemical entity focuses on active moiety, not the broader term active ingredient).

[17] Some countries will accept follow-on applications at some point during this period, but others refuse to do so. If no applications are accepted, there will be a further delay since it takes about eighteen months to review applications. *E.g.*, Junod, *supra* note 14, at 494. The EU will not approve applications for two years after the data exclusivity term expires. Council Directive 2001/83, art. 10, 2001 O.J. (L. 311); *see also* Graham Lewis et al., European Union: Data Exclusivity and Market Protection in the EU (Sep. 21, 2021), www.mondaq.com/uk/data-protection/1113376/data-exclusivity-and-market-protection-in-the-eu-eea-and-uk (last visited Feb. 23, 2023).

[18] *E.g.*, 21 U.S.C. 355(j)(5)(D)(iii), (v) (three-year additional exclusivity); 21 U.S.C. § 355(a)(six-month period of exclusivity for completion of pediatric studies requested by FDA); Council Directive, 2004/27/EC, art. 10.1, ¶ 2, 2004 O.J. (L. 136) 34-57 (one year for new indications).

[19] 21 U.S.C. § 360(cc) (2006); Regulation (EC) No. 141/2000, Dec. 16, 1999 on orphan medicinal products, 2000 O.J. (L.18) 1.

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drugs.[20] However, this is the same justification for the existence of patent protection, such that some have argued there is no need for both data exclusivity and patent protection.[21] That said, the industry and some commentators argue that data exclusivity may be helpful for providing protection for drugs that have some value, even if unpatentable.[22] In addition, the industry has claimed that data exclusivity will promote more investment in countries that provide it.[23]

But is data exclusivity justified? A new drug must provide clinical data of safety and efficacy to be marketed and the clinical data from these tests are not improved in any way if data exclusivity is granted to its creator. Moreover, the policy reason for providing data exclusivity in countries with less economic means seems particularly tenuous given that it slows access to lower cost drugs without any public benefit. This is especially true since the current data does not show any positive effect of adding data exclusivity on the economic development for countries in the Global South, rebutting the claim that data exclusivity will promote more investment in countries that provide it.[24]

HOW DATA EXCLUSIVITY IS DIFFERENT THAN PATENT PROTECTION Patents and data exclusivity have different requirements. A patent is only awarded to an invention after verification that it meets certain requirements (such as being novel and having an "inventive step") and provides a disclosure of information to the public who can then build on this invention; these requirements are considered part of the social bargain to justify the high prices that result from patent protection. In contrast, there are no similar requirements of novelty of a drug, or public disclosure to receive data exclusivity. Rather, it is generally automatically "granted" for a drug deemed to satisfy usual regulatory standards of being safe and effective. Although, like patents, data exclusivity can provide a measure of exclusivity in the marketplace, it cannot be challenged in the same way as patents; for example, whereas patents can be challenged for failing to meet patentability requirements (such as not actually being novel), there is generally no possible challenge to data exclusivity for a drug deemed safe and effective. In addition, unlike the issuance of a patent that comes with an official document that provides its owner legal rights to enforce in a judicial system, data exclusivity is enforced not by its owner, but by government agencies.

[20] *E.g.*, IFPMA, ENCOURAGEMENT OF NEW CLINICAL DRUG DEVELOPMENT: THE ROLE OF DATA EXCLUSIVITY 5 (2000).

[21] Yaniv Heled, *Patents versus Statutory Exclusivities in Biological Pharmaceuticals – Do We Really Need Both?*, 18 MICH. TELECOMM. & TECH. L. REV. 419 (2012).

[22] IFPMA, *supra* note 20, at 5; Rebecca Eisenberg, *Role of FDA in Innovation Policy*, 13 MICH. TELECOMM & TECH. L. REV. 345, 366 (2006).

[23] IFPMA, *supra* note 20, at 5.

[24] *E.g.*, OWAIS H. SHAIKH, ACCESS TO MEDICINE VERSUS TEST DATA EXCLUSIVITY 31–33 (2016); Michael Palmedo, *Evaluating the Impact of Exclusivity on the Price per Kilogram of Pharmaceutical Imports*, Global Development Policy Center (2021), www.bu.edu/gdp/files/2021/04/GEGI_WP_048_Palmedo_FIN.pdf (last visited Feb. 23, 2023).

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Essentially, where it exists, governments are barred from approving a subsequent drug that relies on the previously submitted clinical data during the period of data exclusivity.[25] Unlike with patent protection, nothing is disclosed to the public in exchange for this exclusivity. Whereas patent protection is often justified in part due to the disclosure of how to make and use the invention that might otherwise be kept as a trade secret, there is no similar justification for data exclusivity.[26] And, in fact, even in countries that do not provide data exclusivity, companies must provide the same clinical data to be able to sell their drug. Also, whereas patents and most other types of IP are enforced by the IP owner, data exclusivity is enforced by regulatory agencies. Lastly, although most countries have an exception from usual patent rights for compulsory licenses, most nations do not have an exception from data exclusivity to ensure effective use of a compulsory license.[27]

INTERSECTION OF DATA EXCLUSIVITY AND PATENT PROTECTION When a drug is subject to both data exclusivity and patent protection, the term of data exclusivity may impact whether it lasts beyond patent protection. The effective term of a patent is about twelve years from grant of regulatory approval, which is longer than the five-year term of data exclusivity in most countries.[28] However, data exclusivity can last beyond the patent term for a drug whose patent application was pending a long time, if a regulatory approval process was lengthy, or if a country provides a longer term of data exclusivity or delay before approval of a generic. Also, in the United States, although there is a five-year term of data exclusivity for conventional drugs, there is a twelve-year term for more complex and expensive biological drugs such as insulin. So, in such cases, data exclusivity can sometimes outlast patent protection, but even then, it could depend on whether there are multiple patents. The arthritis drug Humira, for example, was first approved for sale in the United States in 2002 and although the initial patent on the drug composition expired in 2016, due to a thicket of over 100 patents on different aspects of the drug it is still under some

[25] *E.g.*, 21 U.S.C. 355(j)(5)((F)(ii)(A)(generic application relying solely on prior data); *See also* 21 U.S.C. 355(c)(3)I(ii)(application that includes some new clinical data in addition to relying on prior data).

[26] The industry suggests that there is a benefit in that generics can rely on the data. *E.g.*, IFPMA, Encouragement of New Clinical Drug Development: The Role of Data Exclusivity 2 (2000). But some countries permit reliance without data exclusivity; India not only lacks data exclusivity but will even approve generics without a showing of bioequivalence if the originator has been on the market for at least four years. *E.g.*, Sarandindu Bhaduri & Thangminlen Kipgen, *New Drugs Approvals in India: An Institutional Perspective*, 23 Sci. Tech. & Soc. 444, 452 (2018).

[27] Some scholars have even argued that data exclusivity provisions are included in free trade agreements to undermine the utility of compulsory licenses. Adam Alexander Buick, The origins, Globalisation and Impact on Access to Medicine of Intellectual Property Rights in Submitted Pharmaceutical Test Data 35 (2019).

[28] Data Exclusivity and Other TRIPS-plus Measures, World Health Organization 2 (2017); Grabowski & Vernon, *supra* note 6, at 113.

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patent protection more than twenty years later despite a novel challenge on antitrust grounds.[29] There are also situations beyond the United States where generic drugs can be delayed after the patent expires due to data exclusivity or other protection, such as supplementary protection certificates that essentially extend patent protection. For example, a study of these TRIPS-plus provisions imposed on Ukraine found that the average delay of generics was over one year due to such provisions.[30]

In addition, whereas the novelty requirement of patents requires companies to apply promptly (to avoid a bar to patentability), there is no similar criteria that would prompt a company to seek regulatory approval in less profitable countries where data exclusivity applies. Since most countries provide exclusivity from the date of domestic approval, rather than first global approval, there is often no incentive to seek timely approval in all countries – unless a country specifically requires data exclusivity to begin from first global approval. Unless data exclusivity is triggered by first global approval, companies may deliberately introduce products later in less profitable developing countries so that they can first benefit from exclusivity in the wealthier countries, followed by an additional term in the developing country.

Moreover, although patent and data exclusivity are separate barriers, sometimes data exclusivity alone will be a problem. There are different reasons this could be the case. First, there may be no patent either because a patent application was denied, or an issued patent was invalid. So, sometimes data exclusivity alone can be a barrier to generic drugs. This was the case in Russia where the primary patent on a Hepatitis C treatment was partially revoked, but data exclusivity barred generics for six years.[31]

INTERSECTION OF DATA EXCLUSIVITY AND EMERGENCY APPROVAL Data exclusivity, along with the ability to use an expedited path for follow-on approval begins with traditional regulatory approval of a drug. Data exclusivity may not exist when there is *emergency* approval of a new treatment that is likely to occur during a pandemic based on a more limited showing of data.[32] For example, in the United States data exclusivity is reflected in laws that bar a subsequent applicant from

[29] *E.g.*, Mayor v. Abbvie, F.4th 709 (7th Cir 2022) (rejecting the argument that a large number of patents on a single drug constitutes an antitrust violation); *see also* David Shotlander & Tiffany Jang, *Abbvie's Humira Patent Portfolio not an Antitrust Violation*, Bloomberg Law (Sep. 2, 2022), https://news.bloomberglaw.com/ip-law/abbvies-humira-patent-portfolio-not-an-antitrust-violation (last visited Feb. 23, 2023) (discussing court decision reporting issue of first impression).

[30] *New Study Demonstrates the Impact of Patents in Ukraine*, Make Medicines Affordable (Dec. 20, 2020), https://makemedicinesaffordable.org/new-data-demonstrates-the-impact-of-patents-in-ukraine/ (last visited Feb. 23, 2023).

[31] *Hepatitis C: Not Even Close*, Issue Brief 5 (2017), Médecins Sans Frontières, https://msfaccess.org/hepatitis-c-not-even-close (last visited Feb. 23, 2023).

[32] For information about emergency approval, *see* 21 U.S,C, 564; Regulation (EC) No. 507/2006; *see generally* Hiddeki Macda, *Japan's Special Approval for Emergency System during the COVID-19 Pandemic*, 111(3) Clinical Pharmacology & Therapeutics 551 (2021).

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relying on data from a fully approved drug; there is no expedited generic approval based on emergency approval.[33] However, depending on how long an emergency situation lasts, there could be time to obtain full approval of drugs initially approved based on emergency authorization. For example, both the Pfizer and Moderna COVID-19 vaccines received full approval in the United States about eight months after emergency approval.[34]

It is also possible that a drug approved before a pandemic could be discovered to be useful for a pandemic. In such a situation, even if there was emergency approval of the drug for the new use, a data exclusivity period based on the original approval could bar a company from obtaining regulatory approval to make a follow-on drug. This seems especially true in a country that has a longer period of data exclusivity. On the other hand, if a drug is long known, data exclusivity would have expired. That was true for hydroxychloroquine, which was initially considered a promising treatment for COVID-19; it was first approved to treat malaria in 1950, such that no data exclusivity existed during the COVID-19 pandemic that would have barred generics.[35]

Patent Linkage

The term *patent linkage* refers to a conditional relationship between approval of a follow-on drug and the patent status of the original product. If one or more patents are linked to making the follow-on drug, that may delay its marketing approval. Importantly, a follow-on drug could be denied regulatory approval not based on the usual regulatory standards of safety and efficacy, but solely on a *potential* patent problem. Typically, information about whether a drug (or its active ingredient) would be infringed when made is based on assertions by self-interested patent owners. A company that seeks marketing approval for a new drug typically informs a regulatory agency of patent(s) the company asserts would be violated by anyone making that drug. There is often no independent assessment by the regulatory

[33] 21 U.S.C. 355(j)(5)(F)(ii).

[34] *E.g.*, *FDA Grants Full Approval to Moderna Vaccine*, NBCNews (Jan. 31, 2021), www.nbcnews.com/health/health-news/fda-grants-full-approval-modernas-covid-vaccine-rcna14237 (last visited Feb. 23, 2023); *see also* Pfizer Receives US FDA Emergency Use Authorization for Novel COVID_19 Oral Antiviral Treatment (Dec. 22, 2021), www.pfizer.com/news/press-release/press-release-detail/pfizer-receives-us-fda-emergency-use-authorization-novel (last visited Feb. 23, 2023) (noting Pfizer plans to seek full approval for Paxlovid within a year of obtaining emergency approval).

[35] Agata Dabrowska & Victoria R. Green, Treatment of COVID-19: Hydroxychloroquine and Chloroquine, Congressional Research Service 2 (2020); Alfred H. J. Kim, *FDA Approves Hydroxychloroquine New Drug Application to Address COVID-19 Related Shortage* (Apr. 8, 2020), www.healio.com/news/rheumatology/20200408/fda-approves-hydroxychloroquine-new-drug-application-to-address-covid19-related-shortage (last visited Feb. 23, 2023).

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agency that enforces patent linkage of whether the patent(s) associated with a drug are relevant, let alone valid.[36]

IS THERE MORE THAN ONE TYPE OF PATENT LINKAGE? There are different ways that nations provide patent linkage. A country may bar or stay regulatory approval of a generic entirely based on alleged patent infringement.[37] Another possibility is that a country may permit the patent owner to address the patent issue with the alleged infringer in a litigation or administrative proceeding. Yet another possibility is that a country could notify the patent owner of a follow-on application, but without the need to delay approval to resolve a patent issue. In addition to these three mechanisms, nations may provide the same system of patent linkage for all follow-on drugs, or different systems for generics versus biosimilars.[38]

WHAT IS THE JUSTIFICATION FOR PATENT LINKAGE? Companies that develop new drugs generally argue that patent linkage is needed to ensure effective patent enforcement.[39] However, the usual way to enforce patents is for patent owners to pursue their own claims in court. The industry argues that judicial enforcement, even with the possibility of preliminary injunction, is uncertain. It is true that patent linkage can provide more certainty by absolutely barring approval of an allegedly infringing drug. However, it is a costly one for society in terms of preventing timely approval of lower-cost drugs that may not in fact infringe any patents since patent linkage occurs generally without review of patent issues.[40]

WHAT DOES PATENT LINKAGE ADD TO TRADITIONAL PATENT PROTECTION? Patent linkage can be a major hurdle that delays entry of follow-on drugs if a regulatory agency stays approval. This is true even in countries that permit the follow-on manufacturer to challenge the patent because such challenges

[36] The FDA does not verify, but in Canada and Korea, inappropriate patents can be removed. *E.g.*, Kyung-Boi Son et al., *Moderating the impact of Patent Linkage on Access to Medicines: Lessons from Variations in South Korea, Australia, Canada and the United States*, 14 GLOBALIZATION & HEALTH 1, 6 (2018).

[37] Japan regulatory authorities do this. *E.g.*, Hye Eun Shin, *Comparative Study on Patent Approval Linkage System*, Institute of Intellectual Property, Japan (2018), www.iip.or.jp/e/summary/pdf/detail2018/EN_Abstract_Summary_Shin.pdf (last visited Feb. 23, 2023).

[38] The United States has a slightly different process of patent linkage for biosimilars, although the process is the same in other countries such as Canada, Australia and Korea. Son, *supra* note 36, at 6.

[39] *E.g.*, PhRMA Special 301 Submission 27 (2022), www.phrma.org/resource-center/Topics/Intellectual-Property/PhRMA-Special-301-Submission-2022 (last visited Feb. 23, 2023) (considering issues with patent linkage a problem of "weak patent enforcement").

[40] *E.g.*, FEDERAL TRADE COMMISSION GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 13 (2002) (finding generic applicants successfully challenged pharmaceutical patents in 73 percent of the cases); Henry Grabowski, *Generic Challenges: Company Strategies and Litigation*, 3 AM. J. HEALTH EC. (2017) (noting generics win 30–70 percent of the time for secondary patents such as method of use and formulation patents).

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take time, which could be a serious problem during a pandemic. However, patent linkage does not add much to patent protection if a country only notifies the patent owner, rather than delaying regulatory approval.

C *International Requirements and Prevalence of Regulatory Barriers*

Before discussing the prevalence of regulatory protections globally, it is important to consider whether any international agreements require them. The foundational international agreement concerning IP is TRIPS, which applies to all members of the World Trade Organization (WTO) – that is, most countries of the world.[41] Since TRIPS was concluded in 1994, the United States and European Union have continued to seek stronger IP protection in a series of free trade agreements (FTAs) often referred to as "TRIPS-plus" agreements since they require more than TRIPS. Data exclusivity is more often required since only the United States requests patent linkage.

IS DATA EXCLUSIVITY REQUIRED? Whether TRIPS requires data exclusivity has been a major point of contention. The TRIPS provision at issue is part of the provisions related to countries generally requiring trade secret protection. In particular, the relevant part ambiguously states:

> 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.[42]

For countries that require submission of clinical data to approve a drug, which is true in most industrialized countries,[43] the United States, European Union, and the pharmaceutical industry claim this provision requires data exclusivity, arguing that reliance on the data of another is "unfair commercial use," but this point is heavily contested.[44] Although the United States did bring a request for consultation, there

[41] TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 320 (1999), 1869 U.N.T.S. 299.

[42] TRIPS, art. 39(3).

[43] Some jurisdictions grant regulatory approval based on the fact that a drug has been previously approved in another country. Alireza Khadem Broojerdi et al., *Worldwide Assessment of Low and Middle-Income Countries' Regulatory Preparedness to Approve Medical Products during Public Health Emergencies*, FRONTIERS MED 722872, at 5 (2021); *see also* CARLOS CORREA, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT 376–377 (2007)(noting that in some countries including Argentina and Singapore, registration of a similar product in another country was adequate to obtain approval).

[44] *E.g.*, CARLOS CORREA, REGISTRATION OF PHARMACEUTICAL AND AGRICULTURAL PRODUCTS 47–52 (2002).

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has never been a WTO panel decision on this issue, leaving it unresolved.[45] There was an earlier draft that explicitly required data exclusivity, but it was not enacted, such that a proper interpretation should indicate that data exclusivity is not required, as many scholars and policymakers agree.[46]

Although TRIPS should not require it, this provision may have prompted some countries to adopt data exclusivity. For example, Jordan, Switzerland, and New Zealand adopted data exclusivity when amending their laws to comply with TRIPS.[47] Even for countries that did not adopt data exclusivity to comply with TRIPS, they may have been required to adopt it because of FTAs that explicitly mandate such an obligation.

IS PATENT LINKAGE REQUIRED? Unlike data exclusivity, most countries do not consider patent linkage to be part of TRIPS.[48] There is nothing in TRIPS that specifically refers to regulatory authorities and patents. The industry has asserted that the general TRIPS provision about providing expeditious remedies to prevent infringement is violated by a country that does not have patent linkage.[49] However, patent linkage does not require a method to challenge a patent; that is simply a feature of some types of patent linkage. Moreover, even FTAs that require patent linkage do not necessarily require a method of challenging a patent covering a drug.[50]

PREVALENCE OF DATA EXCLUSIVITY There are roughly fifty countries and the EU that provide data exclusivity, which is a substantial number, and yet this represents less than half of the over 100 members of the WTO.[51] Data exclusivity exists not only in the United States and European Union, where it originated, but also in other high-income countries such as Australia, Canada, South Korea, New Zealand, and

[45] WTO, Argentina: Patent Protection for Pharmaceuticals and Test Data Protection, Notification of Mutually Agreed Solution, WT/DS196/4 (Jun. 20, 2022).

[46] *E.g.*, Cynthia Ho, *Avoiding the TRIPS Trap: A Path to Domestic Disclosure of Clinical Data Consistent with International Norms*, 54 CORNELL IN'TL L.J. 101, 136–148 (2021); REPORT OF THE UNITED NATIONS SECRETARY GENERAL'S HIGH LEVEL PANEL ON ACCESS TO MEDICINES 25 (2016); WHO, DATA EXCLUSIVITY AND TRIPS PLUS MEASURES 2–3 (2017); CORREA, *supra* note 44, at 387, 391; Peter Yu, *International Enclosure Movement* 82 IND. L.J. 827, 868 (2007).

[47] BUICK, *supra* note 27, at 99–100, 112.

[48] *E.g.*, Son et al., *supra* note 36, at 1; Raju, *supra* note 15, at 332.

[49] *E.g.*, PhRMA Special 301 Submission 135–136 (2021); *see also* BAKER & MCKENZIE AND AIPM, GLOBAL GUIDE TO PATENT LINKAGE 53 (2019) (noting that TRIPS "supports" the concept of patent linkage).

[50] *E.g.*, CPTPP art. 18.53 (permitting either resolution of patent issue or bar of generic without resolution).

[51] *See, e.g.*, IFPMA, *supra* note 20, at 10–79 (providing laws of countries). Some FTAs bar approval of follow-on drugs even if they are not relying on clinical data, but with similar effect. *E.g.*, BUICK, *supra* note 27, at 114.

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Switzerland.[52] FTAs also require this for lower-income countries such as Bahrain, Brunei, Chile, Colombia, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Laos, Malaysia, Mexico, Morocco, Nicaragua, Oman, Peru, Panama, Singapore, and Vietnam.[53] China proposed data exclusivity in May 2022.[54]

The term of data exclusivity is typically at least five years from approval of the original drug in the country granting such exclusivity.[55] The EU originally required at least six years and permitted variation among member states, but later adopted a uniform eight-year period of exclusivity, largely reflecting industry demands.[56] The United States has a twelve-year term of data exclusivity for follow-on biologics (complex drugs that are injected or infused such as vaccines), but only a five-year term for generics.[57] The United States has tried to mandate longer terms for biologics in FTAs, mirroring its domestic laws, but thus far have been unsuccessful.[58] Other countries often provide the same term for all treatments.[59]

Some FTAs that mandate data exclusivity have mediating factors. For example, some FTAs permit an exception to such exclusivity in the event of compulsory license or public health needs, which Malaysia, Chile, and Columbia have implemented.[60] In addition, some FTAs mandate data exclusivity but permit countries to

[52] Japan also has something akin to data exclusivity that bars approval of follow-on drugs, but not due to an FTA. Since 1980, Japan has a period of reexamination during which generic versions are barred from approval even if not relying on another's data. *E.g.*, Shiho Koizumi et al., *Recent Changes Concerning Regulatory Protection of Pharmaceutical Companies in Japan*, Cross-border Life Sciences Handbook (2011), www.amt-law.com/asset/res/news_2011en_pdf/110225_2055.pdf (last visited Feb. 23, 2023).

[53] *E.g.*, Buick, *supra* note 27, at 105–109.

[54] *E.g.*, Brian Yang, *China Regulatory Express: Patent Linkage, Data Protection, Bio Five-Year Plan*, Pink Sheet (May 18, 2022).

[55] However, some FTAs require countries to deny reliance of data submitted to a *foreign* country. *E.g.*, Dominican Republic–Central America–United States Free Trade Agreement, art. 15.10.1.b, Mar. 15, 2012, 77 FR 15397; The United States–Korea Free Trade Agreement, art. 18.9.1.b, Jun. 30, 2007, 72 FR 16259; The United States–Jordan Free Trade Agreement, art 4.22, Jun. 27, 2007, 72 FR 35154.

[56] Sandra Adamini et al., *Policy Making on Data Exclusivity in the European Union: From Industrial Interests to Legal Realties*, 34 J. Health Pol. Pol'y & L. 979, 993–996 (2009).

[57] 42 U.S.C. 262(k)(7)(A).

[58] The United States first tried to mandate a twelve-year term for biologics specifically in the TPP and then in the USMCA. *E.g.*, Deborah Gleeson et al., *The Trans Pacific Partnership Agreement, Intellectual Property and Medicines: Differential Outcomes for Developed and Developing Countries*, Global Soc. Pol'y 1, 17 (2017); Zachary Zelewski et al., *USMCA Compromise Drops Key Biologics Exclusivity Provisions*, Avalere (2019), https://avalere.com/insights/usmca-compromise-drops-key-biologics-exclusivity-provisions (last visited Feb. 23, 2023).

[59] Regulation (EC) No. 726/2004, art. 14(11), O.J. (L. 136), 1; Owais H. Shaikh, Access to Medicine versus Test Data Exclusivity 126 (2016).

[60] Ellen't Hoen, *Protection of Clinical Test Data and Public Health: A Proposal to End the Stronghold of Data Exclusivity*, 183, 192–193, *in* Access to Medicines & Vaccines (C. M. Correa & R. M. Hilty eds., 2022).

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specify that the data exclusivity may not exceed the term of patent protection,[61] or begin the term of data exclusivity not from the earlier date of approval in a partner country, so long as the originator drug is approved shortly after the approval in a partner country.[62]

PREVALENCE OF PATENT LINKAGE The United States originally negotiated patent linkage in FTAs with high-income countries such as Canada (1993), Singapore (2004), Australia (2005), and South Korea (2007).[63] The United States proposed patent linkage when negotiating the Trans-Pacific Partnership Agreement.[64] Although the United States withdrew from that agreement, the patent linkage provision remains in the renamed and now concluded Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), which includes Vietnam, Malaysia, Chile, and Peru.[65] Japan is also required to provide patent linkage pursuant to the CPTPP, but its official position is that no changes in the law are required[66] since Japan has unofficially considered whether a generic might conflict with a patent on the active ingredient to deny regulatory approval since 1994.[67] China adopted patent linkage in 2019 and is also required to provide patent linkage as a result of a 2020 FTA with the United States.[68] Taiwan, Ukraine, and United Arab Emirates also provide patent linkage.[69] So, in total, there are more than a dozen countries that provide patent linkage, or must provide patent linkage pursuant to FTAs,[70] as well as some countries that adopted patent linkage without a specific FTA.[71] In addition, there are some countries that do not formally provide

[61] BUICK, *supra* note 27, at 104.
[62] *Id.*, at 112–113.
[63] North American Free Trade Agreement, art. 1709, Dec. 17, 1992., 32 I.L.M. 289; US FTA–Australia: U.S.–Austl. Free Trade Agreement, art. 17.10.4, May 18, 2004; US–Korea Free Trade Agreement art. 18.9.5, Jun. 30, 2007, entered into force in 2012.
[64] *E.g.*, Gleeson et al., *supra* note 58, at 18.
[65] Comprehensive and Progressive Agreement for Trans-Pacific Partnership, art. 18.51. In addition, other countries have applied: *e.g.*, Parliament of Australia, *Applications to the CPTPP: The United Kingdom, China, Taiwan and South Korea*, Parliamentary Business, www.aph.gov.au/Parliamentary_Business/Committees/Joint/Foreign_Affairs_Defence_and_Trade/CPTPPMembership/Report/section?id=committees%2Freportjnt%2F024826%2F78218 (last visited Feb. 23, 2023).
[66] BAKER & MACKENZIE, *supra* note 49, at 88.
[67] *E.g.*, Shin, *supra* note 37, at x–xi; ATSUSHI OKADA, THE PHARMACEUTICAL INTELLECTUAL PROPERTY AND COMPETITION LAW REVIEW: JAPAN (2021).
[68] Raju, *supra* note 15, at 342; Economic and Trade Agreement between the Government of the United States of America and the Government of the People's Republic of China, art. 1.11 (2020).
[69] Raju, *supra* note 15, at 353.
[70] Malaysia and Peru have not yet ratified the CPTPP, but once they do so, they will be bound within sixty days.
[71] Jordan has had patent linkage since 2002. Raju, *supra* note 15, at 352.

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patent linkage, but have informal measures such as requiring applicants to indicate a proposed generic is not protected by patents.[72]

Implementation of patent linkage varies much more than data exclusivity. For example, although the United States has a relatively transparent system for patents that are linked to generic drugs, with a public list of patents associated with approved drugs, it does not for biologics.[73] Other countries treat generics and biologics the same for patent linkage but may have no public information available for potential generic manufacturers to know whether there are associated patents.[74] Also, although countries may provide a system for adjudicating whether patent(s) are valid and infringed, this can happen in traditional court systems, or through an administrative procedure that may involve regulatory authorities.[75] In addition, the stay of regulatory approval of the follow-on generic can vary substantially – up to nine months (South Korea), thirty months (United States), or even indefinite (Australia).[76] Although the potential stay in Australia is indefinite, other aspects of its law promote approval of follow-on drugs. Notably, if the follow-on applicant certifies that it will market the drug in a manner that will not infringe, the patent owner is not notified, and no stay of approval will occur.[77] In addition, even if the patent owner is notified, that only happens after approval of the follow-on (instead of upon receiving it), such that there is no undue delay in grant of marketing approval.[78]

Some countries have measures in their patent linkage system that aim to limit abuse by patent-owning companies. Some countries do not permit companies to add patents after the initial application for approval.[79] Some countries impose penalties for false and misleading action by the patent owner.[80] In addition, some countries provide an incentive for a generic applicant to challenge weak or irrelevant patents by providing a short period of exclusivity as the only generic in the market.[81] However, this would not be an incentive in markets where prices of follow-on drugs are regulated. Even if prices are not regulated, the utility of this provision

[72] This is true in Hungary, Thailand, Czech Republic, and Indonesia. Baker & Mackenzie, *supra* note 49; *see also* Raju, *supra* note 15, at 344–345 (Ukraine requires generic applicants certify no infringement, although that may not be the basis for refusing marketing approval and Russia must do so as part of the Eurasian Economic Union Rules).

[73] Son, *supra* note 36, at 5; Bryan S. Walsh et al., *Recent Orange and Purple Book Litigation Suggests a Need to Bridge Drug and Biologic Patent Regimes*, 40 Nature Biotech 167, 167–168 (2022).

[74] Canada, Australia, and Korea do not have a separate system for biologics and Australia has no list of patents. Son, *supra* note 36, at 6.

[75] *Id.*

[76] *Id.*, at 7.

[77] *Id.*, at 6.

[78] *Id.*

[79] *Id.*, at 6 (noting this is true in Korea and Canada).

[80] *Id.*, at 7 (noting this is true in Canada and Australia).

[81] *Id.* (noting the United States and South Korea).

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has been undermined by anticompetitive agreements whereby initial challengers are paid by the originator to not enter the market for a period of time.[82]

2 EXPLORING THE INTERSECTION OF REGULATORY PROTECTIONS AND INTERNATIONAL OBLIGATIONS

This section explains the IP obligations under TRIPS that are not previously discussed, proposed and actual waiver of TRIPS obligations to promote access to needed COVID treatments, and how these reflect incomplete understanding, or at least failure to fully address these regulatory protections. Although there are FTAs that require regulatory protections, they are not specifically discussed here since there have been no proposals to waive these FTA provisions. This likely reflects a strategic decision to first address the international agreement that applies to most countries, especially since some countries believe that TRIPS requires data exclusivity.

A *International Obligations: TRIPS*

Of particular importance to the issue of medical treatments, TRIPS requires all countries to provide minimal levels of patent protection in all fields of invention, including drugs.[83] Although TRIPS requires that inventions be patented and subject to enforcement, there are exceptions from patent rights: a compulsory license and a "limited exception." Since the "limited exception" under TRIPS has been narrowly interpreted thus far,[84] a compulsory license to usual patent rights is the primary flexibility for minimizing the TRIPS requirement that patents must be granted on medical treatments. Consistent with prior international laws, TRIPS permits governments to issue compulsory licenses of patents which essentially permit the government to grant anyone the right to use a patented invention, subject to government-dictated royalties.[85] However, TRIPS imposes additional conditions, including that they must be mostly for domestic use.[86] In addition, after members realized that compulsory licenses were of no utility for countries that lack

[82] For example, Humira was the exclusive biologic available in the United States for arthritis until 2023 due to these agreements whereas competitors are available in Europe. Jill Coghlan et al., *Overview of Humira Biosimilars: Current European Landscape and Future Implications*, 110 J. Pharm. Sci. 1572, 1573 (2021).

[83] TRIPS, art. 27.

[84] A WTO panel interpreted this to require three separate and cumulative conditions, and although some scholars have argued that it can be interpreted more broadly, that is an untested argument. WTO, Canada Generics, para 7.32; Mathiaas Lamping et al., Declaration on Patent Protection: Regulatory Sovereignty under TRIPS, at 8–9 (2014).

[85] Paris Convention for the Protection of Industrial Property, art. 10bis, Aug. 14, 1967, 828 U.N.T.S. 305.

[86] TRIPS, art. 31(f).

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inadequate capacity to domestically manufacture drugs, TRIPS was amended to permit compulsory license for export to such countries with even more conditions.[87]

An important issue is the consequence for failure to comply with TRIPS. There is a WTO dispute settlement process that can mandate a country to bring its laws into compliance or else face sanctions that can include withdrawal of WTO benefits.[88] Member states use this dispute process infrequently, likely due to fear of an undesirable ruling. However, the Global North has often suggested violations of TRIPS and based on this exercised unilateral pressure on countries. For example, there have been no formal WTO challenges concerning compulsory licenses, but the United States and European Union have repeatedly criticized use of these licenses and even done so during COVID.[89]

B *Proposed and Actual Modification of TRIPS Requirements for COVID*

After the Global North engaged in vaccine nationalism by pre-ordering many more vaccines than needed, and companies were unwilling to license adequate numbers of manufacturers, India and South Africa proposed waiving IP obligations under TRIPS so that countries could create COVID vaccines.[90] Modification of TRIPS does not automatically change domestic IP laws. But modification can permit nations to modify domestic laws without international liability under the WTO and hopefully also without unilateral pressure from other countries. This section explains the original proposal, a counterproposal by the EU, and the ultimate agreement as background to understanding the extent to which they would impact regulatory barriers.

India and South Africa Proposal: Waive Multiple TRIPS Obligations to Address COVID

The original TRIPS waiver proposed a broad exemption from multiple provisions of TRIPS for prevention, containment, or treatment of COVID-19, which was later clarified to include vaccines, treatments, diagnostics, and personal protective equipment for three years from the date of the decision.[91] The TRIPS provisions that

[87] Declaration in the TRIPS Agreement and Public Health, Doha WTO Ministerial 2001, para. 6, Nov. 14, 2001, WT/MIN(01)/DEC/2 [*hereinafter* Doha Declaration]; TRIPS, art. 31bis.

[88] Understanding on Rules and Procedures Governing the Settlement of Disputes, art. 22, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, Legal Instruments – Results of the Uruguay Round, 33 I.L.M, 1125 (1994).

[89] WTO, Communication from the Plurinational State of Bolivia, Eswatini, India, Kenya, Mozambique, Mongolia, Pakistan, South Africa, The Bolivarian Republic of Venezuela and Zimbabwe, IP/C/W/672 (Jan. 15, 2021).

[90] WTO, Communication from India and South Africa, Waiver from Certain Provisions of the TRIPS Agreement for the Containment and Treatment of COVID-19, IP/C/W/669 (Oct. 2, 2020).

[91] WTO, Communication from The African Group, The Plurinational State of Bolivia, Egypt, Eswatini, Fiji, India, Indonesia, Kenya, The LDC Group, Maldives, Mozambique, Mongolia,

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would have been suspended during this time period included all the patent provisions and trade secrets, including protection of undisclosed data submitted for regulatory review from "unfair commercial use."[92] This proposal was suggested by South Africa and India but had broad support from developing countries, as well as heads of state and policymakers.[93] The United States also supported this, but only for vaccines.[94]

EU: TRIPS Compulsory License Clarification

In June 2021, the EU sent a communication to the WTO that it believed voluntary licenses were most effective to increase production, and beyond that, it proposed use of compulsory licenses and suggested language to explain their use for COVID-19. The EU suggested clarifying that:

- the COVID-19 pandemic is a national emergency, such that waiver of prior negotiation with patent owner is not necessary;
- remuneration for licenses "should reflect affordable price."[95]

Although these statements may seem helpful, they do not add anything. A global pandemic clearly satisfies a national emergency under the existing TRIPS agreement, such that no prior negotiation is necessary. Moreover, even if there was any controversy concerning what constitutes a national emergency, each WTO country has the right to decide for itself.[96] In addition, TRIPS only requires licenses to provide "reasonable compensation," so it already permits affordable prices; for example, India permits compulsory licenses to be issued if prices are unaffordable.[97]

Limited TRIPS Waiver

In May 2022, the WTO circulated a draft text to all member countries based on language that was negotiated by South Africa, India, the United States, and the

Namibia, Pakistan, South Africa, Vanuatu, the Bolivarian Republic of Venezuela, and Zimbabwe, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, IP/C/W/669/Rev.1 (May 21, 2021).

[92] The proposal also advocated suspension of TRIPS provisions concerning copyright, although that is not relevant to creation of drugs discussed in this chapter.

[93] *E.g.*, Kerry Cullinan, *World Leaders Call on Future German Chancellor to Support TRIPS Waiver*, Health Policy watch (Sep. 15, 2021), https://healthpolicy-watch.news/pressure-on-future-german-leader-to-support-trips-waiver/ (last visited Feb. 23, 2023).

[94] *E.g.*, Shayerah Akhtar & Ian Fergusson, Potential WTO TRIPS Waiver and COVID-19, Congressional Research Service 1 (2021).

[95] WTO, Communication from the European Union to the Council for TRIPS, Draft General Council Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic, IP/C/W/681.

[96] TRIPS, art. 31(b); Doha Declaration, para. 5(c).

[97] TRIPS, art. 31(h); Indian Patents Act, §§ 84(1)(b) (permitting such a license request three years after patent grant).

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European Union in March 2022.[98] Some supporters of the original proposal strongly objected to this text as unduly narrow, with over 100 organizations urging rejection of the proposal,[99] whereas industry claimed it was unnecessary and harmful.[100] In June 2022, the WTO membership adopted a limited waiver of one TRIPS patent obligation for COVID-19 vaccines.[101] This waiver is very limited because it only modifies a complicated and cumbersome provision to circumvent the usual TRIPS requirement that compulsory licenses must be predominantly for domestic use that has only been applied once.[102] Although this is a welcome change given the provision is wholly unsuited for emergency use, the waiver of this provision only applies to developing countries and even explicitly discourages countries with existing capacity to use the procedure.[103] This seems patently illogical in that developing countries in the best position to supply other countries with vaccines are encouraged not to do so.[104]

C *Examining the Intersection of TRIPS Modifications and Regulatory Barriers*

Now that the individual TRIPS proposals and actual waiver have been introduced, this section shows how each incompletely addresses regulatory barriers beyond the obvious fact that additional waivers of TRIPS-plus obligations would be required to

[98] WTO, Communication from the Chairperson, IP/C/W/688 (May 3, 2022). The language mirrors the draft text leaked in March 2022 from these four member countries, that was originally dubbed a Quad proposal, even though only the EU publicly supported the text. *WTO Secretariat Misleads on Status and Content of Intellectual Property Text, Perpetuates Confusion*, Third World Network (May 2, 2022), https://twn.my/title2/wto.info/2022/ti220502.htm (last visited Feb. 23, 2023).

[99] *Open CSO Letter to WTO Trade Ministers: Do Not Accept the Current Draft, Demand a Real Waiver*, Médecins Sans Frontières (Jun. 15, 2022), https://msfaccess.org/open-cso-letter-wto-trade-ministers-do-not-accept-current-draft-demand-real-waiver (last visited Feb. 23, 2023).

[100] Megan Van Ettan, *Intellectual Property Waiver on COVID-19 Innovation is Unnecessary and Harmful*, Catalyst, PhRMA, https://catalyst.phrma.org/intellectual-property-waiver-on-covid-19-innovation-is-unnecessary-and-harmful (last visited Feb. 23, 2023).

[101] WTO, Ministerial Decision on the TRIPS Agreement, WT/MIN(22)/30 (Jun. 22, 2022). It suggests that members will decide on whether to extend the rules to diagnostics and therapeutics within six months (para. 8). However, given objection to the original waiver that included these for over eighteen months, agreement within six months was unlikely.

[102] *E.g.*, Muhammad Abbas, *World Trade Organization's Export-Oriented Compulsory Licensing Mechanism: Foreseen Policy Concern for Africa to Mitigate the COVID-19 Pandemic*, 17 J. Generic Drugs 71, 73–74 (2021).

[103] WTO Chairperson, *supra* note 98, para. 1, fn. 1.

[104] However, this is arguably an improvement over a March 2022 leaked proposal that would have affirmatively barred countries that had exported more than 10 percent of COVID vaccines, such as China. *E.g.*, Human Rights Watch, *More Effort Needed for Meaningful Outcome at WTO on Covid-19, Mar. 18, 2022, 8:00 am EDT* (Mar. 18, 2022), www.hrw.org/news/2022/03/18/more-effort-needed-meaningful-outcome-wto-covid-19 (last visited Feb. 23, 2023).

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remove all international barriers.[105] But before discussing these, a few observations about the relevance of regulatory barriers to the Global South and Global North may be helpful.

Even though these proposals and actual waiver do not fully remove regulatory barriers, this is a nonissue in some countries. For example, neither South Africa nor India currently require data exclusivity or patent linkage. However, this may change; data exclusivity is proposed in the FTA between India and the United Kingdom currently under negotiation.[106] Moreover, even if South Africa and India are successful in resisting FTAs that require regulatory barriers, both will likely soon exist in China, which has been an important source of COVID-19 vaccines. In addition, there are other developing countries that could make follow-on treatments that are currently subject to these regulatory barriers, such as Mexico, Vietnam, and Chile.

High-income countries that have these regulatory barriers may reduce their flexibility to protect domestic citizens during a pandemic. For example, early in the COVID-19 pandemic there were inadequate supplies of the treatment remdesivir, such that many recommended that the United States use its domestic powers to override usual patent rights.[107] Although remdesivir was only approved for emergency use and thus not subject to data exclusivity, if it had been granted orphan drug exclusivity as its manufacturer had planned before public protest, that would have been an additional barrier.[108] Moreover, the statutory provision permitting the United States to override patent rights for government use does not provide for overriding regulatory barriers such as data exclusivity or orphan drug exclusivity.[109]

India and South Africa Proposal

The original proposal to modify TRIPS requirements proposed waiving not only patent obligations, but also ones concerning undisclosed information that some

[105] There is an argument that an adopted TRIPS waiver could yield related subject matter in FTAs through an estoppel doctrine. See Carlos M. Correa et al., Implementation of a TRIPS Waiver for Health Technologies and Products for COVID-19: Preventing Claims under Free Trade and Investment Agreements 7 (2021). However, patent linkage is clearly not within TRIPS.

[106] *E.g.*, Médecins Sans Frontières, *Damaging Provisions for Access to Medicines in the Leaked UK-India FTA Negotiation Text* (Nov. 2022), https://msfaccess.org/sites/default/files/2022-11/IP_UK-India%20FTA_Factsheet_Final_ENG_2.11.2022.pdf (last visited Feb. 23, 2023). For the full text of the leaked draft, see www.bilaterals.org/IMG/pdf/uk-india_fta_ip_chapter_dated_april_2022_68_.pdf (last visited Feb. 23, 2023).

[107] *E.g.*, Letter from Xavier Becerra, Att'y Gen. of Cal., and Jeff Landry, Att'y Gen. of La., to Alex Azar, Sec'y U.S. DHHS, Francis Collins, Dir. Of NIH, and Stephen Hahn, Comm'r of U.S. FDA (Aug. 4, 2020), www.oag.ca.gov/system/files/attachments/press-docs/Remdesivir%20Letter%20202008O4.pdf (last visited Feb. 23, 2023); Christopher Morton et al., *A Powerful Law Gives HHS the Right to Take Control of Remdesivir Manufacturing*, Stat (Jul. 2, 2020).

[108] *E.g.*, Kyle Blankenship, *Gilead Asks FDA to Rescind Remdesivir Orphan Drug Tag after Public Backlash*, Fiercepharma (Mar. 25, 2020, 12:49 pm), www.fiercepharma.com/pharma/gilead-asks-fda-to-rescind-remdesivir-orphan-drug-tag-after-public-backlash (last visited Feb. 23, 2023).

[109] 28 U.S.C. 1498.

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have argued requires data exclusivity.[110] However, discussion of this proposal suggests that some countries failed to understand that data exclusivity can be a barrier. Countries that strongly objected to this proposal repeatedly noted that it would not be effective on several grounds, but data exclusivity was not one; rather, they suggested that voluntary or even compulsory licenses were adequate.[111] But licenses are ineffective in countries where there is data exclusivity without any exception, as developing countries noted.[112] In addition, many that opposed this proposal focused on the fact that a waiver of trade secret obligations under TRIPS would not help scale up manufacture of vaccines since removal of liability does not mandate disclosure of trade secrets.[113] That is true. However, data exclusivity is a bigger, largely undiscussed hurdle. Some countries may be able to mandate or encourage companies to share needed trade secrets.[114] Even without compelled disclosure, companies can develop an alternative method as underscored by South Africa's successful creation of a method to make the Moderna COVID-19 vaccine.[115] In contrast, data exclusivity in most countries is an absolute legal barrier without any exception. The few countries known to have exceptions to data exclusivity, such as Malaysia, are not major sources of generic drugs.[116]

EU Compulsory License-Only Proposal

The EU's proposed clarification of compulsory license provisions does not address regulatory barriers at all. It completely ignores the fact that effective use of compulsory licenses could be blocked by the existence of data exclusivity or patent linkage. Accordingly, this proposal is a strong example of lack of recognition of data exclusivity as a barrier to making needed treatments.

This lack of recognition is somewhat surprising. The EU's own data exclusivity laws have previously been a barrier to use of a compulsory license during the Avian flu pandemic; public health advocates suggested that the EU should amend its laws

[110] WTO, Communication from India and South Africa, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, IP/C/W/669, para. 12 (Oct. 2, 2020).

[111] WTO, Communication from Australia, Canada, Chile and Mexico, Questions on IP Challenges Experienced by Members in Relation to COVID-19, IP/C/W/671 (Nov. 27, 2020).

[112] WTO Bolivia, Eswatini, supra note 89, at 24; *see also id.* at 29 (noting protection of undisclosed information is a separate barrier to patents).

[113] *E.g.*, Kevin Noonan, *Suspending IP Protection: A Bad Idea (That Won't Achieve Its Desired Goals)*, Patent Docs (Apr. 26, 2021), www.patentdocs.org/2021/04/suspending-ip-protection-a-bad-idea-that-wont-achieve-its-desired-goals.html (last visited Feb. 23, 2023).

[114] *E.g.*, Zain Rizvi et al., *Sharing the Knowledge: How President Joe Biden Can Use the Defense Production Act to End the Pandemic Worldwide*, Health Aff. (Aug. 6, 2021).

[115] Amy Maxmen, *South African Scientists Copy Moderna's COVID Vaccine*, 602 Nature 372 (2022).

[116] *E.g.*, *supra* note 61.

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to create such an exception.[117] In addition, the EU is aware that data exclusivity can be a barrier since the EU has an exception to such exclusivity for compulsory licenses of drugs for export.[118] Since the EU has previously recognized data exclusivity as a barrier, its proposal could be considered an intentionally incomplete attempt to address the pandemic.

TRIPS Waiver for COVID-19

Although the final June 2022 waiver (as well as the leaked March 2022 text) is better than the EU proposal in explicitly noting that the provision some argue to require data exclusivity should not bar regulatory approval of subsequent treatments, its utility is limited.[119] First, the waiver seems to improperly suggest that a pandemic is a unique situation for which article 39(3) should not be a barrier, rather than that this provision should *never* be interpreted to require data exclusivity.[120] Moreover, this waiver does not alone eliminate regulatory barriers adopted in domestic laws. Failure to consider that developing countries may be barred from effective use of the waiver due to data exclusivity mandated by TRIPS-plus agreements is a significant omission. Although some countries such as India and China could make vaccines, the waiver explicitly discourages countries with capacity from doing so. In addition, China has both data exclusivity and patent linkage and has proposed data exclusivity.

The waiver is also inadequate for excluding countries of the Global North that could grant compulsory licenses to export drugs and vaccines – but for which such licenses could be stymied by regulatory barriers.[121] Canada, for example, is completely excluded from using the new waiver of the usual complex compulsory license procedure for export. Canada is notably the only country that has ever issued a compulsory license for export in the over twenty years that TRIPS has permitted this to occur. And, while a Canadian company has agreed to provide Bolivia with

[117] *E.g.*, Ellen F. M. 't Hoen et al., *Data Exclusivity Exceptions and Compulsory Licensing to Promote Generic Medicines in the European Union: A Proposal for Greater Coherence in European Pharmaceutical Legislation*, 10 J Pharma. Poly & Prac 1, 6 (2017).

[118] Regulation (EC) No. 816/2006 on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems, art. 18 [2006] O.J. (L. 157/1).

[119] WTO Chairperson, *supra* note 98, para. 4; TRIPS COVID-19 Solution (the outcome of the quadrilateral discussion), Mar. 2020, http://freepdfhosting.com/4d79fc6c70.pdf (last visited Feb. 23, 2023) [*hereinafter* Quad Text].

[120] WTO Chairperson, *supra* note 98, para. 4. The earlier leaked text was more ambiguous about whether this provision was being interpreted differently solely for the pandemic. *E.g.*, Quad Text, *supra* note 119 (stating that "nothing in Article 39.3 of the Agreement shall prevent a Member from taking measures necessary to enable the effectiveness of any authorization issued as per the Decision").

[121] Only a handful of countries have laws permitting compulsory license for export. *E.g.*, Ho, *supra* note 8, at 203; Legislation to Allow for the Export of Pharmaceuticals Produced under Compulsory License, CPtech, www.cptech.org/ip/health/cl/cl-export-legislation.html (last visited Feb. 23, 2023).

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COVID-19 treatments, due to lack of amendment of Canadian laws to permit such a license for those treatments, no shipment has occurred.[122] Moreover, although Canada's law permits an exception from data exclusivity for such licenses, there is no exception from patent linkage, which Canada must provide pursuant to an FTA.[123]

3 LOOKING AHEAD

There are several things nations should do domestically to reduce regulatory barriers to accessing treatments during a pandemic. Since data exclusivity and patent linkage can impose barriers to timely access to lower-cost treatments, these should be avoided if possible. If that is not possible, then adopting patent linkage that simply provides notice to the patent owner and an exception to data exclusivity would be preferable.

At the international level, nations should avoid new agreements or unilateral pressure to mandate data exclusivity or patent linkage. Although this may seem obvious, it is very important considering that available generics for the world could quickly change if India adopts one or both protections. Also, to the extent that there are existing international agreements imposing commitments, nations should create exceptions.

The above steps should be helpful to promote access to medicine in future pandemics as well as non-pandemic circumstances. Even if data exclusivity and patent linkage cannot be eliminated, hopefully awareness will help create exceptions, or at least voluntary waivers of usual data exclusivity or patent linkage to promote access to affordable follow-on treatments.[124]

[122] *E.g.*, Muhammad Zaheer Abbas, *Canada's Political Choices Constrain Vaccine Equity: The Bolivia Biolyse Case*, South Centre Research Paper 136 (2021); Laura Osman, *Bolivia Calls on Canada to Waive and Export COVID-19 Vaccine*s, Globe & Mail (Nov. 9, 2021).

[123] U.S.M.C.A. arts. 20.48(3) (permitting exception from data exclusivity), 20.50 (providing no exception from patent linkage); Health Canada: Data Protection under C.08.004.1 of the Food and Drug , Guidance Document 3.5 (2021).

[124] *E.g.*, Hoen, *supra* note 60, at 194–195 (noting the Medicines Patent Pool licenses include data exclusivity waivers).

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