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A NEW PRESCRIPTION FOR BIOLOGICS EXCLUSIVITY IN U.S. TRADE POLICY (Side Effects Include Lower Prices And Freer Trade)

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INTRODUCTION

As the United States and Europe emerged from the wreckage of World War II, allied governments set out to ameliorate the conditions that led to war. A key component of the post-War order was to integrate economies and expand economic cooperation across borders. In many ways, the seeds for the current state of globalization were planted around this time.

Since the end of World War II, presidents of both parties have pursued a general policy of trade liberalization. The benefits of this policy have been enormous: according to a 2017 study by the Peterson Institute for International Economics, "[Since 1950], U.S. [Gross Domestic Product] (GDP) per capita and GDP per household accordingly increased by $7,014 and $18,131, respectively (both measured in 2016 dollars). Disproportionate gains probably accrued to poorer households."[1] Likewise, there is ample literature to show that economic integration helps facilitate peaceful relations among countries.[2]

Despite this, globalization is not without detractors. Among the most prominent charges leveled by critics is that it has hollowed out domestic manufacturing and that modern trade rules and free trade agreements (FTAs) are rent-seeking exercises that amount to giveaways to certain well-connected multinational corporations and industries, at the expense of average Americans. While much of this charge is without merit,[3] there is a kernel of truth when it comes to overly stringent intellectual property (IP) protections contained in modern FTAs.

In recent years, the United States has pushed to include similar stringent exclusivity standards in various FTAs it has negotiated. It does not have to be this way.

In 2007, as part of the Bush administration's efforts to build congressional support for four FTAs it negotiated with Peru, Colombia, Panama and Korea, the United States Trade Representative (USTR) and House Democrats formalized what became known as the "May 10 Agreement." The Agreement made a number of changes to the four pending FTAs, includ-

1. Gary Clyde Hufbauer and Zhiyao (Lucy) Lu, "The Payoff to America from Globalization: A Fresh Look with a Focus on Cost to Workers," The Peterson Institute for International Economics, May 2017. https://piie.com/system/files/documents/pb17-16.pdf.

2. Jong-Wha Lee and Ju Hyun Pyun, "Does Trade Integration Contribute to Peace," *Review of Development Economics* 20:1 (February 2016), pp. 327-44. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2724298##.

3. See, e.g., Michael J. Hicks and Srikant Devaraj, "The Myth and Reality of Manufacturing in America," Conexus Indiana and Center for Business and Economic Research at Ball State University, updated April 2017. https://conexus.cberdata.org/files/MfgReality.pdf; Douglas A. Irwin, "The Truth About Trade," *Foreign Affairs* (July/August 2016). https://www.foreignaffairs.com/articles/2016-06-13/truth-about-trade; J. Bradford Delong, "NAFTA and other trade deals have not gutted American manufacturing—period," *Vox*, Jan. 24, 2017. https://www.vox.com/the-big-idea/2017/1/24/14363148/trade-deals-nafta-wto-china-job-loss-trump.

ing changing provisions on labor, the environment, investment and intellectual property protections with respect to medicines. As to the latter, the May 10 Agreement established a balanced approach between fostering innovation and promoting competition to lower prices for consumers. These changes eventually facilitated passage of the four FTAs during the Obama administration. Yet, once the Obama administration began negotiating the Trans-Pacific Partnership (TPP), a promising trade pact with Pacific Rim nations, it pushed trading partners to accept stringent IP protections that favored name brand pharmaceuticals over generics.

The most controversial of these provisions involves biologics drugs, a special class of pharmaceuticals made from living cells that are expensive to research and manufacture. U.S. law provides very strong protections for name-brand biologics by guaranteeing them 12 years of market exclusivity without generic competition. During this exclusivity period, the Food and Drug Administration (FDA) is prohibited from approving a follow-on biologic medicine, even if the originator drug is no longer covered by a patent. This 12-year exclusivity period is the longest of any other country in the world.

The Obama administration's initial position in TPP negotiations was that the agreement should mirror domestic law to mandate "at least" 12 years of exclusivity for biologics. This was a nonstarter for a number of countries and also angered congressional Democrats. The issue became moot when the TPP was unwisely abandoned in January 2017, but it has arisen again in the renegotiation of the North American Free Trade Agreement (NAFTA).

Following in its predecessor's footsteps, the Trump administration initially pushed for a provision in the new US-Mexico-Canada Agreement (USMCA) that required the three countries to provide "at least 10 years" of market exclusivity for biologics.[4] But after several months of negotiations with House Democrats, the Trump administration was forced to remove this provision from the Agreement. It is now increasingly likely that the USMCA, without a biologics exclusivity provision, will pass Congress in early 2020.

Trade negotiators over the last two administrations have seriously erred by jettisoning the balanced approach established by the May 10 Agreement. Accordingly, this paper will document how the lengthy term of exclusivity for biologics hinders efforts to promote pharmaceutical competition and lower drug prices in the U.S. market. In doing so, it will describe how and why U.S. negotiators try to include the term in trade agreements, and will recommend concrete policy solutions to rebalance the treatment of IP in future FTA negotiations.

4. USMCA Article 20.49. https://ustr.gov/sites/default/files/files/agreements/FTA/USMCA/Text/20_Intellectual_Property_Rights.pdf.

OVERVIEW OF REGULATORY FRAMEWORK FOR DRUG APPROVALS AND PATENTS

Currently, the federal government micromanages the U.S. pharmaceutical market through a byzantine regulatory framework designed to balance the potentially competing policy goals of innovation, safety and affordability. Regulatory exclusivity periods, which intentionally delay the introduction of non-patented generic drugs, are one part of this complex arrangement.

Pharmaceutical innovation in the United States is promoted primarily through patent protection for new drugs. By granting inventors the temporary right to exclude others from the market, drug patents ensure that companies are able to profit from extensive investments in research and development. Ideally, a drug developer could adequately recoup its costs by charging monopoly prices during the period of patent protection, after which generic versions of the drug could enter the market and drive down prices through competition.

This process is frustrated, however, by the requirement that all new drugs be approved by the FDA. The FDA's job is to ensure that drugs are safe and effective, and it does so by requiring drug companies to conduct extensive clinical trials before selling to the general public. However, these trials take a long time and cost a lot of money,[5] and the lengthy process for FDA approval eats away at the amount of time innovator companies have to enjoy a monopoly market before their patents expire. Moreover, the expense of conducting clinical trials can keep generic companies from entering the market at all, and all of this seriously disrupts the patent system's effectiveness in promoting innovation and competition.

Finding the Right Balance

In 1984, Congress sought to solve these problems by enacting the Drug Price Competition and Patent Term Restoration Act. Generally known as the Hatch–Waxman Act, this law permanently intertwined the otherwise separate policies of patent protection and marketing approval into a single scheme. In order to promote greater competition, the Hatch–Waxman Act allows generic drugs to be approved through an abbreviated process that focuses on whether the drug has the same active ingredient and therapeutic effect as a previously approved drug.[6] That is, generic drug makers do not have to perform redundant clinical trials that merely show the FDA something it already knows about a drug that has already been on the market.

5. J.A. Dimasi et al., "Innovation in the pharmaceutical industry: new estimates of R&D costs," *Journal of Health Economics* 47 (2016), pp. 20-33. https://www.ncbi.nlm.nih.gov/pubmed/26928437.

6. 21 U.S.C. §355(j).

Hatch–Waxman also favors new drug developers by allowing for the extension of patent terms to compensate for time lost during the FDA process and prohibits the FDA from approving a generic drug before all patent disputes are settled by a court.[7] The law also prohibits the FDA from accepting a generic application until five years have passed since the original drug was approved.[8] This regulatory exclusivity period—often called "data exclusivity" because the generic approval depends on the 'data' generated during the originator company's clinical trials to determine safety and efficacy—acts as an FDA-enforced guarantee that a new drug will enjoy at least five years without generic competition, regardless of the duration and scope of the originator company's patent rights.[9]

By all accounts, the scheme established by Hatch–Waxman has worked remarkably well to promote generic competition. For example, in 1984, most of the top-selling drugs had no generic competition and only 19 percent of prescriptions were filled by generics. Today, however, they are widely available and make up about 90 percent of all prescriptions filled in the United States.[10] Such ubiquitous presence of generic alternatives has saved Americans a lot of money—despite making up 90 percent of prescriptions, they account for only 23 percent of drug costs. With generic drugs sold in some cases for 60 percent less than their brand name counterpart, their increased availability saves the U.S. healthcare system hundreds of billions of dollars every year.[11]

Fixing the Biologics Gap

Despite its successes, however, the Hatch–Waxman Act does not apply to a special class of drugs known as "biologics," which are used in innovative treatments for cancer, diabetes and immune disorders. The FDA treats biologics differently because they are more complex than small-molecule drugs and cannot be chemically synthesized. Due to the inevitable differences between different products, follow-on versions of biologic drugs are called "biosimilars" rather than "generics."

Prompted by the lack of competition and resulting high prices in the U.S. biologics market, Congress began designing a pathway for biosimilar approval around 2006. They did not, however, simply copy the existing provisions of the Hatch–Waxman model and thus one of the most hotly debated elements of the new biosimilar pathway was the proper length of regulatory exclusivity periods.

During the negotiation, branded pharmaceutical companies wanted 14 years of exclusivity and pointed to a study that claimed 13–16 years would be needed to ensure future innovators would be able to get an adequate return on R&D investment.[12] They further argued that a longer period was needed for biologics than other drugs, because patents for biologic drugs are generally narrower in scope and more vulnerable to validity challenges.[13] In response, however, the U.S. Federal Trade Commission issued a report claiming that no additional exclusivity time was needed for biologic drugs.[14] In fact, they argued that biologic innovation was actually less dependent on regulatory exclusivity periods than small-molecule drugs, because it is more expensive to develop and gain approval for biosimilars than it is for small-molecule generics, and because existing market and regulatory realities would likely reduce the effect of biosimilar competition on prices for originator drugs.[15]

In light of this debate, in the period between 2006 and 2009, a number of bills were introduced in Congress to create a pathway for biosimilar approval with various exclusivity periods ranging from zero to fourteen years. The ultimate winner among those bills was Senator Ted Kennedy's Biologics Price Competition and Innovation Act (BPCIA)—with 12 years of exclusivity—because that is what was attached to the Affordable Care Act passed by Congress for reasons unrelated to the nuances of pharmaceutical competition and innovation.

More Work Left to Do

In light of ominous U.S. federal debt projections, curbing the rise of drug prices is imperative. In the coming decades, the United States faces a daunting fiscal outlook with profound consequences if we fail to bring debt down to sustainable levels.[16] Much of the projected increase in federal debt

7. 35 U.S.C. §156.

8. 21 U.S.C. §355(j).

9. See *The Role of Patents and Regulatory Exclusivities in Pharmaceutical Innovation*, Congressional Research Service, Jan. 14, 2014, p. 4. https://www.everycrsreport.com/reports/R42890.html.

10. "Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022," IQVIA Institute for Human Data Science, April 2018. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us-a-review-of-2017-and-outlook-to-2022.pdf?_=1570808528676.

11. Atanu Saha et al., "Generic Competition in the US Pharmaceutical Industry Article," *International Journal of the Economics of Business* 13:1 (February 2006), pp. 15-38. https://doi.org/10.1080/13571510500519905.

12. Henry Grabowski, "Follow-on biologics: data exclusivity and the balance between innovation and competition," *Nature Reviews Drug Discovery* 7:6 (June 2008) pp. 479-88. https://www.nature.com/articles/nrd2532.

13. Ibid.

14. *Emerging Health Care Issues: Follow-on Biologic Drug Competition*, Federal Trade Commission, June 2009. https://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf.

15. Ibid., pp. 10-23.

16. Since 2007, federal debt held by the public increased from 35 percent of GDP to 78 percent. Making reasonable assumptions, the Congressional Budget Office (CBO) projects that by 2029, the United States' debt-to-GDP ratio will reach 92 percent and 144 percent by 2049. See: "The 2019 Long-Term Budget Outlook," Congressional Budget Office, June 2019, p. 5. https://www.cbo.gov/system/files/2019-06/55331-LTBO-2.pdf.

levels is due to spending on mandatory healthcare programs including Medicare, Medicaid and the Children's Health Insurance Program (CHIP), which have grown—and are projected to continue to grow—faster than the underlying economy.[17]

Thankfully, however, generic drugs help discipline federal healthcare spending. For example, the Association of Accessible Medicines, which represents generic manufacturers, estimates that "generic usage by Medicare and Medicaid saved taxpayers more than $137 billion last year, with $2,254 in average savings per Medicare beneficiary and $817 per Medicaid enrollee."[18]

But, biologic drug prices have not experienced a significant drop comparable to small-molecule drugs after Hatch–Waxman was implemented. Although almost a decade has passed since Congress created a pathway for biosimilar approval under the BPCIA, competition in the biologics market remains disappointingly low. As of December 2019, the FDA has approved only 27 biosimilar applications to compete with 10 originator drugs.[19] (In comparison, at least 53 biosimilars have been approved in the European Union.)[20]

Indeed, biologics remain the "biggest driver of rising drug prices."[21] Citing data by the IQVIA Institute,[22] Avik Roy of the Foundation for Research on Equal Opportunity recently noted that in 2017, "biologic drugs represented 2 percent of all U.S. prescriptions, but 37 percent of net drug spending. Since 2014, biologic drugs account for nearly all of the growth in net drug spending: 93 percent of it, in fact."[23] Accordingly, the slow pace of biosimilar adoption in the United States thus far also appears to prove the FTC's original predictions supporting its argument for a minimal exclusivity period.

Beyond patent and exclusivity terms, there are regulatory obstacles that make it harder for biosimilars to gain the market share needed to drive down prices. For example, in a 2017 study, the RAND Corporation estimated that future competition from biosimilars will result in cost savings of $24 to $150 billion by 2026.[24] That estimate has such a broad range because there are so many dynamic market and policy factors that could influence the level of market penetration of biosimilars during that period.

The Trump administration also identified a number of regulatory impediments to biosimilar adoption in its 2018 "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs."[25] These include Medicare reimbursement rules that perversely incentivize providers to administer the most expensive biologic drug available, FDA-mandated distribution limitations that inhibit biosimilar research and inadequate rules on the interchangeability of biosimilars and reference biologics. The blueprint therefore calls for policies that "improve the availability, competitiveness, and adoption of biosimilars as affordable alternatives to branded biologics."[26]

The introduction of biosimilars has also been further obstructed by brand biologic companies through aggressive patent litigation. This has included controversial "pay-for-delay" settlements, in which the maker of an original biologic drug pays biosimilar makers to keep their approved competing product off the market.[27] The phenomenon even prompted Congress to pass a law in 2018 requiring litigants in biologics-related litigation to submit any legal settlement for review by antitrust authorities.[28] All of this illustrates that the BPCIA did not achieve the proper balance and the United States needs a more effective pathway for biosimilar approval. In order to continue realizing the economic and fiscal benefits of generic drug competition, policymakers should therefore consider, among other options, shortening the 12-year exclusivity term for biologic drugs.

THE BENEFITS AND LIMITS OF FREE TRADE AGREEMENTS

As the Trump administration dithers by pulling out of TPP and making only modest changes to NAFTA and the U.S.-

17. In 2019, federal spending on these healthcare programs was 5.2 percent of GDP. It is projected to increase to 6 percent by 2029, and jump to 8.8 percent of GDP by 2049. Medicare spending alone accounts for 3.6 percent of GDP in 2019 and is projected to increase to 4.4 percent of GDP by 2029 and 7.0 percent by 2049. There are a number of reasons why healthcare spending is outpacing the economy and revenue growth to the federal government, including an aging population, greater life expectancy and rising healthcare costs. Ibid. pp. 6, 23-24.

18. "The Case for Competition: 2019 Generic Drug and Biosimilars Access and Savings in the U.S. Report," Association for Accessible Medicines, 2019. https://accessiblemeds.org/sites/default/files/2019-09/AAM-2019-Generic-Biosimilars-Access-and-Savings-US-Report-WEB.pdf.

19. "Biosimilar Approval Status," BR&R, last accessed Dec. 5, 2019. https://biosimilarsrr.com/about.

20. "Structural Market Changes Needed in U.S. to Achieve Cost-Savings from Biosimilars Lessons from Europe's Biosimilars Successes: Payer, Physician, and Patient Alignment Will Lower Costs, Increase Access to Biosimilars," Biosimilars Forum, Mar. 19, 2019, p. 5. http://biosimilarsforum.org/PDF/Biosimilars_WhitePaper-final.pdf.

21. Ibid.

22. "Medicine Use and Spending in the U.S." https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us-a-review-of-2017-and-outlook-to-2022.pdf?_=1570808528676.

23. Avik Roy, "Biologic Medicines: The Biggest Driver of Rising Drug Prices," *Forbes*, March 8, 2019. https://www.forbes.com/sites/theapothecary/2019/03/08/biologic-medicines-the-biggest-driver-of-rising-drug-prices/#5a1bcad418b0.

24. Andrew W. Mulcahy et al., "Biosimilar Cost Savings in the United States Initial Experience and Future Potential," RAND Corporation, 2017. https://www.rand.org/pubs/perspectives/PE264.html.

25. "American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs," U.S. Dept. of Health and Human Services, May 2018. https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf.

26. Ibid., p. 23.

27. *Biologics and Biosimilars: Background and Key Issues*, Congressional Research Service, June 6, 2019, pp. 11-14. https://fas.org/sgp/crs/misc/R44620.pdf.

28. Mark Terry, "Trump Signs FTC Law That Allows for Biosimilar Scrutiny," BioSpace, Oct. 11, 2018. https://www.biospace.com/article/trump-signs-ftc-law-that-allows-for-biosimilar-scrutiny.

Korea Free Trade Agreement, the rest of the world is rapidly moving forward.[29] If U.S. trade policy is going to contribute to economic growth and promote peaceful relations, negotiating more free trade agreements must be at the top of the agenda. FTAs open markets in the United States and abroad by reducing or eliminating protectionist trade barriers that serve the interests of politically powerful industries at everyone else's expense. In doing so, these agreements enrich consumers and producers in all countries involved.

The most essential characteristic of free trade agreements is that they provide for reciprocal liberalization. Each government agrees to provide more access to their own market in exchange for access to the other's. The reason these agreements require negotiations is that each government has a unique set of political priorities that make some domestic barriers more difficult to remove and some foreign markets more attractive to pursue. The United States, for example, is always keen to open markets for American farm products and financial services, but is also very reluctant to reduce automobile tariffs or to let foreign-built shipping vessels travel between U.S. ports.[30]

In essence, the commercial interests of exporters is leveraged against the protection currently enjoyed by import-competing businesses under existing trade law and thus the end result of trade negotiations generally reflects the relative political power of each of those two groups. And, although this paradigm does not always lead to radical levels of economic integration, it is virtually guaranteed to provide an improvement in national welfare compared to the status quo before negotiations began.

Why IP Doesn't Fit Well in FTAs

Unfortunately, however, the free trade agreement process has also been abused to pursue policies that have little or nothing to do with cross-border trade in goods and services. For example, U.S. FTAs routinely contain provisions related to the protection of endangered species,[31] workplace discrimination[32] and even anti-spam email laws.[33] Some of these issues have been added to smooth the passage of trade agreements through Congress. Others, however, exist simply because they further the interests of a business constituency that has the ear of U.S. trade negotiators. Provisions in the latter category are especially prolific in the IP chapters of FTAs.

U.S. negotiators have long sought to include increasingly strict and detailed provisions in FTAs mandating minimum levels of IP protection. Just as U.S. negotiators want to secure provisions that benefit American farmers or banks or manufacturers that export abroad, they also work to further the interests of IP rights holders in extending those rights to foreign markets.

But, unlike trade liberalization where more is generally better, other policy areas often require a thoughtful balance of competing interests to promote national welfare. This is especially true for IP policy, where governments seek to promote innovation by restricting competition. Exclusive rights granted to creators and inventors incentivize innovation, but they also incentivize lobbying to expand and extend those rights at the expense of future innovators and the consuming public.

Advocates for the inclusion of IP rules in FTAs argue that the rules simply seek to harmonize policies at current U.S. levels.[34] But this is not entirely true. FTAs include strongly worded provisions that mandate the restrictive parts of U.S. law, while neglecting key limitations and exceptions that make those restrictions workable.[35] Meanwhile, by turning existing levels of protection into trade obligations, IP provisions severely restrict the ability of U.S. policymakers to reform aspects of the U.S. system. In some cases, trade negotiators have secured detailed provisions describing every aspect of a complex regulatory scheme, even when policymakers are actively debating the merits of that scheme.[36] And U.S. trade negotiators often push for provisions that do not accurately reflect U.S. law. Rather than copy and paste the wording of U.S. law into trade agreements, negotiators craft paraphrased versions intended to convey a similar meaning, but those provisions often end up furthering an

29. Emre Peker and Jeffrey T. Lewis, "EU, Mercosur Reach Agreement on Trade," *The Wall Street Journal*, June 28, 2019. https://www.wsj.com/articles/eu-mercosur-reach-agreement-on-trade-11561745957.

30. See, e.g., 19 U.S.C. § 4201 (b)(3).

31. USMCA Article 24.22. https://ustr.gov/sites/default/files/files/agreements/FTA/USMCA/Text/24_Environment.pdf.

32. USMCA Article 23.9. https://ustr.gov/sites/default/files/files/agreements/FTA/USMCA/Text/23_Labor.pdf.

33. USMCA Article 19.3. https://ustr.gov/sites/default/files/files/agreements/FTA/USMCA/Text/19_Digital_Trade.pdf.

34. See, e.g., 19 U.S.C. § 4201 (b)(5)(A)(II).

35. For example, copyright law grants authors the exclusive right to distribute or reproduce their creative works, subject to a broad exception known as "fair use." The U.S. copyright system is completely unworkable without fair use, which prevents copyright holders from blocking criticism, news reporting and even basic online communication about their work. Like all modern U.S. FTAs, the USMCA does not obligate parties to provide this exception.

36. Article 18.10.30 of the U.S.–Korea Free Trade Agreement obligates the parties to require websites to remove potentially infringing content through a notice-and-take-down system modeled after the Digital Millennium Copyright Act. The provision is 1,300 words long and is further clarified by a 1,000-word side letter.

interpretation of U.S. law that is more beneficial for rights holders.[37]

U.S. negotiators have even proposed provisions that directly contradicted U.S. law. For example, in 2013, the Supreme Court held that copyright holders were not entitled to block the importation of used copies of books they authorized for sale abroad.[38] At the same time, the United States was advocating the opposite rule in the TPP. By the time the TPP was signed, without the proposed U.S. provision, the Court had made a similar ruling under the patent law.[39] Interestingly, a provision similar to what U.S. negotiators proposed in the TPP is currently in force under the U.S.—Jordan Free Trade Agreement, which the United States is currently violating.

Moreover, the provisions most aggressively sought by U.S. negotiators are often the ones that get the most resistance from trading partners. Foreign countries without a significant pharmaceutical industry, for example, have no reason to accept provisions mandating the U.S. practice of patent linkage that extends the life of drug patents after delays in marketing approval. In order to get those countries to acquiesce to a provision that raises healthcare costs with no commercial benefit, U.S. negotiators necessarily have to give ground somewhere else in the negotiations. It is difficult to say whether furthering the interests of the pharmaceutical industry in that instance is worth giving up, say, market access for pork or airplanes.

BIOLOGICS PROVISIONS IN FTAS

Long biologic exclusivity provisions fit perfectly into the category of misguided intellectual property provisions pushed by U.S. negotiators in FTAs. Such a provision would not open markets or even promote innovation. Instead, it would tie the hands of U.S. policymakers for the benefit of one part of one industry, while reducing the overall benefits to the U.S. economy.

As discussed above, the 12-year exclusivity period provided in U.S. law for new biologics is just one component of a complex regulatory scheme. That scheme is constantly evolving as policymakers continually review outcomes and tweak the process to find the right balance of policies that will promote both competition and innovation in healthcare. And, the last ten years of experience with increasingly expensive biologic drug prices and minimal competition from biosimilars has convinced leaders on both sides of the aisle that something needs to change.

However, to enshrine the current 12-year term as international law through a trade agreement would arbitrarily designate one component of the U.S. healthcare system as off-limits for reconsideration by Congress. Not only will including lengthy exclusivity periods in trade agreements like the USMCA hamper Congress's ability to lower prices in the U.S. biologics market through private competition, it also encumbers the U.S. trade agenda as a whole. There is no other country with a 12-year exclusivity period for biologics. In fact, the longest period outside the United States is ten years in Europe, while Japan and Canada have eight years. Most other countries provide only five years of exclusivity for new biologics or have no exclusivity period at all. It is therefore unsurprising that the United States has faced strong, unified resistance from trade partners on the biologics issue, and in order to secure inclusion of a biologics provision in any future free trade agreements, the United States would have to make serious sacrifices with respect to other objectives.

Legal and Political Realities

Legal and political considerations require a new approach to biologic exclusivity in trade agreements.

Under the terms of Trade Promotion Authority (TPA), which establish priorities for trade negotiations in exchange for expedited consideration of FTAs, U.S. trade negotiators are required to pursue agreements that "foster innovation and access to medicine."[40] In other words, they must pursue a balanced approach to pharmaceutical IP provisions. On the contrary, however, the USMCA's original biologics standard, which required the parties to provide "at least" ten years of exclusivity, fell short of the approach contemplated by Congress when it passed TPA in 2015.

There are also domestic and international political hurdles that face excessively generous exclusivity periods. As mentioned, during the TPP negotiation, U.S. trade negotiators spent a lot of time and political capital pushing for a 12-year exclusivity period that would mirror domestic law—and this was largely at the behest of then-Chairman of the Senate Finance Committee, Orrin Hatch (R-Utah).[41] This was a controversial position opposed by virtually every other TPP member.[42] Indeed, even Ambassador Michael Froman, the USTR during the latter stages of the negotiation,

37. Margot E. Kaminski, "The Capture of International Intellectual Property Law Through the U.S. Trade Regime," *Southern California Law Review* 87:977 (2014), pp. 1015–31. https://web.law.columbia.edu/sites/default/files/microsites/kernochan/11-capture-of-international-ip-through-us-trade-regime.pdf.

38. *Kirtsaeng v. John Wiley & Sons*, Inc., 568 U.S. 519 (2013).

39. *Impression Prods. v. Lexmark Int'l, Inc.*, 137 S. Ct. 1523 (2017).

40. 19 U.S.C. § 4201 (b)(5)(C).

41. Vicki Needham, "Finance chair: Trade deal may need to be renegotiated," *The Hill*, Nov. 11, 2015. https://thehill.com/policy/finance/259426-hatch-concerned-tpp-may-fall-short-of-congressional-expectations.

42. Jeffrey J. Schott, "Five Flaws in the USMCA and How to Fix Them," The Peterson Institute for International Economics, Aug. 6, 2019. https://www.piie.com/blogs/trade-and-investment-policy-watch/five-flaws-usmca-and-how-fix-them.

acknowledged that the biologics provisions were the toughest portion to negotiate.[43] Eventually, TPP members settled on between five and eight years of exclusivity[44] before the remaining members jettisoned the provision altogether, once the Trump administration withdrew the United States from the agreement.[45]

Lengthy exclusivity provisions also face political problems domestically. Many congressional Democrats pointed to the biologics provisions in the TPP as a reason to oppose the agreement.[46] Likewise, more than 100 House Democrats recently wrote a letter to the USTR expressing reservations about the USMCA's biologics provisions.[47] After intense negotiations, the United States, Mexico and Canada agreed to remove the provision from the Agreement. A bipartisan bill recently introduced in the House of Representatives by Reps. Jan Schakowsky (D-Ill.) and Bruce Westerman (R-Ark.) would decrease the period of exclusivity domestically to five years.[48] By enshrining "at least" 10 years of market exclusivity into the USMCA, any efforts to shorten the period would violate the terms of the agreement.

POLICY SUGGESTIONS

With both domestic and international political opposition to lengthy biologic exclusivity periods, it is time to establish a new standard in FTAs. First, removal of the provision from the USMCA is a good start. This should help smooth passage of the Agreement. However, while removing the biologics provision is a good first step, U.S. trade negotiators should be willing to go even further. To ensure that Congress maintains the flexibility needed to manage the complexities of U.S. pharmaceutical regulation, future trade agreements should include a provision explicitly recognizing each country's right to define its own exclusivity period.

Beyond the issue of biologics exclusivity, the U.S. trade agenda would benefit immensely from a decoupling of intellectual property policy and trade governance. There are already numerous international agreements in place that set minimum standards for IP protection at a multilateral level, and those standards are already enforceable through the World Trade Organization's dispute settlement mechanism. If the U.S. government is dissatisfied with the substance of existing obligations, it is free to advocate for the adoption of stricter standards within the multilateral system. Such an approach would significantly reduce the potential for rent-seeking by narrow groups of rights holders. Moreover, removing IP from the U.S. trade agenda entirely would keep future negotiations from being bogged down by contentious issues of questionable economic value, while making trade liberalization as a whole less controversial politically.

CONCLUSION

Aggressive trade liberalization has been one of the post-War era's greatest policy achievements. And, although it has proven its merits, today efforts to further liberalize trade face a number of headwinds. One way to enhance the prospects for future U.S.-led liberalization would be to purge controversial IP policies from the U.S. trade agenda. The Trump administration has taken a good first step in that direction by removing the biologics exclusivity provision it originally pushed for in the USMCA. Likewise, given the rising price of prescription medicines and the long-term debt projections facing the United States, a more balanced approach to IP and exclusivity in trade agreements would augment ongoing bipartisan efforts to reduce healthcare costs through expanded access to generic pharmaceuticals and biosimilars.

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