PhRMA
RESEARCH • PROGRESS • HOPE

Making Trade Work for America's Biopharmaceutical Innovators

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Introduction

To lead the world in medical innovation, America must remove international trade barriers

The vast majority of the world's medical innovation occurs in the United States because of a reliable patent system where risk is rewarded, innovators are protected, and a predictable flow of resources fuels continuous research and development. In 2016 America's biopharmaceutical sector invested nearly $90 billion in research and development (R&D) and supported nearly 4.8 million American jobs while at the same time driving a total economic output of $1.3 trillion in goods and services. Trade agreements with other nations extend this mutually beneficial arrangement into new frontiers, helping us reach patients and consumers with the latest treatment and cures.

But these gains are at risk. Governments around the world are using unfair trade practices to undermine American innovation and disadvantage our companies in foreign markets.
In many cases, as with Australia and South Korea, the United States has well-written trade agreements — but key commitments have not been implemented. In other cases, as with Canada, Turkey and Saudi Arabia, U.S. trade partners attempt to circumvent restrictions by taking actions designed to favor local competitors at the expense of U.S. innovators. A new or revised North American Free Trade Agreement (NAFTA) agreement is needed to ensure our trading partners protect intellectual property (IP) and value U.S. innovation.

The U.S. government must hold its trading partners to account. Millions of jobs in America — and millions more patients around the world — hang in the balance. America's trade policy should:

1. **Enforce existing trade agreements** by ensuring that our trade partners value U.S. innovation and fulfill their trade obligations.
2. **Eliminate government price controls that do not appropriately value U.S. innovation** by holding decision-makers accountable to the frameworks established under existing trade agreements.
3. **Uphold sound patent law** by not allowing trade partners to twist rules and dilute globally-defined patentability criteria which undermines a system that has delivered life-saving treatments, vaccines and cures to every corner of the world.
4. **Challenge illegal localization barriers** by addressing requirements designed to block foreign imports and enrich local competitors.
5. **Reject compulsory licensing** by preventing foreign governments from expropriating—or threatening to expropriate—American innovations through the abuse of temporary measures used in emergencies.

The U.S. government must enforce existing trade obligations robustly and negotiate new trade commitments to ensure that pricing and reimbursement regimes are transparent, provide procedural fairness, are non-discriminatory and provide full market access for United States products. Everyone wins when trade partners value innovation by creating efficient and transparent procedures for bringing new medicines to market.

Enforcing Unmet Intellectual Property Obligations

Trade depends on trust. When the United States inks a deal with trade partners, we must be able to trust our partners to properly enforce the rules of that agreement. When such obligations are disregarded, trust is eroded and the fabric of international cooperation begins to fray. Governments must enforce the rules they agreed to in trade deals if they want access to American innovation.

Intellectual property rights are the bedrock of innovation. Strong patent and regulatory data protections, coupled with mechanisms to quickly resolve patent disputes, create powerful incentives to invest in R&D for new medical treatments that benefit patients around the world. Confidential information provided to trading partners to verify and approve innovative products must not be misused by government authorities or shared with competitors. This is why we take pains to ensure that international trade agreements include robust intellectual property rules to protect U.S. innovators.

Unfortunately, many countries are failing to honor their trade obligations.

Regulatory data protection (RDP), also sometimes referred to as "data exclusivity," is an important complement to patent protection. RDP promotes investment in clinical trials by securing the regulatory test data that flow from them. Trade agreements like the World Trade Organizartion (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) bar both disclosure and unfair commercial use of regulatory test data submitted as a condition of obtaining marketing approval for medicines.[1]

Pursuant to "Trade Promotion Authority," U.S. trade agreements are supposed to, "reflect a standard of protection similar to that found in United States law," which provides 12 years of RDP for biologics and five years for "small molecule" medicines.[2] As such U.S. trade agreements require RDP to be protected for a specified period of time. Nonetheless, a number of countries have not or not adequately implemented RDP regimes as required in these agreements.

Biopharmaceutical innovators must also be able to enforce their patents in order to support continuous investment in expensive, risky R&D for new medicines. Early resolution of patent disputes helps prevent infringing follow-on products from prematurely entering a market. Despite agreeing to provide effective enforcement mechanisms, several U.S. trade partners have yet to act.

Ineffective Regulatory Data Protection: Mexico, India, Argentina and Saudi Arabia

In **Mexico**, the leaders of regulatory and patent agencies have committed to provide data protection for all pharmaceutical products, including biologics. However, concerns remain regarding an apparent distinction drawn in the provision of RDP to chemically synthesized (small molecule) and biologic drugs. TRIPS does not condition the provision of RDP on the manner in which the medicine is synthesized. In addition, while COFEPRIS issued guidelines to implement RDP for a maximum period of five years, no firm regulations have been put in place.

Unfortunately, many countries are failing to honor their trade obligations.

In **India**, regulatory bodies do not provide any RDP and rely on test data submitted by originators to seek approval in India and/or another country to grant marketing approval to copy products – a practice prohibited by TRIPS. Likewise, **Argentina** provides no protection for clinical trial and other data submitted for marketing approval. Indeed, Argentina's law expressly permits government officials to rely on data submitted by innovators to approve requests by competitors to market similar products.

In **Saudi Arabia**, the Kingdom has regulations providing for at least five years of RDP. Nevertheless, in 2016, two local manufacturers received marketing approval for a Hepatitis C treatment based on the clinical trial data submitted by a U.S. innovator that was still under the five years of protection afforded by Saudi law. The locally-produced product was subsequently acquired and distributed by the Saudi Ministry of Health. Saudi Arabia is a member of the WTO and subject to TRIPS.

[1] WTO Agreement on Trade Related Aspects of Intellectual Property Rights, Article 39(3).
[2] 2015 Bipartisan Congressional Trade Priorities Act.

Early Resolution of Patent Disputes: Australia

The U.S.-Australia FTA provides that when marketing approval is sought by an applicant for a generic product or use that is protected by a patent, **Australia** should prevent marketing of the generic product or use during the patent term without consent of the patent owner, and that the patent owner shall be notified of such request.[3] However, originator pharmaceutical companies in Australia currently do not receive advance notice of a third party's intention to enter the market, and the information is not made available until after the generic has already been registered. Thus, Australia is not complying with a critical obligation in this agreement.

Patent Term Adjustment and Restoration: Korea

Recognizing that lengthy patent examination delays and long regulatory approval processes reduce the period over which a biopharmaceutical innovator can seek to recoup the significant costs of their R&D investments, a number of U.S. FTAs require trading partners to adjust and/or restore the patent term to compensate for this lost time. While such provisions are included in the U.S.-Korea FTA, recent decisions by the **Korean** courts have impermissibly limited the restored term only to the product actually approved for marketing, rather than to the patented invention related to the product, thereby undermining the purpose and value of patent term restoration.

A number of countries are failing to abide by long-standing obligations under TRIPS and bilateral agreements to protect RDP, to implement an effective mechanism to resolve patent disputes early and to provide patent term adjustment and restoration. The U.S. government must enforce these obligations in existing U.S. trade agreements and bilateral government-to-government discussions. It must also seek opportunities to reinforce and secure new RDP commitments in trade agreement negotiations that reflect the high standards found in U.S. law, including ongoing NAFTA talks.

[3] U.S.-Australia FTA, Art. 17.10.4.

Eliminate Government Price Controls

Price Controls Corrode Public Health

Government-imposed price controls stifle innovation and limit patient access to quality healthcare. As more countries enact direct and indirect price controls, Americans have borne a disproportionate share of the cost and risks in financing medical advances while manufacturers in other countries reap the rewards. Comprehensive and intelligently crafted trade agreements with Australia and South Korea should guide American policy on price controls in regions across the world—and the practice of price controls should end. As the administration embarks on trade talks with NAFTA countries and others, the elimination of government price controls that do not appropriately value U.S. innovation should be top on its list of priorities. Canada, one of our NAFTA partners, has one of the most oppressive pricing and reimbursement systems. The administration should use the NAFTA modernization negotiations to ensure that Canada's pricing and reimbursement regimes are transparent, provide procedural fairness, are non-discriminatory and appropriately value U.S. innovative medicines.

America leads the world in the discovery and development of new medicines. To stay on top, our biopharmaceutical sector invested nearly $90 billion in R&D in 2016 and supported 4.8 million jobs nationwide. Yet too often, the fruits of these labors are diminished by international trade barriers. Foreign governments deploy a number of tactics to artificially lower the prices paid for medicines developed in the U.S., rather than letting markets determine their value. This includes obscuring negotiations through a lack of transparency and denying due process of pricing and reimbursement policies.

These tactics amount to government-imposed price controls on medicines. Price controls – often in the form of government regulation – hamper investment in research and development, harm patients, and jeopardize millions of American jobs.

The U.S. government has long-recognized the importance of appropriately valuing medical innovation — and the risks that price controls pose to American patients. The U.S. Department of Commerce has stated that price controls and similar measures not only "reduce social welfare by depressing the number of new drugs" brought to market, but also "delay or reduce the availability of some innovative medicines"— thereby limiting competition and denying national health systems the benefits of innovation in reducing health care costs[1] This same study also highlighted how non-transparent approval criteria and procedures for new drugs can operate "much like price controls" and "create registration delays and increased costs for manufacturers, thus limiting the rewards of innovation."[2] In order to address these concerns, the U.S. government has worked with its trading partners to secure commitments that their pricing and reimbursement mechanisms appropriately value innovation, and to eliminate unnecessary delays and uncertainties associated with bringing new medicines to market. It must continue to do so in future agreements and at the same time ensure that obligations under existing trade deals — including the KORUS agreement — are implemented.

CASE STUDIES: South Korea, Japan and Canada

Building on the strong foundation established with Australia, the United States-Korea Free Trade Agreement (KORUS) included groundbreaking provisions on transparency and due process in pharmaceutical pricing and reimbursement policies. KORUS was negotiated against the backdrop of widespread concerns regarding the lack of transparency and other procedural deficiencies in the Korean health regulatory and reimbursement systems.[3]

To address these concerns, U.S. negotiators secured important commitments from **Korea** to base pricing and reimbursement decisions either on "competitive market-derived prices" or at least that the determination "appropriately recognize the value of the patented pharmaceutical product ...." Article 5.3 of KORUS also requires parties to publicize laws relating to pricing and reimbursement, and, to the extent possible, publish these measures in advance of adoption, and permit interested persons a reasonable opportunity to comment on the proposed measures. These provisions were "expected to give stakeholders a meaningful opportunity to participate in the development of rules and regulations in the pharmaceutical sector."

[1] U.S. Department of Commerce, International Trade Administration, Pharmaceutical Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation at (2004).
[2] Id. at 6-7.
[3] See United States International Trade Commission, U.S.-Korea Free Trade Agreement: Potential Economy-wide and Selected Sectoral Effects at 3-65 USITC Pub. 3949 (Sep. 2007), available at https://www.usitc.gov/publications/pub3949.pdf [hereinafter ITC KORUS Report]; The United-States Korea Trade Promotion Agreement, Report of the United States Industry Trade Advisory Committee for Chemicals, Pharmaceuticals, Health/Science Products and Services [ITAC-3] at 7, available at https://ustr.gov/sites/default/files/uploads/Countries%20Regions/africa/agreements/korus/ITAC%203%20-%20Chemicals,%20Phamaceuticals,%20Health%20Science%20Products%20&%20Services.pdf.
[4] United States-Korea Free Trade Agreement (entered into force March 15, 2012), art. 5.2(b).

Unfortunately, Korea has failed to live up to these trade obligations in a number of respects.

For example, the current government sets prices for new medicines based on the weighted average price within the therapeutic class, which includes off-patent and generic drugs. This allows the government to significantly undervalue innovation. The government institutes drastic price reductions on the off-patent and generics market, and then bases new drug prices on the prices of those now heavily-discounted medicines. As a result, the government inappropriately depresses the prices of innovative medicines, calling into question Korea's commitment under Article 5.2 of KORUS to "recognize the value of the patent pharmaceutical product."

In addition, since 2010, Korea's Ministry of Health and Welfare (MOHW) has repeatedly changed its pharmaceutical pricing and reimbursement policies without considering the long-term implications for innovation and market predictability. These policies have at times targeted innovative pharmaceutical companies. Despite Korea's obligations to provide transparency and due process,[6] government consultations with stakeholders are too often perfunctory.

Korea also agreed to "make available an independent review process that may be invoked at the request of an applicant directly affected by a recommendation or determination."[7]

Unfortunately, Korea has failed to live up to these trade obligations in a number of respects.

The Korean government has taken the position, however, that reimbursed prices negotiated with pharmaceutical companies should not be subject to the independent review mechanism (IRM) because the National Health Insurance Service (NHIS) does not make "determinations" and merely negotiates the final price at which a company will be reimbursed. This interpretation seems to run counter to the original purpose of the IRM by failing to apply to the negotiation process for prices of all reimbursed drugs, especially for patented medicines.[8] The administration should use the reinvigorated KORUS talks with South Korea to ensure implementation of these important provisions.

In **Japan**, the drug pricing package announced in December 2017 contains a number of new policies that run counter to the government's pledge to fuel and appropriately value innovation. Of particular concern, the number of innovative products to qualify for the Price Maintenance Premium (PMP) will be reduced dramatically and fewer companies will qualify for the full benefit of the PMP under the newly-established company requirements that favor local companies. Recent estimates indicate that approximately one-third of patented medicines would no longer qualify, resulting in $1.7 billion in lost revenues annually. This move threatens to severely and inappropriately undervalue U.S. intellectual property and the discriminatory eligibility criteria are biased towards local companies and seriously call into question Japan's commitment to fair and non-discriminatory policies.

[5] KORUS ITC Report at 3-65.
[6] Under Article 5.3 of KORUS.
[7] Under Article 5.3(5)(e) of KORUS.
[8] As the ITC observed, KORUS creates "an independent review mechanism that would allow medical device manufacturers to challenge the Korean government's pricing and reimbursement decisions for medical devices." ITC KORUS report at 3-91. The ITC also noted that KORUS requires authorities "to establish an independent review process that may be invoked at the request of an applicant directly affected by a reimbursement decision or recommendation." Id. at D-8. Emphases added.
[9] Patent Act, R.S.C. 1985, c.P-4, ss.79-103.

With regard to **Canada**, the Canadian government has proposed changes to the Patented Medicine Prices Review Board (PMPRB)–an independent quasi-judicial body created under the Canadian Patent Act,[9] that solely regulates the maximum allowable price that a manufacturer can charge for patented medicines in both in the public and private segments of the Canadian market.

The proposed changes include:

1. replacing the United States in the reference basket of so-called "comparator countries" with countries, such as Korea, that do not appropriately reward the value of patented medicines;
2. injecting unnecessary pharmacoeconomic analysis into the PMPRB's ceiling price determination; and
3. compelling companies to divulge confidential rebates and other discounts that they may offer to both public and private payers.

These policy changes threaten to significantly undervalue U.S. innovative medicines and further harm the innovative biopharmaceutical industry looking to provide medicines to patients in Canada. Innovative Medicines Canada (IMC) estimates that the proposed changes could reduce industry revenues by as much as 25-30 percent or (CAN) $26.1 billion over the course of ten years. NAFTA renegotiations – and other available trade tools such as the Special 301 Report – are a vehicle to secure reforms of existing harmful PMPRB policies (e.g., regulation of private market prices) and prevent changes to the PMPRB's mandate that would harm U.S. biopharmaceutical innovators.

Many U.S. trading partners fail to properly value innovation in their pricing and reimbursement mechanisms. Coupled with delays and a lack of transparency in the process of bringing new medicines to foreign markets, these failures can result in significant negative impacts on American patients and the U.S. biopharmaceutical industry. Our government must robustly enforce trade obligations and negotiate new trade commitments reflecting the mandate under Trade Promotion Authority to ensure that pricing and reimbursement decisions are **transparent, fair and appropriately value patented pharmaceuticals**.[10] Everyone wins when trade partners value innovation by creating efficient and transparent procedures for bringing new medicines to market.

[10] The 2015 Bipartisan Congressional Trade Priorities Act established a U.S. trade negotiation priority to "ensure that government regulatory reimbursement regimes are transparent, provide procedural fairness, are non-discriminatory, and provide full market access for United States products."

Uphold Sound Patent Law

Trade Partners are Undermining U.S. Intellectual Property

Patents are vital to innovation. Sound patent law ensures that U.S. biopharmaceutical companies can maximize the reach of their life-saving medicines around the world. Yet some countries undermine these protections by imposing additional criteria — precisely to prevent American innovators from securing patents. Others selectively tighten criteria to prevent the patenting of new inventions that are protected in the U.S. and other jurisdictions. These arbitrary and inconsistent changes to patent law undercut a system that has created so much innovation for the world — and sustained millions of American jobs.

To produce valuable new medicines, U.S. biopharmaceutical manufacturers rely on fair, stable and predictable patent systems. These protections are fundamental to innovation, providing vital incentives for the discovery of breakthrough treatments and cures for a wide range of chronic and infectious diseases. They also form the foundation for our industry—which produced $1.3 trillion in economic output for the United States in 2016 and supported 4.8 million jobs across America.

That's why it's so troubling that India, Indonesia and Argentina are actively undermining the global patent system through policies that impose additional or heightened patentability criteria—and sometimes even prohibit patents altogether on certain biopharmaceutical inventions. These policies violate long-standing internationally-established patent standards, restrict patient access to new medicines and undermine investment in future treatments and cures.

In violation of recognized global obligations,[1] some of our trading partners are changing their rules on patentability, causing patents on legitimate inventions to be denied or revoked. This trend has significantly increased costs for industry—putting American jobs at risk—and encourages other countries to follow suit.

Imposition of heightened or additional patentability criteria

Under Section 3(d) of the Indian Patents Act, **India** prohibits patents on known pharmaceutical products unless patent applicants can demonstrate that they can meet an "enhanced efficacy" test, while **Indonesia's** new patent law also incorporates a similar test. These efforts deliberately discriminate against U.S. biopharmaceutical products in violation of the WTO TRIPS Agreement.

Restrictions on scope of patent-eligible subject matter

A number of countries have adopted laws and regulations that, per se, prevent the patenting of a wide range of specific improvements to existing medicines—improvements that are valuable to patients and payers and that require significant investment and research to develop. For example, in 2012, **Argentina** adopted regulations, and in 2016, **Indonesia** adopted a new patent law that prevent biopharmaceutical innovators from securing patents on certain types of inventions, including new forms and new uses of known products. Such laws and regulations, which narrow the scope of patentable subject matter are inconsistent with the WTO TRIPS agreement.

When foreign governments undermine U.S. patents, it causes a chain reaction that hurts patients all around the world. If U.S. biopharmaceutical innovators are to continue to invest in the development of life-saving treatments and cures, the erosion of patent protections must stop. The U.S. government must ensure that its trading partners live up to their obligations under the WTO—as well as regional and bilateral trade agreements, which reaffirm the WTO standards on patentability of biopharmaceutical innovations. The U.S. government should leverage the Special 301 process, existing dialogues (such as the U.S.-India Trade Policy Forum), and in certain cases dispute settlement to stem this damaging trend.

[1] The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and U.S. trade agreements set minimum standards for the protection and enforcement of patents and other intellectual property rights. These agreements require that patents be available to all inventions that are new ("novel"), non-obvious (e.g., "inventive step") and capable of industrial application (e.g., are demonstrated to have "utility" or be "useful"). They also obligate WTO members to make patents available for inventions in all fields of technology, with limited specified exceptions. The U.S. government has also affirmed the importance of incentivizing the development of improvements to existing medicines by making clear in trade agreements that "patent applications for inventions that are otherwise novel, non-obvious, and useful are not rejected merely because they are related to a known product." (Office of the U.S. Trade Representative, 2016 Special 301 Report at 12 (2016)).

Challenge Illegal Localization Policies

Trade Partners are Discriminating Against American Innovators

America leads the world in innovation—and we can stay on top if we level the playing field for U.S. companies. Some of our trading partners use "local standards" to discriminate against affordable, high-quality American products. These governments effectively rig the market, ignoring their trade obligations by obstructing American products even as they enjoy access to the U.S. market. This hurts patients and hampers economic growth in both countries.

In our efforts to provide patients around the world with the latest life-saving treatments and cures, U.S. biopharmaceutical companies face an increasing number of discriminatory and excessive "localization" barriers. These include:

- Local content or production requirements—when companies are forced to use local inputs or build unnecessary "brick-and-mortar" facilities;
- Mandated technology transfers—requiring foreign investors to give up their intellectual property as a condition for entering the market; and
- Public procurement restrictions—giving price or other advantages to local firms in government tenders.

These restrictions limit market access, discourage innovation, and deny vulnerable patients access to medicines. Such measures are often designed to prop up fledgling local industries at the expense of U.S. jobs and new R&D investment, undermining economic growth in both countries.[1] Trading partners wield the threat of "compulsory licensing" or expropriating a U.S. company's intellectual property should that company refuse to enter a particular market in the face of these flagrant measures.

A number of U.S. trading partners—including Argentina, Japan, China, India, Indonesia, Saudi Arabia, Turkey and Vietnam—impose localization barriers that hamper every aspect of medical innovation, from securing a patent and regulatory approval to market entry and that are intended to rig the market for local manufacturers.

Trade Principles

Localization requirements that discriminate against imports explicitly to prop up local producers are inconsistent with the principles and rules of the global trading system.[2] While the U.S. has successfully sought to enforce such obligations against its trading partners that impose discriminatory local content requirements,[3] the increasing use of and threat posed by localization restrictions has led to heightened focus on the problem.

For example, the 2015 Bipartisan Congressional Trade Priorities Act ("Trade Promotion Authority") introduced a new principle negotiating priority to "to eliminate and prevent measures that require U.S. producers and service providers to locate facilities, intellectual property, or other assets in a country as a market access or investment condition, including innovation measures." The U.S. has also included provisions to combat localization, such as by forbidding mandatory technology transfers in the 2012 U.S. Model Bilateral Investment Treaty (BIT),[4] and proposed including such provisions in the Trade in Services Agreement.[5] Although government procurement is excluded from some trade obligations, the U.S. has joined the WTO's voluntary Agreement on Government Procurement (GPA), which seeks to open government procurement markets.[6]

[1] The discriminatory and distortive measures at issue here stand in contrast to incentive-based and broadly-applied practices — such as robust research and development and standards-based regulations – that encourage voluntary investment in local industry based on market conditions.

[2] Including the national treatment provisions of World Trade Organization (WTO) agreements, as well as the General Agreement on Tariffs and Trade Article III, the Agreement on Technical Barriers to Trade Article 2.1, the Agreement on Trade-Related Aspects of Intellectual Property Rights Article 3, and the Agreement on Trade-Related Investment Measures Article 2.

[3] See, e.g., Canada – Administration of the Foreign Investment Review Act, L/5504 - 30S/140, ¶ 6.1 (July 25, 1983) ("[T]he practice of Canada to allow certain investments subject to the Foreign Investment Review Act conditional upon written undertakings by the investors to purchase goods of Canadian origin, or goods from Canadian sources, is inconsistent with [GATT] Article III:4."); India – Certain Measures Relating to Solar Cells and Solar Modules, WT/DS456/AB/R, 5.40-41 (Sep. 16, 2016) (affirming the panel's decision that India's local content requirements are inconsistent with GATT article III:4 and TRIMS article 2.1).

[4] The 2012 U.S. Model BIT forbids the parties from requiring investors to purchase or use domestic technology, and conversely forbids parties from preventing investors from using particular technology. See 2012 U.S. Model BIT, article 8(1)(h), available at https://ustr.gov/sites/default/files/BIT%20text%20for%20ACIEP%20Meeting.pdf.

[5] See Rachel F. Fefer, Trade in Services Agreement Negotiations; Overview and issues for Congress, Congressional Research Service (Jan. 3, 2017), https://fas.org/sgp/crs/misc/R44354.pdf.

[6] World Trade Organization, Agreement on Government Procurement, available at https://www.wto.org/english/tratop_e/gproc_e/gp_gpa_e.htm.

CASE STUDIES:
Turkey and Japan

Discriminatory local inspection requirements

Since 2010, **Turkey** has required medical products to undergo a time-consuming and opaque certification process before entering the market. Turkish authorities lack the resources to expeditiously complete these inspections, causing significant delays and disproportionate impact on entry of imported pharmaceuticals to the market. This local inspection requirement grew more restrictive in 2016, when Turkish authorities began requiring full on-site inspections for essentially all imports — but not for domestic products. Turkey's recognition of legitimate foreign inspections is limited, and by forcing imports to undergo a full inspection, from which domestic products are excused, Turkey discriminates against U.S. manufacturers and as such is inconsistent with Turkey's national treatment obligations under General Agreement on Tariffs and Trade (GATT).

Coercive local manufacturing and tech transfer rules

Turkey has also imposed or proposed laws designed to coerce the use of local manufacturing. These measures include a December 2015 proposal to provide preferential reimbursement and faster regulatory approval for domestic healthcare products, coupled with the removal of imports from reimbursement lists when local products are available. In February 2017, the Social Security Institute released a list of 50 products to be delisted from the reimbursement list within one year unless they are produced locally, and a second wave of 176 products was released in May 2017. This policy clearly violates a number of Turkey's obligations under the WTO and GATT Agreements.

Discriminatory criteria in government pricing systems

In **Japan**, the drug pricing package announced in December 2017 contains a number of new policies that run counter to the government's pledge to fuel and appropriately value innovation. Of particular concern, the number of innovative products to qualify for the Price Maintenance Premium (PMP) will be reduced dramatically and fewer companies will qualify for the full benefit of the PMP under the newly-established company requirements that favor local companies. Recent estimates indicate that approximately one-third of patented medicines would no longer qualify, resulting in $1.7 billion in lost revenues annually. This move threatens to severely and inappropriately undervalue U.S. intellectual property and the discriminatory eligibility criteria are biased towards local companies and seriously call into question Japan's commitment to fair and non-discriminatory policies.

The U.S. should use all available means to ensure trade partners play by the rules and stop discriminatory and distortive localization restrictions — including the Special 301 process, bilateral dialogues, and the potential use of dispute settlement. These restrictions disadvantage U.S. companies in the global marketplace and create economic distortions that ultimately hurt patients.

Reject Compulsory Licensing

A Misused and Politicized Tool

While international trade law allows for compulsory licensing in very exceptional circumstances, too many countries, chief among them India, Indonesia and Malaysia, have abused this "compulsory licensing" exception, effectively using it as cover to steal — or, as a negotiating tactic to undervalue — medical technologies developed by American scientists. This is among the biggest threats to U.S. medical innovation and the nearly 4.8 million jobs it supports. Patent abuse and rampant imposition of price controls by America's trading partners jeopardizes investment in new treatments that we need to tackle the biggest threats to global health, such as diabetes, cancer, and multi-drug resistant

Biopharmaceutical innovators support strong national health systems and timely access to safe and effective medicines. In fact, our global business depends on it. However, our business also depends on strong and predictable intellectual property protections and pricing and reimbursement systems that value innovative medicines to attract investment and minimize risks inherent to medical innovation. Shepherding a single new medicine from the lab bench to the pharmacy costs more than $2.5 billion over 12 years, on average.[1]

Compulsory licensing — through which a government permits the making, use, sale or importation of patented pharmaceuticals without the patent-holder's permission — is among the most commercially disruptive and politically sensitive challenges facing America's pharmaceutical industry today. A disturbing trend has emerged where our trading partners use the threat of compulsory licensing as a negotiating tactic and industrial policy tool.

Numerous studies have shown that compulsory licensing is not a cost-effective or sustainable means to increase access to medicines.[2] Drug donation and voluntary licensing have simply produced better results.[3] The use of compulsory licensing by our trading partners as a negotiating tactic must stop.

International trade law limits on compulsory licenses and protections against discrimination

Before a compulsory license is granted, the acting government must first seek a voluntary license on "reasonable commercial terms and conditions"[4] in coordination with the patent-holder. In general, a compulsory license may be authorized only after these negotiations fail. Compulsory licenses also cannot be granted en masse or under general terms, and must be based on the individual merits of the request.[5] Furthermore a compulsory license must be limited in terms of its scope and duration to the purpose for which the compulsory license was authorized.[6]

The TRIPS agreement requires extensive protections to patent holders as part of any compulsory licensing process. For example, the patent holder is entitled to remuneration that is "adequate . . . in the circumstances of each case, taking into account the economic value of the authorization,"[7] and requires that patent holders be guaranteed the right to appeal both the authorization of a compulsory license and the amount of remuneration.[8] Finally, compulsory licenses are also subject to the foundational principle of non-discrimination.[9]

CASE STUDIES: Malaysia, Indonesia and India

In recent years, certain U.S. trading partners have adopted — or may soon adopt — laws and regulations that open the door to abuse of compulsory licensing. The governments of **Malaysia**, **Indonesia** and **India**, in particular, have demonstrated an increased willingness to use compulsory licenses to promote local manufacturing at the expense of U.S. biopharmaceutical manufacturers, while also failing to provide a number of procedural and due process protections as required by the TRIPS Agreement.

[1] PhRMA adaptation based on Dimasi JA. Cost of developing a new drug. Tufts Center for the Study of Drug Development (CSDD). R&D Cost Study Briefing (Nov. 18, 2014), available at http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf.

[2] See, e.g., Beall, Reed F. et al., "Compulsory Licensing Often Did Not Produce Lower Prices for Antiretrovirals Compared to International Procurement," Health Affairs, March 2015, available at http://content.healthaffairs.org/content/34/3/493.abstract?etoc.

[3] See, e.g., Chien, Colleen, "HIV/AIDS Drugs for Sub-Saharan Africa: How Do Brand and Generic Supply Compare?" PLoS One, Mar. 2007, available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1805689/; UNAIDS Report on the global AIDS epidemic (2012) at 50 ("Since 1995, antiretroviral therapy has added 14 million life-years in low- and middle-income countries, including 9 million in sub-Saharan Africa.")

[4] Article 31(b) of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

[5] TRIPS Article 31(a).

[6] TRIPS Article 31(c).

[7] TRIPS Article 31(h).

[8] TRIPS Article 31(i) and (j).

[9] As set forth in TRIPS Article 3, in the General Agreement on Tariffs and Trade (GATT) at Article III, and the Agreement on Trade-Related Investment Measures (TRIMS) at Article 2.

In late 2017, for example, the **Malaysian** government summarily announced plans to issue a "government use" compulsory license for the patent on a breakthrough Hepatitis C treatment that delivers cures for many.[10] That action will do nothing to help Malaysian patients. Indeed, the American company that developed the treatment had already offered to include Malaysia in a broader network of voluntary licensing agreements that allow more than 90 countries to produce cheaper versions of its therapies. Rather, it appears to be part of a broader plan to develop a competing local product that combines the innovative treatment with another molecule.[11] All that stood in the way was the patent.

Likewise, **Indonesia** adopted a new Patent Law in 2016 that enables the government to grant compulsory licenses on broad public interest grounds as well as in circumstances where the inventor is not manufacturing a patented product in Indonesia. Such a "local working" requirement is inconsistent with Article 27.1 of the TRIPS Agreement, which prohibits discrimination based on whether a product is imported or produced locally. In addition, this new law fails to take into account a number of the limitations set forth in TRIPS Article 31. For example, the law does not clearly provide that compulsory licenses are to be considered on their "individual merits" or guarantee that remuneration will be "adequate . . . in the circumstances of each case, taking into account the economic value of the authorization". Moreover, by requiring disclosure of private licensing agreements, Indonesia's new law could also discourage the use of voluntary licenses.

Similarly, in **India** the grounds for issuing a compulsory license are broad, vague, and inconsistent with the TRIPS Agreement. India has also sought to use compulsory licenses to promote local production at the expense of U.S. manufacturers and workers. In 2013, India's Intellectual Property Appellate Board affirmed a compulsory license for a patented oncology medicine, based in part on a finding that the patented medicine was not being *manufactured* in India.[12] In a similar manner, Indian pharmaceutical companies appear to be using India's patent law as a commercial tool under the guise of better access to medicines, rather than as a measure of last resort. These practices are discriminatory and inconsistent with the basic requirements of not only TRIPS, but also GATT, TRIMS, and other trade agreements.

International trade law includes fundamental protections for patent-holders that have fueled medical innovation for decades, both extending and improving life for hundreds of millions of people worldwide. Unfortunately, compulsory licensing abuse is eroding this system as more countries flout international rules. America's innovative biopharmaceutical industry depends on the stability of this system to support 4.8 million U.S. jobs and produce $1.3 trillion in economic output each year. The U.S. government must forcefully reject any efforts by countries to issue compulsory licenses for domestic industrial policy reasons, or otherwise in a manner inconsistent with international trade obligations. Furthermore, the U.S. government should leverage the Special 301 process as well as bilateral dialogues such as the U.S./India Trade Policy Forum to address this troubling situation.

[10] https://kpkesihatan.com/2017/09/20/press-statement-minister-of-health-20th-september-2017-implementation-of-the-rights-of-government-for-sofosbuvir-tablet-to-increase-access-for-hepatitis-c-treatment-in-malaysia/

[11] Drugs for Neglected Diseases Initiative (DNDi), "DNDi welcomes Malaysia's move to secure access to more affordable treatments for hepatitis C," September 2017, available at https://www.dndi.org/2017/media-centre/press-releases/dndi-welcomes-malaysia-move-access-affordable-treatments-hepc/.

[12] Bayer v. Union of India, Writ Petition No. 1323 of 2013.

Eliminate "Market-Size Damages" and Other Discriminatory Policies

Contrary to its trade agreements with the U.S., Australia has undermined innovators' ability to fight patent infringement. Its policies are designed to paralyze — and penalize — U.S. patent-holders while questionable copies swamp the market. Australia is setting a dangerous precedent that encourages others to free ride on American investments and biomedical progress. Broad adoption of these policies would handicap the U.S. biopharmaceutical industry — which invested $90 billion in R&D in 2016 — and jeopardize resources needed to produce new life-saving treatments and technologies.

To mobilize the massive resources needed to bring to market a new medicine, pharmaceutical innovators must be able to rely on *and* enforce patents. A company's ability to protect its intellectual property is the cornerstone of an R&D-intensive business model. Even after they're granted, patents routinely come under dispute. When this happens, patent-holders must have the ability to protect their inventions by asking a court to give temporary relief with a preliminary injunction. This stops competitors from flooding the market with product copies while the dispute is resolved.

Australia has adopted policies that undermine and discourage U.S. innovators from seeking injunctive relief during patent disputes. Its policies raise the specter of unpredictable damages for each new U.S. medicine that aims to help Australian patients. If these policies continue and spread, it will have a chilling effect on U.S. biopharmaceutical investment—which leads the world in developing new medicines and supports nea4.8 million American jobs.

How "Market-Size Damages" Works

Australian policies allow the government to seek "market-size damages" — i.e., the difference in price between a patented drug and its generic counterpart during the period of a preliminary injunction, where the patent is later ruled invalid or not infringed. This amounts to a catch-22 for biopharmaceutical companies. They can either stand idly by as generics storm the market, or they can risk seeking a preliminary injunction that, if later revoked, could result in a financial penalty even greater than the total returns they would have earned over the life of the patent.

"Market-size damages" can be devastating. They don't account for the costs borne by innovators to develop new medicines. On average, biopharmaceutical companies will spend more than $2.5 billion to produce a single new medicine, which means the returns earned for a patent can be far less than the difference between simply comparing branded and generic prices. Allowing the government, which is not a party to the patent dispute, to collect punitive damages undermines legal certainty, predictability and the incentives patents provide for investment in new treatments and cures.

The Australian government's pursuit of "market-size damages" also violates its obligations under the U.S.-Australia Free Trade Agreement (FTA)[1] and TRIPS.[2] The FTA addresses the authority of courts to require innovators to provide a "reasonable security or equivalent assurance" as a condition of seeking a preliminary injunction. Specifically, Article 17.11.17 provides that this assurance is to be "set at a level sufficient to protect the respondent and to prevent abuse, and so as not to unreasonably deter recourse to such procedures."[3] Allowing governments or other non-parties to a patent dispute to collect punitive damages after the fact exposes innovators to additional compensation claims that cannot be determined at the time the provisional enforcement measures were granted. By significantly increasing the cost and risk associated with provisional injunction measures, Australia effectively deters recourse to such procedures, contrary to its FTA obligations.[4]

[1] United States–Australia Free Trade Agreement, May 18, 2004 (entry into force Jan. 1, 2005) [hereinafter "U.S.-Australia FTA"].
[2] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C [hereinafter "TRIPS"].
[3] U.S.-Australia FTA, Art. 17.11.17 (emphasis added).
[4] Additionally, TRIPS provides that courts providing preliminary relief "shall have the authority to order the applicant, upon request of the defendant, to provide the defendant appropriate compensation for any injury caused by these measures." Because "market-size damages" are recovered by the non-party government, not a "defendant" in a patent dispute, such damages may also be inconsistent with TRIPS.

USTR has expressed concern about the consistency of Australia's measures authorizing "market-size damages" with its international commitments. Soon after the FTA's ratification, in a letter to the Australian Minister for Trade regarding the agreement's implementation, then-USTR Robert B. Zoellick emphasized U.S. government concerns that the Therapeutic Goods Act amendments would risk imposing "significant penalties" on pharmaceutical patent owners "seek[ing] to enforce their patent rights."[5] The letter "urge[d] the Australian Government to review this matter, particularly in light of Australia's international legal obligations," and reserved the United States' right to challenge the consistency of these amendments with Australia's international obligations.[6]

Australia's continued pursuit of "market-size damages" denies American companies the opportunity to stop patent infringement. The U.S. government should use the Special 301 process to engage the Australian government on the potential inconsistencies between its "market-size damages" law and policy and its FTA and WTO obligations. U.S. innovators should not be unfairly penalized for pursuing their right to preliminary injunctive relief—and the U.S. government must ensure that Australia ends this practice.

[5] Letter from Amb. Robert B. Zoellick to Hon. Mark Vaile MP, Nov. 17, 2004, at 3.
[6] Id.