Alliance for Fair Trade with India

Mr. Erland Herfindahl
Deputy Assistant U.S. Trade Representative for the Generalized System of Preferences and Chair of the GSP Subcommittee of the Trade Policy Staff Committee
Office of the United States Trade Representative
600 17th Street, N.W.
Washington, D.C. 20508

Re: 2018 India Country Practice Review, Docket Number USTR-2018-0006

Dear Mr. Herfindahl:

The Alliance for Fair Trade with India ("AFTI") is comprised of a diverse group of organizations that support a robust U.S.-India economic relationship but believe that the relationship has long underperformed its potential, confounded by longstanding trade and investment barriers. In this letter, and in accordance with the Federal Register notice,[1] AFTI submits its comments to the GSP Subcommittee on whether India provides equitable and reasonable access to its market under 19 U.S.C. § 2462(c)(4).

I. Summary of Interest

AFTI's diverse membership is comprised of companies and organizations representing a range of U.S. industries adversely impacted by problematic Indian policies and discriminatory trade barriers, including the erosion of protections for intellectual property rights ("IPR"). AFTI works to improve the U.S.-India commercial relationship, which remains weak due to persistent trade barriers in India that hurt a wide range of manufacturing and services industries and cost U.S. jobs.

AFTI has for several years submitted comments to USTR to inform its annual National Trade Estimate ("NTE") and Special 301 Reports. While the U.S.-India dialogue on a range of issues has improved since Prime Minister Narendra Modi was elected, it has not resulted in concrete action or substantial improvements to address AFTI's core policy concerns in a meaningful way. In fact, India has been identified as either a Priority Foreign Country or included in the Priority Watch List every year since USTR began issuing Special 301 Reports in 1989. That includes the recently released 2018 Special 301 Report, in which India was once again placed on the Priority Watch List. USTR stated in its report that "despite administrative actions aimed at improving India's IP system, India has yet to address key longstanding deficiencies in its IP regime," and that "India remains one of the world's most challenging major economies with respect to protection and enforcement of IP."[2]

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[1] Initiation of Country Practice Reviews of India, Indonesia, and Kazakhstan, 83 Fed. Reg. 18618 (Apr. 27, 2018), https://www.federalregister.gov/documents/2018/04/27/2018-08868/initiation-of-country-practice-reviews-of-india-indonesia-and-kazakhstan.

[2] Office of the United States Trade Representative, 2018 Special 301 Report at 48, https://ustr.gov/sites/default/files/files/Press/Reports/2018%20Special%20301.pdf.

AFTI appreciates this opportunity to comment on the many market access barriers that face American manufacturers in India. We note that USTR has accepted GSP petitions filed by two AFTI members, AdvaMed and the National Milk Producers Federation; these comments below supplement industry-specific challenges and speak to India's broader failure to provide equitable and reasonable access to its market.

II. India Is Not Providing Equitable and Reasonable Access to its Markets

India is required to provide "equitable and reasonable access to [its] markets" to enjoy GSP benefits. However, India maintains significant barriers to market access. In its review of India's eligibility as a GSP beneficiary, the GSP Subcommittee should examine India's conduct concerning (A) forced localization; (B) price controls; (C) dairy imports; (D) intellectual property and enforcement; (E) high tariffs and taxes; and (F) discriminatory testing requirements.

A. Forced Localization

India has implemented a series of deeply concerning forced localization measures that limit the access of U.S. industries to the Indian market in violation of 19 U.S.C. § 2462(c)(4). The 2018 Special 301 Report notes that "[i]nnovative industries also face pressure to localize the development and manufacture of their products, including under provisions of the Drug Price Control Order and also due to high customs duties directed to IP-intensive products, such as medical devices, pharmaceuticals, ICT products, solar energy equipment, and capital goods."[3] The localization requirements affect several IP-intensive, high-tech sectors such as solar energy and telecommunications.

India's local content requirements for solar energy projects have been subject to dispute settlement at the WTO. In February 2013, the United States requested consultations with India concerning certain domestic content requirements relating to the Jawaharlal Nehru National Solar Mission ("JNNSM"), including tender documents stating that a share of the projects were to be reserved for domestically-manufactured solar cells and modules. In August 2015, a WTO panel found that India had in fact violated the national treatment obligations in Article III:4 of the General Agreement on Tariffs and Trade ("GATT") and Article 2.1 of the Agreement on Trade-Related Investment Measures ("TRIMs").[4] In September 2016, the Appellate Body affirmed the panel's ruling, rejecting all of India's defensive arguments.[5] Just in December 2017, the United States indicated to the WTO dispute settlement body that India had failed to comply with the rulings and recommendations of the panel and Appellate Body.[6] Pursuing

[3] *Id.* at 49.

[4] Panel Report, *India – Certain Measures Relating to Solar Cells and Solar Modules*, WT/DS456/R (Feb. 24, 2016).

[5] Appellate Body Report, *India – Certain Measures Relating to Solar Cells and Solar Modules*, WT/DS456/AB/R (Sept. 16, 2016).

[6] Tom Miles, *U.S. Takes India Back to WTO in Solar Power Dispute*, Reuters, Dec. 20, 2017, https://www.reuters.com/article/us-usa-india-wto/u-s-takes-india-back-to-wto-in-solar-power-dispute-idUSKBN1EE1BK.

forced localization for commercial measures rather than national security purposes is in violation of India's international obligations.

India's forced localization measure in the solar industry is not an isolated case. In May 2018, the Department of Pharmaceuticals issued final guidelines effective immediately for public procurement of medical devices. Despite strong industry opposition and multiple coordinated submissions and in-person representations by American and other stakeholders, the final local content requirements (LCR) range from 25-50% for medical devices procured in the public system. The LCRs are due to increase as the program is phased in over the next 3 years.

India's Machine-to-Machine Roadmap for the development and deployment of Internet of Things ("IOT") technologies, launched in 2015, aims to have local manufacturers produce 80 percent of IOT products procured by the Indian public sector by 2020. The Roadmap also introduces the possibility of India's first forced local data storage requirement by requiring that all IOT gateways and application servers that supply customers in India be located in India.[7]

These are just several instances of India failing to provide "equitable and reasonable access to [its] markets." In fact, Senator Bob Corker (R-TN) invoked these sentiments in October 2017 during his opening remarks for the nomination hearing for U.S. Ambassador to India Kenneth Juster, stating that he was "frustrated by the slow pace of Indian reforms in the economic sphere," as "American companies continue to face barriers to Indian market access, including high tariffs and strict localization policies."[8]

B. Price Controls

In recent years, India has introduced price controls across a number of industries that effectively discriminate against U.S. products that incorporate advanced intellectual property, thereby preventing equitable and reasonable American access to Indian markets.

1. Medical Devices

Since 1996, India has maintained a National List of Essential Medicines ("NLEM"), a list designed to capture medicines (including pharmaceuticals and medical devices) that are deemed to improve the quality of health care. The National Pharmaceutical Pricing Authority ("NPPA") may regulate the price of those items listed on the NLEM. In July 2016, the Indian Health Ministry added coronary stents to the NLEM. As a result, on February 13, 2017, NPPA issued an order that immediately capped the price of coronary stents sold at public and private hospitals, resulting in a nationwide cut of innovative stent prices by up to 75-85%.[9] The inclusion of coronary stents in the NLEM raises several concerns regarding access to markets.

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[7] Government of India, National Telecom M2M Roadmap (New Delhi: Government of India, Ministry of Communication and Information Technology, Department of Telecommunications, 2015).

[8] Press Release, Bob Corker Statement at Hearing on Nomination for U.S. Ambassador to India (Oct. 3, 2017), https://www.corker.senate.gov/public/index.cfm/2017/10/corker-statement-at-hearing-on-nomination-for-u-s-ambassador-to-india.

[9] Order, National Pharmaceuticals Pricing Authority (Government of India), Feb. 13, 2017, http://nppaindia.nic.in/ceiling/press13Feb2017/so412e-13-02-17.pdf.

First, the NLEM does not account for variables that may affect the price of different types of stents. Rather, it sets a single price category across newer and older technologies. That rewards less advanced and older technology products made by local Indian manufacturers and hurts the many U.S. companies who have invested in the expensive research and development and clinical research needed to develop new and innovative products. Moreover, the order prohibits manufacturers from withdrawing product models from the market even when the price is below cost for some high-end models, effectively ordering U.S. companies to sell leading edge technology in India at a loss. By lumping together all drug eluting stents, regardless of their level of technology or the clinical data supporting their safety and performance, U.S. medical device companies that produce the most innovative stent technologies will be severely impacted by this decision. By undercutting the value of U.S. innovation, price controls on medical devices directly impact U.S. exports and inhibit market access.

Second, the inclusion of coronary stents in the NLEM is just the first step in what appears to be a broader effort to bring medical devices within the authority of NPPA price controls. The Indian government has indicated that it will look to cap the price of other medical devices in India. It has issued a notice summoning industry to discuss the process for collecting and monitoring the price of all medical devices in India notified as drugs.

In August 2017, the NPPA issued an order capping the price of knee implants.[10] Instead of adding knee implants to the NLEM, NPPA cited a little-used Paragraph 19 of the DPCO that allows the government to, "in case of extra-ordinary circumstances, if it considers necessary so to do in public interest, fix the ceiling price or retail price."[11] In addition, the NPPA recently revised price controls on medicines for which prices were already fixed under the DPCO 2013. These pricing decisions, as well as the broad authority granted to NPPA, do not adhere to the need for transparency, predictability, and trust in the decision-making process, which hinders the U.S. medical device industry's ability to further invest in India and obtain reasonable access to the Indian market.

2. Pharmaceutical Industry

Despite decades of government price controls in India, essential medicines still are not easily accessible. Yet, India has thousands of manufacturers of pharmaceuticals that operate in a very competitive environment and, as a result, some of the lowest prices of medicines in the world.[12] Focusing on the key barriers to access in India (e.g., insufficient health care funding, infrastructure, and quality) rather than price controls would significantly improve access to medicines for patients. A 2015 study by IMS titled "Analyzing the Impact of Price Controls on Access to Medicines" found that price controls are neither an effective nor a sustainable strategy

[10] *India Introduces Price Controls For Knee Implants*, Reuters (Aug. 16, 2017), https://www.reuters.com/article/us-india-health-pricecontrol/india-introduces-price-controls-for-knee-implants-idUSKCN1AW1IX.

[11] The Drugs (Prices Control) Order, 2013 (May 15, 2013), http://www.nppaindia.nic.in/DPCO2013.pdf.

[12] Analysis based on IMS MIDAS Data.

for improving access to medicines. The study further found that the primary beneficiaries of price controls have been high-income patients, rather than the intended low-income population.[13]

Drug Price Control Order (DPCO) 2013 sought to establish price stability by setting ceiling prices for medicines listed on Schedule I every five years. Despite doing so in 2013, the NPPA announced in June 2016, per Paragraph 18 of the DPCO, that it would set new ceiling prices for all medicines, including those for which a ceiling price already had been set only three years prior. These pricing decisions, as well as the broad authority granted to the NPPA under this provision, do not respect the need for transparency, predictability, and trust in the decision-making process, and ultimately negatively impact patient access to medicines. Furthermore, frequent repricing imposes an unnecessary administrative burden, due to the need to recall and re-label medicines to reflect the new prices, and in turn can result in product shortages.

Finally, Paragraph 32 of the DPCO 2013 exempts from the pricing formula, for a period of five years, new medicines developed through indigenous research and development. This section creates an inequitable and unreasonable playing field that favors local Indian companies and discriminates against American and other foreign pharmaceutical companies, contrary to India's national treatment obligations.

3. Agriculture Biotechnology Industry

Price controls for the agricultural biotechnology industry in India inhibit market access for U.S. companies and depress further investment in the Indian market. For example, cotton seeds are covered in the Essential Commodities Act, 1955 (the "ECA"), which provides for central government control of the production, supply, and distribution of certain key commodities if necessary. However, the Indian government has delegated its pricing authority to individual states that are setting maximum sales price (the "MSP").

AFTI and its members were concerned with the recent draft Licensing Guidelines and Formats for Genetically Modified Technology Agreements ("Licensing Guidelines"), which was issued in May 2016. In response to significant opposition from industry, the Licensing Guidelines, originally in final form, were withdrawn and reissued as a draft for comments from the public.[14] Nonetheless, the draft proposed Licensing Guidelines would have forced Monsanto – the company that manufactured the successful genetically modified ("GM") Bt Cotton seed that so dramatically improved crop yields and the livelihood of Indian farmers[15]– and other biotech companies to share their technology with local seed companies. As such, they have only contributed to the uncertain business and regulatory environment in India. As a result, in August

[13] IMS, *Assessing the Impact of Price Control Measures on Access to Medicines in India*, June 2015.

[14] Department of Agriculture, Cooperation & Farmers Welfare, Government of India, http://agricoop.nic.in/.

[15] Association of Biotechnology Led Enterprises, *Keeping farmer interest in mind Association of Biotech Led Enterprises – Agriculture Focused Group (ABLE- AG) opposes Government`s Cotton Seed Price Control Order* (Dec. 21, 2015), http://ableag.org/wp-content/uploads/2016/01/Keeping-farmer-interest-in-mind-Association-of-Biotech-Led-Enterprises-Agriculture-Focused-Group-ABLE-AG-opposes-Governments-Cotton-Seed-Price-Control-Order.docx.

2016, Monsanto made the decision to withdraw its application seeking approval for its next generation of GM cotton seeds in India.[16]

Such price controls significantly disrupts agricultural exports into India. These state governments have exceeded their authority and violated established contracts. These measures do not provide equitable and reasonable access to Indian markets.

C. Dairy Import Ban

India is one of the largest dairy markets in the world. Since 2003, India has maintained unscientific requirements for dairy imports and refused extensive good-faith efforts to restore United States dairy exports to India, one of the largest dairy markets in the world. The effective block of U.S. dairy products has been well documented in National Trade Estimate (NTE) and Sanitary and Phytosanitary Measures ("SPS") Report submissions. Currently, the United States lacks a required dairy certificate required by the Indian Government to accompany all exports. The 2017 NTE noted that "this requirement, along with high tariff rates, continues to prevent market access for U.S. milk and dairy product exports to India."[17] The United States Dairy Export Council has estimated that resolution of this issue could yield additional exports ranging from $30 million to $100 million. The United States has proposed making use of an existing Indian labeling regulation and proposing to adopt an approach that would similarly label U.S. products as "vegetarian" or "non-vegetarian." India should accept this proposal and thereby restore access.

It is important to note that solving the dairy certificate issue would not establish fully open dairy trade with India. India still maintains sizable dairy tariffs which allow it to control access to its market. Rather, fixing this issue would simply ensure that U.S. dairy producers have an equal opportunity to supply any needed imports into this large and growing market.

D. Intellectual Property Protections and Enforcement

The Government of India's failure to provide appropriate and predictable IP protections and enforcement hinders the ability of U.S. innovators across a range of globally competitive American industries to equitably and reasonably access the Indian market.

1. Copyright

India has also failed to provide equitable and reasonable market access with regard to U.S. companies' copyrighted products. For instance, in September 2016, the Modi Administration issued a memorandum on Section 31D of the Copyright Act requiring a statutory license for all kinds of broadcasting, including internet broadcasting. [18] Section 31D was

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[16] Mayank Bhardwaj, *Exclusive: Monsanto pulls new GM cotton seed from India in protest*, Reuters (Aug. 25, 2016), http://www.reuters.com/article/us-india-monsanto-idUSKCN10Z1OX.

[17] *2017 National Trade Estimate Report on Foreign Trade Barriers*, Office of the United States Trade Representative, https://ustr.gov/sites/default/files/files/reports/2017/NTE/2017%20NTE.pdf

[18] *Office Memorandum*, Department of Industrial Policy and Promotion (Sept. 5, 2016), http://dipp.nic.in/sites/default/files/OM_CopyrightAct_05September2016.pdf.

intended to have a limited scope, mandating statutory licenses only to non-interactive radio and television broadcasting. It was not intended to cover internet music streaming services. By including internet music streaming services, the memorandum on Section 31D is inconsistent with clearly defined international copyright law, including the WIPO Berne Convention and WIPO Internet Treaties. India is departing from worldwide commercial practice, which dictates that digital music services are licensed individually on free market terms.

Additionally, India is one of the world's greatest sources of illegal copying of books and publications. The practice is largely condoned in the country, and police are hesitant to enforce copyright law. In September 2016, the Delhi High Court ruled that it was permissible for Delhi University to sell photocopied sections of copyrighted textbooks without licenses from the books' authors, significantly undermining the value of the authors' works and the protection of Indian copyright law.[19]

2. Restrictive Patentability Criteria

India has created an impermissible hurdle for patenting medicines. The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) requires that an invention be entitled to patent protection as long as it is new, involves an inventive step, and is capable of industrial application.[20] In contrast to this baseline three-part patentability test, Section 3(d) of India's Patents Act adds an impermissible fourth substantive criterion of "enhanced efficacy."[21] This additional patentability hurdle, which was reinforced by the Pharmaceutical Patent Examination Guidelines issued in October 2014,[22] not only undermines incentives for critical medical innovations but also is inconsistent with the patentability framework under TRIPS. Restrictions that narrow patentability prevent innovators from building on prior knowledge to develop valuable new and improved treatments that can enhance health outcomes.[23] Such improvements also can lead to reduced costs by making it easier for patients to take medicines and improving patient adherence to prescribed therapies. Moreover, the additional hurdle required by Section 3(d) appears to target pharmaceuticals specifically, contrary to India's international obligations not to discriminate against a field of technology.[24]

Section 3(d) has resulted in the denial of a number of U.S.-developed medicines, despite the fact that these same medicines have received patent protection in the United States and other countries. Examples include, in 2016 alone, two anti-cancer products and a schizophrenia

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[19] Akanksha Jain, *University Copying Books for Teaching Not Copyright Violation: Delhi HC*, The Hindu, Sept. 16, 2016, http://www.thehindu.com/news/cities/Delhi/University-copying-books-for-teaching-is-not-copyright-violation-Delhi-HC/article14984190.ece.

[20] TRIPS, Art. 27.1.

[21] India Patents Act § 3(d).

[22] Office of the Controller General of Patents, Designs and Trademarks, Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals (Oct. 2014), available at http://www.ipindia.nic.in/writereaddata/Portal/IPOGuidelinesManuals/1_37_1_3-guidelines-for-examination-of-patent-applications-pharmaceutical.pdf (last visited May 14, 2018).

[23] As USTR noted in its most recent report on foreign trade barriers, Section 3(d) "may have the effect of limiting the patentability of an array of potentially beneficial innovations." Office of the United States Trade Representative, Nat'l Trade Estimate Report on Foreign Trade Barriers 230 (2018).

[24] TRIPS, Art. 27.1.

product were denied patents under this additional patentability criterion. Moreover, industry commissioned a recent search of patenting activity by leading Indian pharmaceutical companies in the United States indicates that whereas U.S. companies are unable to secure patents for new uses and indications in India as a result of Section 3(d), such protections are afforded to Indian companies seeking patent protection for such innovations in the United States.

India has yet to address the challenges posed by Section 3(d), which have been highlighted year-after-year by USTR. Section 3(d) not only is inconsistent with India's core patentability and non-discrimination obligations but also is an ineffective and inherently flawed policy.

3. Weak Patent Enforcement

India's law also creates hurdles to effective patent enforcement. For example, Indian law permits state drug regulatory authorities to grant marketing approval for a generic version of a medicine four years after the original product was first approved.[25] Meanwhile, state regulatory authorities are not required to verify or consider the remaining term of the patent protection on the original product. Therefore, an infringer have obtained marketing authorization from the government for a generic version of an on-patent drug, forcing the patent holder to seek redress in India's court system, which often results in irreparable harm to the patent holder. In one example, the patent holder waited two and a half years before a court provided injunctive relief. In another example, the patent holder waited seven years before receiving a court decision upholding its patent.[26] In that case, the court ultimately did not grant an injunction because by the time the decision was issued the patent was close to expiration.[27]

As a result, patent owners are unable to effectively defend their patent rights. Moreover, as highlighted by USTR in the past, interested parties are not notified of marketing approvals for follow-on pharmaceuticals in a manner that would allow for the early resolution of potential patent disputes.[28]

4. Compulsory Licensing

The threat of a compulsory license (CL) often is used as a negotiating tactic and industrial policy tool in India to compel local manufacturing, namely in the pharmaceutical and agriculture biotechnology industries. The grounds for issuing a CL in India are broad, vague, and

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[25] *See* Rule 122-E of the Drugs and Cosmetics Rules and the Drugs and Cosmetics Act for guidelines as to how to obtain a manufacturing license for a new drug. (As amended up to the 30th June, 2005), http://www.cdsco.nic.in/writereaddata/Drugs&CosmeticAct.pdf .

[26] *Delhi High Court Restrain Glenmark from Selling Anti-diabetes Drugs*, Times of India, Oct. 7, 2015, available at https://timesofindia.indiatimes.com/business/india-business/HC-restrains-Glenmark-from-selling-MSD-drug/articleshow/49266041.cms.

[27] *Cipla Infringing Roche's Cancer Drug Patent: HC*, Times of India, Nov. 28, 2015, available at http://timesofindia.indiatimes.com/business/india-business/Cipla-infringing-Roches-cancer-drug-patent-HC/articleshow/49956000.cms.

[28] *See* 2018 Special 301 Report at 49 ("India still lacks an effective system for notifying interested parties of marketing approvals for follow-on pharmaceuticals in a manner that would allow for the early resolution of potential patent disputes.").

inconsistent with the TRIPS Agreement. India also has sought to use CLs to promote local production at the expense of U.S. manufacturers and workers. Such practice is discriminatory and inconsistent with India's international obligations.

For example, India's Ministry of Health (MOH) continues to entertain potential recommendations to impose CLs on certain anti-cancer medicines under Section 92 of India's Patents Act, a special provision that provides the Government of India with discretion in issuing CL.[29] Moreover, Indian pharmaceutical companies continue to make requests for voluntary licenses under Section 84(6)(iv) of the Patents Act; rather than using this CL measure as a last resort, these companies are inappropriately utilizing a CL strategy as a commercial tool.[30]

India also has sought to use CLs to promote local production at the expense of U.S. manufacturers and workers. Under India's Patents Act, grounds on which a compulsory license may be granted include when "the patented invention is not worked in the territory of India."[31] In addition, rules promulgated under Section 146 of the India Patents Act require all patent holders to file an annual statement summarizing "the extent to which the patented invention has been worked on a commercial scale in India."[32] The local working requirement is discriminatory and inconsistent with India's obligations under the TRIPS Agreement, the General Agreement on Tariffs and Trade (GATT) and the WTO Agreement on Trade-Related Investment Measures (TRIMs), which generally prohibit WTO members from discriminating based on whether products are imported or locally produced.[33]

5. Regulatory Data Protection Failures

In its 2018 Special 301 Report, USTR noted that "India continues to lack an effective system for protecting against the unfair commercial use, as well as the unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for such products."[34] Despite repeated urgings by USTR, India continues to provide inadequate protection for IP holders, in violation of its international obligations and global IP standards.

The Government of India requires U.S. companies to submit extensive and valuable information for evaluation before bringing a product to market.[35] Data protection is critical at this stage. In the biopharmaceuticals context, U.S. companies spend an average of 10 to 15 years investing in research and development ("R&D") for a new product, at a tremendous cost. Some have estimated that "[t]he development of test data typically represents more than sixty percent

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[29] India Patents Act § 92(1).

[30] *Id.* § 84(6)(iv).

[31] *Id.* § 84(1).

[32] India Patents Act, Section 146(2).

[33] TRIPS, Art. 27.1 (providing that " patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."); GATT, Art. III:4 (requiring imports to receive "treatment no less favourable" than like domestic products); TRIMs, Art. 2.1 (incorporating GATT Article III).

[34] USTR 2018 Special 301 Report at 49.

[35] CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, GUIDANCE FOR INDUSTRY, http://www.ayushmuhs.in/public/Guidelines/CDSCO.pdf.

of the R&D costs of new drugs."[36] In the plant science industry, to develop one crop protection product, the cost and time required is a significant $256 million and approximately 10 years, while plant biotechnology products cost nearly $136 million and require over 13 years.[37]

In contrast, India does not provide meaningful protection for this regulatory data, and the Modi Administration has not advanced any notable improvements to the regulatory framework for data protection. As noted in previous submissions to USTR, while the draft National IPR Policy set out as an area of study "[p]rotection of undisclosed information," but intentionally excluded "data exclusivity" as an area for future policy development, the National IPR Policy removed the mention of undisclosed information altogether. The absence of regulatory data protection creates an unfair commercial advantage for generic companies in India, and India must implement effective and meaningful periods of regulatory data protection.

6. Trade Secrets

Currently, India does not have a unified law to protect information that qualifies as a "trade secret" under international law, as defined by TRIPS Article 39.2, which severely impacts U.S. companies attempting to access Indian markets. India's 2008 National Innovation Bill included language on trade secrets, but not a legal definition or clear, direct legal channels to address these issues.

Instead, companies are forced to resort to definitions laid out by India's Contract Act of 1872. That Act voids contractual agreements that are "in restraint of trade," providing a clear disincentive for companies to be able to protect trade secrets through these means and opening the clause to numerous legal disputes over trade secrets over the years. Before bringing a product to market, the Indian government requires U.S. companies, including those in the pharmaceutical and bio-agricultural industries, to submit valuable trade secret information that may be protected by various levels of patents in the United States. U.S. companies suffer billions of dollars in losses from theft of trade secrets annually as a result, undermining the extensive research and development costs incurred to develop the protected innovation.

E. High Tariffs and Taxes

India maintains high tariffs on a range of manufactured products, including automobiles, motorcycles, textiles, distilled spirits, pharmaceuticals, and rubber, for example, to protect its domestic industries. At the time of this submission, imported spirits into India face a tariff of 150 percent. Moreover, Indian national policies, including its annual budget process and other announcements, have been venues for local groups to promote protectionism by seeking relief from foreign competition through tariff hikes. Both of these create obvious market access problems for U.S. producers.

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[36] Carlos M. Correa, *Protecting Test Data for Pharmaceutical and Agrochemical Products Under Free Trade Agreements*, UNCTAD-ICTSD (2004), http://www.iprsonline.org/unctadictsd/bellagio/docs/Correa_Bellagio4.pdf.

[37] CROPLIFE INTERNATIONAL, FIVE THINGS YOU NEED TO KNOW ABOUT AGRICULTURAL INNOVATION AND INTELLECTUAL PROPERTY (2013), https://croplife.org/news/five-things-you-need-to-know-about-agricultural-innovation-intellectual-property/.

In February 2018, Finance Minister Arun Jaitley released the country's Union Budget for Fiscal Year 2018-2019, revealing a high level of protectionist measures with regard to trade, despite the Prime Minister's anti-protectionist speech at the World Economic Forum in Davos, Switzerland the previous month.[38] The budget proposes an increase of customs duties applied to imports in sectors including but not limited to: processed foods, electronics, auto components, footwear, and furniture. The increased customs duties apply to 49 industry product groups in total. The budget is also consistent with the protectionist campaign of "Make in India," in which the Modi Government has increased biases toward local manufacturing preferences. Another example includes India's increased tariffs on information technology products, including on many products that should enjoy duty-free treatment in accordance with India's commitments as a signatory to the 1996 WTO Information Technology Agreement.

Innovative pharmaceutical companies operating in India face high effective import duties for APIs and finished products. Compared to other Asian countries in similar stages of development, import duties in India are very high. The basic import duties for pharmaceutical products average about 10 percent, due to the Integrated Goods and Service Tax imposed on imports, the effective import duty can exceed 20 percent. Moreover, excessive duties on the reagents and equipment imported for use in research, development, and manufacture of biotech products make biotech operations difficult to sustain.

F. Discriminatory Testing Requirements

Currently, U.S. companies in India are threatened with three distinct discriminatory testing requirements: (1) Compulsory Registration Order/safety testing, in effect since 2013; (2) telecom security testing and (3) new testing and certification procedures for information and communication technology (ICT) equipment sold to telecommunications operators. Many of these testing requirements deviate significantly from internationally accepted safety and certification norms and protocols and would be practically impossible for American manufacturers to comply with.

In some cases, there is not even sufficient Indian testing capacity to implement these requirements, at best requiring time-intensive, duplicative testing processes and at worse risking effective blocks from the market. For example, India's security testing mandate has been postponed repeatedly. The most recent deadline passed on April 1, 2018, although U.S. industry has received reports that the deadline was postponed once more until October 1, 2018. Yet as in years past, the Department of Telecommunications has not issued any further information or guidance regarding the scope or product coverage. This lack of clarity has created enormous uncertainty both for equipment manufacturers and their customers. Moreover, the Indian Government has approached several Indian IT companies to help establish testing labs in India to implement the new requirements. American companies could, therefore, be compelled to hand over sensitive design information to a lab controlled by Indian competitors or else risk being barred from selling in the Indian telecom market.

[38] *Summary of Budget 2018-19*, Press Information Bureau, Government of India, Ministry of Finance, http://pib.nic.in/newsite/PrintRelease.aspx?relid=176062.

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For decades, India has failed to provide equitable and reasonable access to its markets for American companies. As previously stated, we urge the U.S. government to use this review of India's eligibility to receive GSP benefits to secure concrete policy improvements that address these inequities and allow U.S. companies to fairly compete with their Indian counterparts.