Alliance for Fair Trade with India

October 30, 2018

Edward Gresser
Chair, Trade Policy Staff Committee
Office of the U.S. Trade Representative
Executive Office of the President
600 17th Street, NW
Washington, D.C. 20508

RE: Comments Regarding Foreign Trade Barriers to U.S. Exports for 2019 Reporting, Docket Number USTR 2018-0029-0001, (Request for Public Comments to Compile the National Trade Estimate Report on Foreign Trade Barriers, 83 Fed. Reg. 42966) (August 24, 2018)

Dear Mr. Gresser:

The Alliance for Fair Trade with India ("AFTI") is comprised of a diverse group of organizations that supports a robust U.S.-India economic relationship but believes that the relationship has long underperformed its potential, confounded by longstanding trade and investment barriers. In light of its mandate, AFTI provides comments to the Office of the United States Trade Representative ("USTR") for its 2019 National Trade Estimate Report on Foreign Trade Barriers ("NTE Report"), specifically regarding India.

AFTI members encourage the U.S. government at all levels to push for a more robust and reciprocal U.S.-India economic relationship. In June, the United States and India began negotiations in an attempt to resolve several pressing market access concerns on both sides, particularly India's price controls on medical devices and the review by the U.S. government of India's compliance with the obligations for Generalized System of Preferences ("GSP") program participants. It is AFTI's firm hope that the trade talks succeed in the very near term and create momentum for a new economic relationship that achieves the goal set by President Donald Trump and Prime Minister Narendra Modi in June 2017 "of expediting regulatory processes; ensuring that technology and innovation are appropriately fostered, valued, and protected; and increasing market access in areas such as agriculture, information technology, and manufactured goods and services."[1]

In these comments, we describe the wide variety of onerous, costly, and cross-cutting market access barriers that many of America's most globally competitive industries currently face in India, including (1) weak protection of intellectual property rights, (2) high tariffs and tariffs inconsistent with India's World Trade Organization ("WTO") commitments, (3) price controls, (4) forced localization, (5) discriminatory testing requirements, (6) discriminatory labeling standards, and (7) an effective ban on dairy imports. Further, India undermines market

[1] The White House, *United States and India: Prosperity Through Partnership* (June 2017), https://www.whitehouse.gov/briefings-statements/united-states-india-prosperity-partnership/.

access of American producers in third markets by working within international bodies to weaken global intellectual property enforcement. As noted by the U.S. Commercial Service, "India has strongly supported and sometimes led the charge in calling for open technology transfer, liberal use of compulsory licensing cross sectors, price controls and protection of traditional knowledge."[2]

I. Weak Protection of Intellectual Property Rights

A. Copyright

1. Section 31D

Section 31D of the Indian Copyright Act concerns the broadcasting or performance of a literary or musical and sound recording. The original intent of section 31D was to have a limited scope of the statutory license to non-interactive radio and television broadcasting, not to cover internet music streaming services. In September 2016, however, the Modi Administration issued a memorandum on section 31D expanding the scope of statutory licenses in India to apply to all kinds of broadcasting, including internet broadcasting. By including internet music streaming services under section 31D, the memorandum is inconsistent with clearly defined international copyright law, including the WIPO Berne Convention and WIPO Internet Treaties. India is departing from worldwide commercial practice in which digital music services are licensed individually on free market terms.

2. Internet/Camcording Piracy and Illegal Downloading

As USTR noted in its most recent NTE Report, "procedural hurdles and effective enforcement remain a concern" in India, as "online piracy and illegal camcording continue to proliferate."[3] Piracy is the biggest barrier to the Indian market for U.S. film and television studios. Overall, about 90 percent of new movie releases in India appear illegally online. Video camcording incidents in India have been on a decline since 2015, with 35 video camcording incidents reported between 2015-2018, compared to 113 video camcording incidents between 2011-2014. However, there has been a major shift to audio camcording in the last three years.

Heavily backlogged courts, fractured state-level enforcement, and weak laws contribute to the prevalence of digital piracy in India. Some recent steps, such as assigning copyright enforcement at the federal level to the Department of Industrial Policy and Promotion ("DIPP"), Ministry of Commerce and Industry ("MOCI"), standing up IPR enforcement units in the states of Maharashta and Telegana, and steps taken by the National Internet Exchange of India to suspend fraudulently registered websites, must serve as initial steps towards effective enforcement. India must enact legislative reforms that provide rightsholders basic tools to fight the production and distribution of pirated content. India should also enact legislation that prohibits camcording, enables the disabling of infringing websites through administrative action

[2] Export.gov, *India – Protecting Intellectual Property* (Oct. 10, 2018), https://www.export/gov/article?id=India-Protecting-Intelectual-Property.

[3] Office of the United States Trade Representative, Nat'l Trade Estimate Report on Foreign Trade Barriers 229 (2018) ("2018 NTE Report").

rather than the courts, and implements the WIPO Copyright Treaty and WIPO Performers and Phonograms Treaty in a manner fully consistent with India's commitments under the WIPO Berne and WTO Trade-Related Aspects of Intellectual Property Rights ("TRIPS") agreements. Unfortunately, India has proven reluctant to advance legislation to enhance IPR; since 2013, the United States government and industry advocates including AFTI have advocated for the passage of anti-camcording legislation, but have not seen any results.

3. Illegal Copying of Books and Written Publications

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.

B. Patents

1. 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, particularly in the pharmaceutical and agriculture biotechnology industries. USTR explained in its 2018 NTE Report that the United States "continues to monitor India's application of its compulsory licensing law," but AFTI believes that India's compulsory licensing practices continue to be a significant barrier to trade.[4] The grounds for issuing a CL in India are broad, vague, and 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 CLs.[5] 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.[6]

2. Section 3(d)

India has created an impermissible hurdle for patenting medicines under Section 3(d) of the India's Patent Act. Article 27 of the TRIPS Agreement requires that an invention be entitled to patent protection as long as it is new, involves an inventive step, and is capable of industrial

[4] *Id.*

[5] India Patents Act § 92(1).

[6] *Id.* § 84(6)(iv).

application.[7] 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."[8] This additional patentability hurdle, which was reinforced by the Pharmaceutical Patent Examination Guidelines issued in October 2014,[9] not only undermines incentives for critical medical innovations, but also is inconsistent with the patentability framework under the TRIPS Agreement. Restrictions that narrow patentability prevent innovators from building on prior knowledge to develop valuable new and improved treatments that can enhance health outcomes.[10] Such improvements can also lead to reduced costs by making it easier for patients to take medicines and improve 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.[11]

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. The Modi Administration is continuing to ignore repeated calls to rectify this onerous and WTO-inconsistent standard for patentability to the detriment of both foreign and Indian IP holders.

C. Confidential Test Data and Trade Secret Protection

1. Continued Lack of Confidential Test Data Protection

In its 2018 NTE Report, USTR noted that India "lacks an effective system for protecting against unfair commercial use, as well as unauthorized release of undisclosed test or other data generated to obtain marketing approval for pharmaceutical and agricultural products."[12] Despite repeated urgings by USTR, India continues to provide inadequate protection for IP holders, in violation of its international obligations and global IP standards.

As an example, the Government of India requires U.S. companies to submit extensive and valuable information for evaluation before bringing a product to market.[13] 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

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[7] TRIPS Agreement, Article 27.1.

[8] India Patents Act § 3(d).

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

[10] 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." 2018 NTE Report at 230.

[11] TRIPS Agreement, Article 27.1.

[12] 2018 NTE Report at 230.

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

sixty percent of the R&D costs of new drugs."[14] 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.[15]

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. The absence of regulatory data protection creates an unfair commercial advantage for generic companies in India. India must implement effective and meaningful periods of regulatory data protection.

2. Continued Lack of Trade Secret Protection

Currently, India does not have a unified law to protect information that qualifies as a "trade secret" under international law, as defined by Article 39.2 of the TRIPS Agreement. This severely impacts U.S. companies attempting to access Indian markets, as these companies are forced to rely on Indian courts to ultimately decide issues of trade secrets protection.

U.S. companies must therefore 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 clauses to numerous legal disputes over trade secrets over the years. Criminal remedies are generally not available; instead, Indian courts primarily rely upon contract and tort law principles.[16]

Additionally, before bringing a product to market, the Government of India 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.

The 2018 NTE Report explains that there is a bilateral effort to eliminate gaps in India's trade secrets regime, such as through the adoption of standalone trade secrets legislation.[17] AFTI hopes that continued bilateral engagement can lead to a fruitful resolution.

II. Tariffs

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[14] 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.

[15] 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/.

[16] Tariq Ahmad, *Protection of Trade Secrets – India*, Library of Congress (April 2013), https://www.loc.gov/law/help/tradesecrets/india.php.

[17] 2018 NTE Report at 230.

India maintains high tariffs on a range of manufactured products, including automobiles, motorcycles, textiles, distilled spirits, pharmaceuticals, and rubber to protect its domestic industries. At the time of this submission, imported spirits into India face a tariff of 150 percent, which severely restricts access to the Indian market for U.S. spirits exporters into the world's largest market for whiskey, which was valued at $25 billion in 2017. Moreover, Indian national policies, including its annual budget process and other announcements, have been used by local groups to promote protectionism by seeking relief from foreign competition through tariff hikes.

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.[18] 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 elements of Prime Minister Modi's "Make in India" campaign, which promotes manufacturing in India but often bolsters efforts to pressure companies to localize manufacturing or to promote local manufacturers at the expense of foreign companies and imported products. Another example is 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 WTO Information Technology Agreement ("ITA").

Innovative pharmaceutical companies operating in India face high effective import duties for active pharmaceutical ingredients ("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. The Integrated Goods and Service Tax imposed on imports can result in the effective import duty exceeding 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.

III. Price Controls

A. Medical Device Price Controls and Procurement Policies

Since 1996, India has maintained a National List of Essential Medicines ("NLEM"), a list designed to capture medicines (including pharmaceuticals and medical devices) deemed to improve the quality of health care. The National Pharmaceutical Pricing Authority ("NPPA") may regulate the prices of those items listed on the NLEM. In early 2016, NPPA issued an order that capped the price of coronary stents resulting in a nationwide cut of stent prices by 75-85 percent.[19] By lumping together all drug eluting stents, regardless of their level of technology or the clinical data supporting their safety and performance, this decision harmed U.S. companies that produce the most innovative stent technologies. By setting a single price category across

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

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

newer and older technologies, the order rewards the less advanced products of local Indian manufacturers not backed by the investment in R&D and clinical research needed for the innovative products of U.S. companies. Moreover, the order prohibits manufacturers from withdrawing product models from the market, despite the fact that the price is below the cost of production for some high-end models, effectively ordering companies based in the United States to sell leading edge technology in India at a loss.

The NPPA also issued a similar order in August 2017 on knee implant systems.[20] In addition, in March 2018, the Department of Pharmaceuticals issued an order mandating local content requirements ranging from 25-50 percent for medical devices sold in the public market.[21] These pricing and procurement decisions do not adhere to the need for transparency, predictability, and trust in the decision-making process, hindering the industry's ability to further invest in India and deliver innovative technologies to Indian patients.

B. 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.[22] Focusing on the key barriers to access in India – such as insufficient health care funding, infrastructure, and quality – rather than price controls, would significantly improve access to medicines for patients. A 2015 study by IMS Health found that price controls are neither an effective nor a sustainable strategy 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.[23]

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 2013, 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.

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[20] Teena Thacker, *After Stents, NPAA Puts a Price Cap on Knee Implants*, LiveMint (Aug. 17, 2017), https://www.livemint.com/Politics/AVfhAyvbr6NZAk19ugQT9H/Govt-cuts-knee-implant-prices-to-much-lower-than-market-rate.html.

[21] *Guidelines For Implementation of "Public Procurement (Preference to Make In India) Order – 2017" – reg.* (Mar. 15, 2018), http://pharmaceuticals.gov.in/sites/default/files/Guidelines%20for%20implementation%20of%20Public%20procurement.pdf.

[22] Analysis based on IMS MIDAS Data.

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

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.

C. Agricultural Biotechnology Industry

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

AFTI and its members were concerned with the draft Licensing Guidelines and Formats for Genetically Modified Technology Agreements ("Licensing Guidelines") 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.[24] 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[25] – 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 2016, Monsanto made the decision to withdraw its application seeking approval for its next generation of GM cotton seeds in India.[26]

IV. 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. 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, information and communication technology ("ICT") products, solar energy equipment, and capital goods."[27]

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

[25] 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.

[26] 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.

[27] Office of the United States Trade Representative, *2018 Special 301 Report*, at 49.

In April 2018, the Reserve Bank of India issued a now-implemented directive requiring that data related to payment transactions be stored only in India for "unfettered supervisory access."[28] India has also recently proposed data localization measures that include the draft national e-commerce policy framework,[29] a draft cloud computing policy requiring local storage of data,[30] and the draft Personal Data Protection Bill.[31] The Data Protection Bill would require companies to store a copy of all "personal data" in India, while subjecting "sensitive" personal data to stronger requirements and mandating that "critical" personal data only be processed within India. These recent actions build on concepts included in India's Machine-to-Machine Roadmap for the development and deployment of Internet of Things ("IOT") technologies, launched in 2015, which introduced the possibility of India's first local data storage requirement by requiring that all IOT gateways and application servers that supply customers in India be located in India.[32] The Roadmap also sought to localize production of IOT goods by setting a goal that local manufacturers produce 80 percent of IOT products procured by the Indian public sector by 2020.

Local content requirements affect several other 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 was to be reserved for domestically-manufactured solar cells and modules. A WTO panel found in August 2015 that India had in fact violated the national treatment obligations in Article III:4 of the General Agreement on Tariffs and Trade 1994 ("GATT") and Article 2.1 of the Agreement on Trade-Related Investment Measures ("TRIMs").[33] In September 2016, the Appellate Body affirmed the panel's ruling, rejecting all of India's defensive arguments.[34] Then, 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, and the matter is now before a compliance

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[28] Aditya Kalra and Aditi Shah, *RBI Sticking With Plan to Force Payments Firms to Store Data Locally: Sources*, Reuters (Oct. 10, 2018), https://in.reuters.com/article/india-data-localisation/rbi-sticking-with-plan-to-force-payments-firms-to-store-data-locally-sources-idINKCN1MK2G9.

[29] Sankalp Phartiyal and Aditya Kalra, *India Looking to Compel E-Commerce, Social Media Firms to Store Data Locally*, Reuters (July 30, 2018), https://www.reuters.com/article/us-india-ecommerce/india-looking-to-compel-e-commerce-social-media-firms-to-store-data-locally-idUSKBN1KK0IZ.

[30] Adiyta Kalra, *Exclusive: India Panel Wants Localization of Cloud Storage Data in Possible Blow to Big Tech Firms*, Reuters (Aug. 4, 2018), https://in.reuters.com/article/us-india-data-localisation-exclusive/exclusive-india-panel-wants-localization-of-cloud-storage-data-in-possible-blow-to-big-tech-firms-idINKBN1KP08J.

[31] Government of India, Ministry of Electronics & Information Technology, *Data Protection Framework*, http://meity.gov.in/data-protection-framework.

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

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

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

panel.[35] Pursuing forced localization for commercial measures rather than national security purposes is in violation of India's international obligations.

Lastly, 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 percent for medical devices procured in the public system. The LCRs are due to increase as the program is phased in over the next three years.

V. Discriminatory Testing Requirements

U.S. companies in India across a range of sectors face a range of testing and certification requirements. These include the Compulsory Registration Order for safety testing, in effect since 2013, as well as a range of sector-specific testing and certification requirements, such as local telecom security testing, testing and certification procedures for ICT equipment sold to telecommunications operators, and duplicative local testing for sectors such as toys. 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 ICT security testing mandate has been postponed repeatedly. The most recent deadline passed on October 1, 2018, although that deadline was postponed once more until October 1, 2019. This lack of clarity has created enormous uncertainty both for equipment manufacturers and their customers. Moreover, the Government of India 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.

VI. Mandatory Beverage Alcohol Standards and Labeling Requirements

On April 5, 2018, India's Food Safety and Standards Authority ("FSSAI") published the final version of its mandatory beverage alcohol standards and labeling requirements.[36]

In October 2015, FSSAI issued a draft for public comment that was subsequently notified to the WTO on December 1, 2015. In September 2016, FSSAI published a revised draft standard, and provided an opportunity for stakeholders to submit comments through its domestic process, but did not notify the revised draft standard to the WTO.

The final standard issued in April 2018 did not address concerns related to the general definition of whiskey, the requirement to provide an ingredient list, maximum alcohol content

[35] *See* WTO website, https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds456_e.htm.

[36] FSSAI, *FSSAI Notifies the Alcoholic Beverages Regulations 2018*, (Apr. 6, 2018) https://foodsafetyhelpline.com/2018/04/fssai-notifies-the-alcoholic-beverages-regulations-2018/.

levels, the use of analytical parameters, and other required statements. In a particularly troubling development, the final draft did not provide explicit protection for Bourbon and Tennessee Whiskey as distinctive products of the United States.

VII. Access to Dairy Markets

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 trade in dairy products between the United States and India. Currently, the United States lacks a required dairy certificate required by the Government of India to accompany all exports. 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 that allows it to control access to its market. Rather, fixing this issue would simply ensure that U.S. producers have an equal opportunity to supply any needed imports into this large and growing market.

VIII. Conclusion

AFTI appreciates the opportunity to comment for the 2019 NTE Report on Foreign Trade Barriers and would be happy to answer any questions that the Committee may have.