Alliance for Fair Trade with India

Mr. Daniel Lee
Acting Assistant U.S. Trade Representative for Innovation and Intellectual Property
Office of the United States Trade Representative
600 17th Street, N.W.
Washington, D.C. 20508

Re: 2019 Special 301 Review, Docket Number USTR–2018-0037

Dear Mr. Lee,

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. These barriers include persistent unresolved challenges to the protection of intellectual property rights ("IPR") and market-access for IP-intensive U.S. industries, and AFTI represents a range of those industries adversely impacted by India's IPR policies and practices.

In light of this mandate, AFTI submits to the Office of the U.S. Trade Representative ("USTR") this report which calls on USTR, under Section 182 of the Trade Act of 1974, to again place India on its Priority Watch List. The Act instructs USTR to consider whether foreign countries provide adequate and effective means for U.S. persons to secure, exercise, and enforce their rights relating to patents, copyrights, and trade secrets.[1] As discussed in detail throughout this submission, there is strong evidence that India has not made meaningful efforts to upgrade from its current status under the Priority Watch List, or made sufficient efforts to protect IPR holders' interests with respect to patents, copyright, and trade secrets.

The Government of India has made some improvements to the overall IP environment in India since the last Special 301 report that could yield improved market access for American exporters, including:

- The Department for Promotion of Industry and Internal Trade ("DPIIT"), formerly the Department of Industrial Policy and Promotion ("DIPP"), continued to make progress to reduce longstanding delays in patent and trademark examinations;

- India's Supreme Court decision in December 2018 supporting Monsanto's patent rights sets a thoughtful precedent that, if followed, could increase yields for Indian farmers and boost American agricultural biotechnology exports to India;

- Proposed Patents (Amendment) Rules 2018 would expedite examinations available to small entities, female inventors, and government undertakings and should help a broader range of small business owners boost their livelihoods with IPR; and

[1] 19 U.S.C. § 2242(d)(2).

- The Ministry of Information and Broadcasting ("MIB") proposed amendments to the Cinematograph Act to criminalize film piracy, which is rampant and costly in India, one of many signals from the government championing the needs of the film industry.

Each of these reforms is in some way incomplete. We ask that USTR engage with the Government of India throughout the implementation process to realize the full potential of these reforms for American rightsholders.

Unfortunately, the Government of India has still not addressed numerous critical shortcomings identified in the 2018 and prior Special 301 Reports. Of note, these critical shortcomings include:

- Pressure to localize manufacturing for industries as diverse as medical devices, pharmaceuticals, information and communications technology products, solar energy equipment, and capital goods;

- The lack of an effective system for protecting data generated to obtain marketing approval for pharmaceutical and agricultural chemical products;

- Major hurdles to patent protections for innovative medicines, such as the application of narrow patentability criteria, Section 3(d) of the India Patents Act, and the possible use of compulsory licensing and patent revocation; and;

- Costly and time-consuming patent opposition hurdles for patent applicants, and long timelines for receiving patents.

AFTI encourages and expects that India will continue to engage with the United States through various channels of bilateral economic dialogue, notably the U.S.-India Trade Policy Forum and Commercial Dialogue. Despite the broad scope of issues discussed in the dialogues and general positive atmosphere surrounding them, they have not resulted in substantive and measurable improvements. AFTI will continue to track this space closely, praising positive actions where meaningful but also demanding tougher responses when appropriate to make real progress.

We thank you for our continued work on these issues of vital importance to U.S. industry.

I. Forced Localization

Forced localization continues to be a chronic issue facing U.S. IPR holders in India. The Modi Administration has not taken meaningful action to revise protectionist forced localization policies clearly aimed at favoring domestic IP holders at the expense of goods, services, and IP from other countries. In fact, the National Intellectual Property Policy, released in May 2016, includes a recommendation for the exploration of "the possibility of expedited examination of

patent applications to promote manufacturing in India."[2] The 2018 Special 301 Report echoes this sentiment, noting 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."[3]

In October 2018, the Reserve Bank of India began requiring that data related to payment transactions be stored only in India for "unfettered supervisory access."[4] India has also recently proposed data localization measures that include the draft national e-commerce policy framework,[5] a draft cloud computing policy requiring local storage of data,[6] and the draft Personal Data Protection Bill.[7] 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.[8] 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.

In May 2018, the Department of Pharmaceuticals issued final guidelines effective immediately for public procurement of medical devices.[9] 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.

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[2] Ministry of Commerce and Industry, "2016 National Intellectual Rights Policy," at p. 12, May 12, 2016, http://dipp.nic.in/sites/default/files/National_IPR_Policy_English.pdf ("National IPR Policy").

[3] USTR, 2018 Special 301 Report, at 49.

[4] 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.

[5] 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.

[6] 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.

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

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

[9] Department of Pharmaceuticals, *Guidelines for Implementing the Provisions of Public Procurement (Preference to Make in India) Order PPO, 2017, Related to Procurement of Goods & Services in Medical Devices – Reg.* (May 18, 2018), http://pharmaceuticals.gov.in/sites/default/files/Final%20Guidelines.pdf.

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 were most recently subject to dispute settlement at the World Trade Organization ("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 national treatment obligations,[10] which the Appellate Body subsequently affirmed.[11] Then, in December 2017, the United States indicated to the WTO that India had failed to comply with the rulings and recommendations of the Dispute Settlement Body, and the matter is now before a compliance panel.[12] Pursuing forced localization for commercial measures rather than national security purposes is in violation of India's international obligations.

II. Lack of Regulatory Data Protection

In its 2018 Special 301 Report, USTR again urged India to provide an "effective system for protecting against unfair commercial use, as well as the unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for [pharmaceutical and agricultural chemical sector] products."[13] Despite these repeated urgings, 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.[14] 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 of the R&D costs of new drugs."[15] 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.[16]

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

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

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

[13] USTR 2018 Special 301 Report, p. 49.

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

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

[16] CROPLIFE INTERNATIONAL, FIVE THINGS YOU NEED TO KNOW ABOUT AGRICULTURAL INNOVATION AND INTELLECTUAL PROPERTY (2013), *available at* www.croplife.org/view_document.aspx?docId=4057.

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.

III. 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. USTR acknowledged in its 2018 Special 301 report that "[c]ompanies . . . continue to face uncertainty caused by insufficient legal means to protect trade secrets in India."[17] The U.S. and Indian governments had previously "agreed to deepen cooperation on trade secrets through… convening a joint workshop involving interested stakeholders on effective trade secret protection mechanisms,"[18] but this engagement has not led to positive reforms in India.

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.[19]

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. In seeking to implement an ICT security testing mandate, the Government of India has approached several Indian IT companies for help. Such an arrangement would compel American companies 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. 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.

IV. Patents

In its 2018 Special 301 Report, USTR explained that "India has yet to take steps to address longstanding patent issues that affect innovative industries."[20] India has since taken

[17] 2018 Special 301 Report at 50.

[18] United States and India Joint Statement on the Trade Policy Forum, October 29, 2015, https://ustr.gov/about-us/policy-offices/press-office/press-releases/2015/october/united-states-and-india-joint.

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

[20] 2018 Special 301 Report, at 49.

noteworthy steps to improve the patent process. AFTI applauds DPIIT for continuing to reduce longstanding delays in patent and trademark examinations. Some states, in turn, have created specialized structures to coordinate IP enforcement or increased campaign efforts.

AFTI also applauds DPIIT for its proposed Patents (Amendment) Rules 2018, which will amend the Patent Rules, 2003.[21] AFTI is pleased that under the proposed amendments, DPIIT will, for example, make expedited examination available to small entities, female inventors, and government undertakings. These changes will further reduce filing fees and provide technical assistance to Indian small and medium-size enterprises ("SMEs") and start-ups.

A. Guidelines on Computer-Related Inventions ("CRIs")

In previous submissions to the U.S. government, AFTI has raised concerns and provided specific recommendations to strengthen the Final CRI Guidelines released by the Indian Government in February 2016. AFTI is encouraged by the July 2017 revised "Guidelines for Examination of Computer Related Inventions," which significantly improves the patenting environment for CRIs in India. Unlike previous drafts of the guidelines, there is no requirement for hardware innovation.

AFTI encourages the Government of India to provide further guidance on what will be considered patentable under the new rules, which is critical to fostering technological innovation across India and ensuring India can unleash the benefits provided by a more effective IP regime.

B. Compulsory Licensing

AFTI continues to have concerns that the National IPR Policy seems to encourage broadly the issuance of compulsory licenses ("CL"). In particular, AFTI notes that the National IPR Policy specifically states that "India will continue to utilize the legislative space and flexibilities available in international treaties and the TRIPS Agreement" to gain access to licenses for drugs as it deems necessary.[22] This is concerning as the Indian Patents Act allows compulsory licenses for drugs if they are considered unaffordable and if the Indian government grants permission for drug makers to manufacture them.

India's compulsory licensing practices are troubling because they evidence India's clear intent to benefit domestic Indian industries to the detriment of U.S. exporters. Such compulsory licensing practices detract from U.S. exports by taking high-paying American IP-manufacturing jobs and compelling companies to move those jobs to India.

India's Draft National Pharmaceutical Policy ("NPP") 2017 refers to the potential use of compulsory licensing under Paragraph 19 of the Drug Price Control Order ("DPCO") 2013 to control prices for patented products. AFTI is concerned that the NPP 2017 proposes to use compulsory licenses as a mechanism for price control of patented drugs.[23] An active

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[21] Notification, Ministry of Commerce and Industry, Draft Patent Rules 2018, https://dipp.gov.in/sites/default/files/draft_PatentRule_10December2018.pdf.

[22] National IPR Policy, at p. 9.

[23] "Draft Pharmaceutical Policy – 2017," *available at* http://www.indiaenvironmentportal.org.in/files/file/draft%20pharmaceutical%20policy%202017.pdf.

compulsory licensing mechanism and a demonstrated government bias toward its use signals to innovative investors that patent rights are discretionary, largely undermining the forward-looking aspects of the NPP 2017. Furthermore, pricing that does not properly value innovation has the impact of undermining and devaluing IP and access to innovation.

As another 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.[24] 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.[25]

AFTI notes that the number of compulsory licenses issued over the past year has again dropped, as the Indian government seems to have tackled these issues more carefully. While AFTI welcomes the changed approach to this complex issue, it notes at the same time that this shift does not resolve the broader concerns with India's compulsory licensing regime. The policy tools that allow Indian government agencies to issue such licenses remain in place and could be used again in the future. Moreover, while no additional compulsory licenses for biopharmaceuticals were issued by India in 2018, India continues to examine potential compulsory licenses under Section 92 of the Indian Patent Act, which provides for the issuance of compulsory licenses if there is a "national emergency" or "extreme urgency," and Indian companies continued to seek compulsory licenses under Section 84, which provides for any interested person to apply for a compulsory license after three years from the grant of a patent if the patented invention: (1) does not satisfy the reasonable requirements of the public; (2) is not available to the public at a reasonably affordable price; and (3) is not worked in the territory of India. AFTI urges the Modi Administration to repudiate the use of compulsory license as a commercial tool.

C. Patent Enforcement Mechanisms

Indian law permits the Central Drugs Standard Control Organization ("CDSCO") to approve third-party manufacturers to commercialize copies of innovator pharmaceutical products, regardless of whether those products infringe on an innovator's patent(s). After four years of the medicine's first approval in India[26] when the medicine ceases to be a new drug,

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[24] India Patents Act § 92(1).

[25] *Id.* § 84(6)(iv).

[26] Rule 122E of the Drugs and Cosmetics Rules states that a new drug shall continue to be considered as new drug for a period of four years from the date of its first approval or its inclusion in the Indian Pharmacopoeia, whichever is earlier. The Drugs and Cosmetics Act goes on to specify that "Where an application under this Rule is for the manufacture of drug formulations falling under the purview of new drug as defined in rule 122-E, such application shall also be accompanied with approval, in writing in favor of the applicant, from the licensing authority." Thus, to obtain a manufacturing license for a new drug, the Central Drug Regulatory must provide written approval. In the case of drugs which do not meet the definition of a new drug, an "Application for grant and renewal of license to manufacture for sale or distribution of drugs shall be made to the licensing authority appointed by the State Government." *See* Ministry of Health and Family Welfare, "The Drugs and Cosmetics Rules, 1945 (As amended up to the 30th June, 2005)," available at http://www.cdsco.nic.in/writereaddata/Drugs&CosmeticAct.pdf (last visited Dec. 29, 2018).

approval from CDSCO is not required and a mere license to manufacture from any of the state drug regulators to manufacture and market the product in India suffices. State regulatory authorities are not required to verify or consider the remaining term of the patent protection on the original product. Therefore, an infringer can obtain marketing or manufacturing authorization from the state 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. India's National IPR Policy calls for identification of important areas of potential policy development related to ambiguities between IP laws and other laws or authorities whose jurisdictions impact administration or enforcement of patents.[27] India should amend the definition of a "new drug," as well as adopt measures to ensure innovators have timely notice of marketing approval applications and are able to seek injunctive relief before potentially infringing products enter the market. On August 10, 2018, the Government of India solicited stakeholder input on its SUGAM initiative. We urge the Ministry of Health and Family Welfare ("MOHFW") to take immediate steps to increase transparency and cooperation between central and state medicines regulatory authorities. At a minimum, MOHFW should ensure all pharmaceutical manufacturers, the relevant Indian authorities and the broader public have timely notice of marketing and manufacturing applications filed with central and state regulators.

D. Section 3(d) and Related Sections of the Patents Act

Indian authorities have intentionally created an additional hurdle for protection against foreign biopharmaceuticals and chemicals, Section 3(d) of the Indian Patents Act, with the aim of benefitting India's domestic industries. The Modi Administration has ignored repeated calls to fix this onerous and WTO-inconsistent standard for patentability, which directly requires U.S. companies to hand over their hard work to Indian companies. This requirement harms American exports both to India and to third countries, as Indian companies export large quantities of their production.

In addition to the three permitted criteria outlined in TRIPS Article 27, Section 3(d) adds a fourth condition for patentability – inventions constituting a "new form of a known substance" must also "result in the enhancement of the known efficacy of that substance." The addition of this fourth requirement is blatantly inconsistent with TRIPS Article 27. Further, Section 3(d) appears to target the pharmaceutical and agricultural chemical sectors, possibly resulting in an additional violation of Article 27. Specifically, Article 27 requires Members to ensure patentability "in all fields of technology" as long as the three criteria are met.

USTR in its 2018 Special 301 Report recognized that Section 3(d) of the India Patents Act "restricts patent eligible subject matter in a way that poses a major obstacle to innovators seeking timely entry into the Indian market."[28] The Indian Patent Office has continued to reject applications for pharmaceutical products relying on Section 3(d), using the provision to reject hundreds of applications in recent years. AFTI believes these anomalous outcomes result from inconsistent application of conventional patentability criteria. AFTI is concerned that the Patent Guidelines as applied are biased against pharmaceutical patents, and the Modi Administration is

[27] *See* Secs. 3.8 and 3.8.3 of the National IPR Policy.

[28] 2018 Special 301 Report, at p. 49.

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.

While the India government has applied Section 3(d) more onerously than other provisions of Section 3, we would encourage the 2019 Special 301 Report to highlight that other parts of Section 3 contain similar restrictions that could be used to deny other patentable manufacturing-relevant technologies. Examples of potential risk include 3(j) for agricultural products, 3(i) for diagnostic and treatment processes, 3(k) for software, and 3(o) for integrated circuits.

India has yet to address the challenges posed by Section 3 broadly and Section 3(d) specifically, 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.

V. Price Controls

The Government of India has instituted price controls across several sectors that discriminate against advanced manufactured products that contain valuable IP.

A. Pharmaceutical Industry

As previously discussed, in 2013, the Government of India issued a new DPCO that imposed price controls on a wide range of biopharmaceutical products. Then, in August 2014, the National Pharmaceutical Pricing Authority ("NPPA") issued orders setting prices for 108 non-scheduled diabetes and cardiovascular medicines. While the guidelines have since been withdrawn, the NPPA continues to pursue its authority to do so in court. Such pricing decisions, as well as the broad authority granted to the NPPA under this provision, do not provide for a transparent and predictable environment and can ultimately negatively impact patient access to medicines.

Additionally, DPCO egregiously favors domestic Indian products, providing a five-year exemption from the pricing formula new medicines developed through indigenous research and development that obtain a product patent, are produced through a new process, or involve a new delivery system. The provision both favors local Indian companies and encourages forced localization.

AFTI notes that the Ministry of Pharmaceuticals recently announced amendments to the DPCO, which have been prompted by steady advocacy by the U.S. government and stakeholders.[29] The amendments include providing foreign-developed drugs the same five-year exemption that locally developed medicines currently enjoy and creating an exemption for orphan drugs from price controls. The status quo has made it difficult for U.S. pharmaceutical companies to compete fairly in India, but the full effect of these worthy reforms will only come when paired with meaningful patent protection, as well as new pathways for orphan drugs. AFTI

[29] Order, Ministry of Chemicals and Fertilizers, Jan. 3, 2019, http://pharmaceuticals.gov.in/sites/default/files/Gazette%20Notification_DPCO.pdf.

is concerned that, consistent with the compulsory licensing section above, the Indian Health Ministry was "actively mulling compulsory licensing," apart from price capping, or orphan drugs, before issuing the exemption.[30]

B. Medical Devices

In July 2016, the Indian Health Ministry added coronary stents to the National List of Essential Medicines ("NLEM"), which gives the NPPA the authority to regulate the price of listed drugs and stents. As a result, on February 13, 2017, the NPPA issued an order that immediately capped the price of coronary stents sold at public and private hospitals, resulting in a nationwide cut of stent prices by up to 75-85 percent.[31] By lumping together all drug stents, regardless of their level of technology or the clinical data supporting their safety and performance, this decision harms U.S. companies that produce the most innovative stent technologies. By setting a single price category across newer and older technology, the order rewards less advanced products by local Indian manufacturers not backed by the investment in R&D and clinical research needed for innovative products by American companies. Moreover, the order prohibits manufacturers from withdrawing product models from the market, despite the fact that the price is below cost for some high-end models – effectively ordering companies based in the United States to sell leading edge technology in India at a loss.

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, and 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 cutting the price of knee implants by as much as 70 percent.[32] In contrast to the February order which was enacted by first adding coronary stents to the NLEM, the NPPA exercised a rarely-invoked provision of the DPCO, Paragraph 19, which permits India in extraordinary circumstances to raise or lower the price of non-scheduled drugs. 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 the NPPA, do not adhere to the need for transparency, predictability, and trust in the decision-making process, which hinders industry's ability to further invest in India.

C. Agricultural Biotechnology Industry

Price controls also negatively impact the agricultural biotechnology industry in India, and inhibit further investment from American companies and unfairly prevent innovative U.S.

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[30] Sushmei Dey, *Health Ministry Mulled Compulsory Licencing of Rare Disease Drugs,* THE INDIA TIMES, Jan. 7, 2019, https://timesofindia.indiatimes.com/india/health-ministry-mulled-compulsory-licencing-of-rare-disease-drugs/articleshow/67412634.cms.

[31] Rhythma Kaul, "*Govt Caps Coronary Stent Price at Rs 30,000 in Relief for Lakhs of Patients,*" HINDUSTAN TIMES, Feb. 14, 2017, *available at* https://www.hindustantimes.com/india-news/in-a-relief-to-lakhs-of-patients-govt-caps-coronary-stent-price/story-WfmpwOUxvvW0SiTW7h0BEO.html.

[32] "*India Introduces Price Controls For Knee Implants*," REUTERS, Aug. 16, 2017, *available at* https://www.reuters.com/article/us-india-health-pricecontrol/india-introduces-price-controls-for-knee-implants-idUSKCN1AW1IX.

exports. Recent developments surrounding the pricing of cotton seeds serve as a representative example. Cotton seeds, like pharmaceuticals, are included 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. Despite this authority, the Indian government has delegated the regulation of cotton seed prices to various state authorities. Beginning in 2006, several states in India enacted nearly identical laws enabling their state governments to set the maximum sales price (the "MSP") of cotton seeds. These state governments have exceeded their authority and violated established contracts.

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.[33] 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[34] – 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.[35]

AFTI was pleased to see Monsanto's victory in India's Supreme Court last month, overturning a Delhi High Court order stating that Monsanto could not claim patent on its GM cotton seeds.[36] This decision sets a thoughtful precedent that, if followed, could increase yields for Indian farmers and boost American agricultural biotechnology exports to India. More broadly, the ruling sends a positive signal to potential investors in India's innovative industries. We are especially encouraged by recent comments from one government official that "Publicly funded science in this broad area can now be assured of protection of its intellectual property. Indian agriculture and other biotech scientists should feel encouraged to innovate further."[37] Strong IPR increases U.S. exports, but also draws in new investment and increases India's competitiveness. We encourage Indian government to demonstrate that in fact GM cotton seeds are patentable and that biotechnology innovators "can now be assured of protection of its intellectual property."

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[33] Please see the Department of Agriculture, Cooperation & Farmers Welfare website at http://agricoop.nic.in/.

[34] 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), *available at* 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.

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

[36] IndUS Business Journal, *SC Rules in Favour of Monsanto's Patent of GM Cotton Seeds*, Jan. 8, 2019, https://indusbusinessjournal.com/2019/01/sc-rules-in-favour-of-monsantos-patent-of-gm-cotton-seeds/.

[37] Nature, *Indian court's decision to uphold GM cotton patent could boost industry research*, Jan. 30, 2019, https://www.nature.com/articles/d41586-019-00177-y.

VI. Copyright

India's failure to protect copyrights allows for widespread theft of American products across multiple industries. The problem is growing and serves as a significant barrier to U.S. exports of goods and services, and to U.S. foreign direct investment. India is ranked 36th out of the fifty countries listed in the International IP Index created by the Global Innovation Policy Center of the U.S. Chamber of Commerce, and scored a 2.22 out of a possible seven for copyright protections in 2018.[38] The problem is daunting. Piracy of movies, music and illegal downloads in India is estimated to cost the music and entertainment industry approximately $4 billion per year, the bulk of which affects local content. However, AFTI commends the High Court of Delhi, the High Court of Bombay, Maharashtra Cyber Digital Crime Unit, the Telangana Intellectual Property Crime Unit ("TIPCU"), and the National Internet Exchange of India for continuing to provide content creators injunctive relief against websites offering pirated and infringing content, and the Department of Telecommunications for helping to carry out the orders. AFTI encourages this work to continue.

Notably, in January 2019, India's MIB proposed amendments to the Cinematographic Act, 1952 that would criminalize any nonconsensual recording and transmission of audiovisual works using any audiovisual devices, given that "[f]ilm piracy, particularly release of pirated version of films on internet, causes huge losses to the film industry and government exchequer."[39] AFTI welcomes these proposed amendments because if adopted, they would better protect intellectual property for producers and distributors of entertainment content in both the United States and India.

A. Copyright Act Amendments

The Copyright Act amendments passed in 2012 have proven inadequate in addressing the realities of a 21st century economy that relies heavily on e-commerce and digital products. Although the amendments offered remunerative rights for composers and songwriters whose products are used in film, the legislation did not lay out adequate protections to guard against the illegal internet downloads of music, movies, software, and other data files.[40]

The Act further provides multiple unwarranted and loosely worded exceptions for personal use and for personal reproduction. The Indian government provided assurances that it

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[38] GLOBAL INNOVATION POLICY CENTER, INSPIRING TOMORROW: U.S. CHAMBER INTERNATIONAL IP INDEX (2019), available at https://www.uschamber.com/ipindex .

[39] *Public Comments Sought on Cinematograph Act (Amendment) Bill*, Jan. 3, 2019, https://mib.gov.in/sites/default/files/Public%20Notice%20-%20Amendment%20of%20Cinematograph%20Act%20Bill.pdf.

[40] Nyay Bhushan, *Indian Copyright Act Amendments Give Music Artists Ownership Rights*, HOLLYWOOD REPORTER, May 25, 2012, *available at* http://www.hollywoodreporter.com/news/indian-copyright-act-amendments-329624.

would establish a permanent Copyright Board to ensure compliance with the provisions of the Act, but this body has not yet been formed, making many provisions of the Act inoperable.[41]

Notably, India acceded to the World Intellectual Property Organization ("WIPO") Copyright Treaty ("WCT") and WIPO Performances and Phonograms Treaty ("WPPT") in July 2018. AFTI applauds this decision and strongly encourages India to move forward with implementation in order to comply with its obligations. Necessary amendments to the Copyright Act include: (i) defining technological protection measures, and including civil and criminal penalties; sanctions should apply to both acts of circumvention and trafficking in devices, components and services that circumvent; and (ii) adopting definitions and sanctions for the unauthorized removal of rights management information. Implementation will allow India the opportunity to benefit from the commercial opportunities enabled by these instruments. In addition, AFTI recommends that India amend Section 52c of the Copyright Act to bring it in line with the existing safe harbor provisions in the Information Technology Act, as well as with international standards pertaining to temporary copies.

B. Memorandum Interpreting Section 31D of the Copyright Act

AFTI is concerned with the September 2016 Memorandum on Section 31D of the Copyright Act, which sets out that a statutory license applies to all kinds of broadcasting, including internet broadcasting.[42] This interpretation is inconsistent with the original intent of Section 31D, which limited the scope of the statutory license to non-interactive radio and television broadcasters, and was not intended to cover interactive internet music streaming services. Moreover, the policy position adopted in the 2016 Memorandum was included at the request of internet companies, without proper consultation with copyright-intensive industries, which are directly and negatively impacted by this measure. Unlike radio and television broadcasters, which claim financial challenges with respect to licensing, the digital music streaming services operating in India are performing well by all metrics (e.g., number of users, revenues, low licensing payments that are far below international standards), thereby falling further outside of the purported rationale for Section 31D.

By including internet music streaming services within the scope of broadcasting, the 2016 Memorandum is also inconsistent with international copyright law. The scope of broadcasting is well established and clearly defined in international law, including in the WIPO Berne Convention and WIPO Internet Treaties. There is no ambiguity in these treaties that broadcasting excludes interactive music streaming services. Likewise, India is departing from worldwide commercial practice where digital music services are licensed individually on free market terms.

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[41] Abhai Pandey, *Inside Views: The Indian Copyright Act, 2012 and Its Functioning So Far*, IP WATCH, Oct. 23, 2014, *available at* http://www.ip-watch.org/2014/10/23/the-indian-copyright-amendment-act-2012-and-its-functioning-so-far/.

[42] "Office Memorandum," Department of Industrial Policy and Promotion, Sept. 5, 2016, *available at* http://dipp.nic.in/sites/default/files/OM_CopyrightAct_05September2016.pdf.

C. Illegal Copying of Books and Written Publications

It is estimated that nearly a quarter of books in India are pirated.[43] Not only does India have one of the highest prevalence of illegal copying of books and publications, but the practice is also largely condoned in the country.[44] Even Indian authors largely accept the copying of their own work, and police are hesitant to enforce copyright law.[45] In September 2016, the Delhi High Court rejected a copyright infringement petition brought under the Copyright Act by international publishers against a bookstore on the Delhi University campus, which had been selling photocopied sections of copyrighted textbooks. The judge found that photocopying equated to copying by hand.[46] One commentator in India called the judgment "a bold articulation of the principles of equitable access to knowledge – and one that deserves to be emulated globally."[47] AFTI encourages the Ministry of Human Resource Development to issue a statement or circular to academic and research institutions to combat the illegal use of photocopied and scanned materials.[48]

VII. Conclusion

For the foregoing reasons, AFTI requests that USTR once again place India on its Priority Watch List, where it has been placed – except for the few years it was listed as a Priority Foreign Country – since the first Special 301 Report in 1989.

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[43] Ariel Bogle, *The World of India Book Piracy*, MELVILLE HOUSE, Jan. 7, 2013, *available at* http://www.mhpbooks.com/the-world-of-indian-book-piracy/.

[44] *Hearing on U.S.-India Trade Relations: Opportunities and Challenges Before the H. Comm. On Ways and Means*, 113th Congr. (2013) (statement of the Int'l Intell. Prop. Alliance), *available at* http://waysandmeans.house.gov/uploadedfiles/iipa_statement_for_the_record_sc_trade_india_hearing_march_13_2013.pdf.

[45] Sonia Faleiro, *The Book Boys of Mumbai*, N.Y. TIMES, Jan. 4, 2013, *available at* http://www.nytimes.com/2013/01/06/books/review/the-book-boys-of-mumbai.html?_r=0.

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

[47] Lawrence Liang, "A Blow for the Right to Knowledge," THE HINDU, Sept. 19, 2016, *available at* http://www.thehindu.com/opinion/lead/A-blow-for-the-right-to-knowledge/article14987252.ece.

[48] Glyn Moody, *India Wants Students and Researchers To Have The Right To Photocopy Books*, TECHDIRT, Oct. 23, 2013, *available at* http://www.techdirt.com/articles/20131023/08004824979/india-wants-students-researchers-to-have-right-to-photocopy-books.shtml.