Dear Mr. Chang:

The Alliance for Fair Trade with India (“AFTI”) is comprised of a diverse group of organizations that support increased action to address the barriers to trade and investment U.S. companies are facing in India. These barriers include the erosion of intellectual property rights (“IPR”), and AFTI represents a range of U.S. 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. Under the Trade Facilitation and Trade Enforcement Act of 2015, USTR has an obligation to develop “action plans” for each country that USTR identifies as a Priority Watch List country and that has been on the Priority Watch List for at least one year. The Act also 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. As discussed in detail throughout this submission, there is strong evidence that India has not made sufficient efforts to emerge from its current status under the Priority Watch List, or to protect adequately IPR holders’ interests with respect to patents, copyright, and trade secrets.

It is important to note that the Government of India made some noteworthy improvements to the overall IP environment in India in 2017. The Department of Industrial Policy and Promotion (“DIPP”) began a new national awareness campaign on the harms associated with counterfeiting and piracy, run by the Cell for IPR Promotion and Management. DIPP also released new training resources and toolkits for local enforcement officials, steps that have prompted creation of new IP enforcement units in a handful of Indian states. DIPP also made notable progress to reduce longstanding delays in patent and trademark examinations by expediting the patent approval process and increase examiner capacity. In addition, the Government of India announced in July 2017 revised “Guidelines for Examination of Computer Related Inventions (“CRIs”)” that have the potential to significantly improve the patent environment for those inventions.

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1 19 U.S.C. § 2242(g)(1).
Unfortunately, the Government of India did not address numerous critical and longstanding shortcomings to its IPR regime identified in the 2017 and prior Special 301 Reports. These critical shortcomings include:

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

- The lack 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,

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

Moreover, AFTI members saw several new actions over the past year that created significant new IP challenges. These include troublesome steps related to Section 8 of the Patent Law, new court rulings related to “patent working,” and a stronger push by India in international forums to weaken strong international rules for IPR protection.

AFTI continues to track implementation by the Government of India of the 2016 National Intellectual Property Rights (“IPR”) Policy. The Government of India needs to act swiftly to translate the concepts that support IPR contained in the National IPR Policy into concrete policy measures, as well as refine the policy to address several outstanding issues where India continues to fall short of its international obligations.

In this respect, 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.

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 addition, his “Make in India” campaign has given some additional fodder to those who wish to promote local IPR and local manufacturing at the expense of U.S. companies and products. In fact, the National IPR Policy includes a recommendation for the exploration of “the possibility of expedited examination of patent applications to promote
These localization requirements impact a variety of sectors, including several 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 were to be reserved for domestically-manufactured solar cells and modules. In August 2015, a WTO panel found that India had in fact violated 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”), which establishes the national treatment obligation. In September 2016, the Appellate Body affirmed the panel’s ruling, rejecting all of India’s defensive arguments. 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. AFTI urges India to bring its measure into full compliance with these rulings and recommendations.

India also continues to maintain localization requirements in its Machine-to-Machine Roadmap for the development and deployment of Internet of Things (“IOT”) technologies, launched in 2015. The Roadmap aims to have local manufacturers produce 60 percent of information and communication technology products procured by the Indian public sector by 2017, rising to 80 percent in 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. Such measures go well beyond the regimes in existence in the United States and other countries, and well beyond what is necessary to address any security concerns. They are intended to reduce U.S. exports to India. The Indian government is considering pursuing these measures for commercial rather than security purposes.

II. Lack of Regulatory Data Protection

In its 2017 Special 301 Report, USTR urged India to provide an “effective system for protecting against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for [pharmaceutical] products.” Despite

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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 USTR 2017 Special 301 Report, p. 42.
these repeated urgings, 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. 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.” 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.

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. In its 2017 Special 301 Review Comments, AFTI expressed concern that 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.

III. Continued Lack of Trade Secret Protection

Theft of trade secrets is a serious issue that undermines companies’ ability to compete in the global market place. A recent report from the Congressional Research Service notes U.S. companies suffer billions of dollars in losses resulting from the theft of trade secrets annually. The report also identifies India as an emerging economy with very weak laws and enforcement practices.

India’s limited efforts at protecting trade secrets are sorely lacking, and do not afford U.S. companies adequate protection as required by international law under the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”) Article 39.2. However, the WTO Secretariat noted in its report following India’s Trade Policy Review, “[i]t is not clear precisely

12 2017 AFTI Special 301 Comment, at p. 5.
14 Id.
how India protects against disclosure of trade secrets by third parties not party to any formal or informal contracts or confidence.”

India does not have any unified national trade secrets law that would protect information that qualifies as a trade secret under international law. India’s 2008 National Innovation Bill includes language that, on its face, appears to protect trade secrets, but does not provide any protection of trade secrets. Companies in India have no choice but to resort to contract law to seek protection for their trade secrets, but India’s Contract Act of 1872 voids contractual agreements that are “in restraint of trade” and has been the subject of many legal disputes over trade secrets. Moreover, India’s new National IPR Policy proposes no improvements to the protection of trade secrets, but simply identifies “protection of trade secrets” as one of many “important areas of study and research for future policy development.” The U.S. and India as recently as 2016 co-hosted a workshop on trade secrets that produced a handful of Indian commitments in the right direction, including a new study on legal approaches to trade secrets protection, development of a toolkit for industry on existing channels for trade secret protection, and potential judicial training on trade secrets issues. Since that time, however, little action has occurred, leaving no real progress on these issues.

IV. Patents

In its 2017 Special 301 Comments, AFTI expressed optimism with respect to Prime Minister Narendra Modi’s April 2015 remarks calling for India to align its patent laws with international standards in order to encourage foreign investment. Unfortunately, Prime Minister Modi’s commitments have yet to come into fruition, and several longstanding issues and concerns remain that serve as significant barriers to U.S. trade and investment. However, AFTI applauds the Controller General for Patents, Designs and Trademarks for working to reduce longstanding delays in patent and trademark examinations by expediting the patent approval process and increase examiner capacity, and to offer new training resources for local enforcement officials. Some states, in turn, have created specialized structures to coordinate IP enforcement or increased campaign efforts.

A. Guidelines on Computer-Related Inventions (“CRIs”)

In its 2017 National Trade Estimate (“NTE”) submission, AFTI 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” significantly improves the patenting

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18 National IPR Policy, at p. 10.
19 2017 AFTI Special 301 Comment, at p. 7.
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. 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. Of serious concern, in December 2014, the Indian Supreme Court rejected Bayer’s appeal of a July 2014 Bombay High Court decision refusing to revoke a CL issued to Indian drug maker Natco Pharma Ltd. (“Natco”). This CL was initially granted in March 2012 by the Indian Controller General of Patents under the amended Patents Act, and granted Natco the right to produce and sell Bayer’s anti-cancer drug Nexavar in India. Despite significant international scrutiny, this decision (the “Nexavar decision”) was subsequently affirmed by the Intellectual Property Appellate Board (the “IPAB”) in March 2013.

The legal basis for the Nexavar decision is very likely in violation of India’s WTO obligations. USTR has stated that this decision could be used to inappropriately pressure innovators outside of India – including those in sectors well beyond pharmaceuticals to manufacture in India in order to avoid being compelled to license an invention to third parties. When asked multiple times within its Trade Policy Review at the WTO to clarify, the government of India simply responded by citing the IPAB decision, adding no further clarity to the issue.

In addition, 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

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20 National IPR Policy, at p. 9.
21 Andrew Ward and Amy Kazin, Bayer Loses Bid to Block Cheap Version of Cancer Drug in India, FINANCIAL TIMES, Dec. 12, 2014.
proposes to use compulsory licenses as a mechanism for price control of patented drugs. An active 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.

While AFTI welcomes a more careful approach the Indian government and key courts (such as the Delhi High Court) seems to have taken in recent years towards potential CL cases, this it notes at the same time that this shift does not resolve the broader concerns with India’s compulsory licensing regime, and could be reversed at any moment. 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 2017, 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 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. Section 3(d)

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 non-compliant 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 2017 Special 301 Report recognized the “challenges faced by the pharmaceutical industry due to Section 3(d) of the India Patents Act.” The Indian Patent Office has continued to reject applications for pharmaceutical products relying on Section 3(d). For

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24 2017 Special 301 Report, at p. 42.
example, in November 2016, the Indian Patent Office denied a patent to Xtandi, claiming that the invention is “not patentable under section 3(d).” Additionally, between May and December 2017, at least 149 patent applications faced rejections under Section 3(d). 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 continuing to ignore repeated calls to rectify this onerous and WTO non-compliant standard for patentability, to the detriment of both foreign and Indian IP holders.

V. Other Effective Barriers for IP-Intensive Industries

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

A. Pharmaceutical Industry Price Controls

In 2013, the Government of India issued a new Drug Price Control Order (the “DPCO”) which imposed price controls on a wide range of biopharmaceutical products. Then, in August 2014, the National Pharmaceutical Pricing Authority (the “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 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, exempting from the pricing formula, for a period of five years, 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.

B. Medical Devices Price Controls

On February 13, 2017, NPPA issued an order which 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.[1] 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 which 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

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some high-end models – effectively ordering companies based in the United States to sell leading edge technology in India at a loss.

In August 2017, NPPA issued an order cutting the price of knee implants by as much as 70 percent. In contrast to the February order which was enacted by first adding coronary stents to the National List of Essential Medicines (NLEM), 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 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

Price controls also negatively impact the agricultural biotechnology industry in India, and inhibit further investment from American companies and unfairly prevent innovative U.S. exports. Recent developments surrounding the pricing of cotton seeds serve as a representative example. Cotton seeds, like pharmaceuticals, are included 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. 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 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 Please see the Department of Agriculture, Cooperation & Farmers Welfare website at http://agricoop.nic.in/.


VI. Copyright

India’s failure to protect copyrights allows for widespread theft of American products across multiple industries. The problem is growing, and is a significant barrier to U.S. exports of goods and services, and to U.S. foreign direct investment. 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 and High Court of Bombay for providing 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.

A. Copyright Act Amendments

The Copyright Act amendments passed in 2012 have proven over the last four years 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. The amendments also failed to introduce much needed anti-camcording legislation, despite its status as a longstanding nuisance to foreign and domestic film industries. The illegal recording of cinema in India continues to represent one of the worst cases in the world, affecting local and foreign distributors alike. In 2012, there were 69 incidents of major U.S. motion pictures for which audio, video, or audio/video captures were detected as being sourced from Indian movie theaters. Incidents originating from India continuously occur, including the recently-released movie “The Fate of the Furious” in April 2017. India needs to secure, exercise, and enforce the rights related to the copyright protection in the film industry in particular.

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

B. Memorandum Interpreting Section 31D of the Copyright Act


30 India, China the Problem Areas in Camcorder Piracy Cases, HOLLYWOOD REPORTER, Dec. 8, 2014.

31 Id.


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. 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.

C. Illegal Copying of Books and Written Publications

It is estimated that nearly a quarter of books in India are pirated. Not only does India have one of the highest prevalence of illegal copying of books and publications, the practice is actually largely condoned in the country. Even Indian authors largely accept the copying of their own work, and police are hesitant to enforce copyright law. 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. 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.”39 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.40

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.
