February 5, 2016

Ms. Christine Peterson  
Director for Intellectual Property and Innovation  
Office of the United States Trade Representative  
600 17th Street, N.W.  
Washington, D.C. 20508


Dear Ms. Peterson:

The Alliance for Fair Trade with India (“AFTI”) was launched in June 2013 in support of increased action to address the barriers to trade and investment U.S. companies are facing in India, including the erosion of intellectual property rights (“IPR”), and to serve as a mechanism for engaging with U.S. policymakers on such issues. AFTI’s diverse membership is comprised of organizations representing 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, and to conduct an Out-of-Cycle Review (“OCR”) of India’s IPR regime.

AFTI and its members were encouraged by the Obama Administration’s efforts at commercial engagement with India over the course of the last year. Our members watched with cautious optimism as the two countries held their first ever Strategic and Commercial Dialogue and a meeting of the U.S.-India Trade Policy Forum in the fall of 2015. However, despite the convening of these dialogues, the Indian Government has yet to take any significant steps towards improving the business climate for innovative American companies. In fact, numerous longstanding issues remain unresolved. These include:

• Weaknesses in the Indian copyright system that harm U.S. and Indian creators alike;

• The use and threatened use of compulsory licensing on biopharmaceutical, environmental technology, and other products as a tool of industrial policy; and

• Measures in Indian law that add a legally questionable additional criterion for the patentability of medicines and agrochemical products.

Additionally, AFTI and its members have serious concerns with several of the policy pronouncements and proposals included in a leaked draft of the revised National IPR Policy dated April 2015. As an extension of a campaign promise made by now-Prime Minister Narendra Modi, the Department of Industrial Policy and Promotion (“DIPP”) constituted a think tank, the National IPR Think Tank (“NITT”) in October 2014 to draft a national IPR policy. NITT has since drafted and circulated a revised plan, which was leaked to the public in October
of last year. Among the most disconcerting aspects of the document are plans for increasingly onerous local manufacturing requirements, and a continued failure to ensure regulatory data protection. These issues, which have been longstanding frustrations of AFTI and its members, are discussed in greater detail in Sections II and III, below.

AFTI and its members are concerned by the apparent disconnect between the diplomatic momentum, positive rhetoric, and commitments emerging from the recently convened dialogues, as there has been no concrete movement on key issues. Particularly as we enter the final year of the Obama Administration, we are left wondering, how can these bilateral forums be used to productively address the issues we set forth below?

We agree with the sentiment USTR expressed in announcing its 2015 Special 301 Report that “[a]ttention to our IPR priorities and action to resolve concerns through bilateral fora can benefit both the United States and India.” We note that USTR stated it expected India would make “substantive and measurable improvements in India’s IPR regime for the benefit of a broad range of innovative and creative industries.” USTR added that it would “monitor progress over the coming months, and [is] prepared to take further action, if necessary.” As detailed below, we believe that India has not made “substantive and measurable improvements” in its IPR regime “for the benefit of a broad range of innovative and creative industries,” and that therefore “further action” in the form of an Out-of-Cycle Review at a minimum is warranted.

For these reasons, we recommend maintaining India as a Priority Watch List country and would encourage the U.S. Government to maintain its focus on key IP issues by implementing a new Out-of-Cycle Review. We believe that this increased pressure and oversight is necessary to make progress and to avoid backsliding on issues of concern to AFTI and its members.

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

I. Forced Localization

India continues to adopt laws and regulations that evidence its misapplication of global IPR standards and WTO rules, and that are clearly designed to favor domestic industries and IP at the expense of goods, services, and IP from other countries. This tendency has been on display in recent years in the implementation of a number of “forced localization” policies designed to boost India’s domestic manufacturing, high-technology, and research and development capabilities. Within the aforementioned leaked National IPR Policy, the NITT included a recommendation that certain patent applications be examined on an expedited basis if given assurance that the “manufacturer has either started manufacturing the invention in India or undertakes to do so within two years from the date of filing of the request for expedited examination.”1 Given the significant patent backlog in India, this policy, if implemented, would clearly favor Indian businesses with pre-existing domestic operations. Moreover, it would directly discriminate against American intellectual property holders who are unable or unwilling to establish manufacturing operations in India.

1 Department of Industrial Policy and Promotion, Draft of the National Intellectual Property Rights Policy, April 2015. See also, Draft Patent Rule 24(C).
The Modi Government has shown itself prone to encouraging such discriminatory localization requirements in several strategic industries, most recently the telecommunications sector. In spring 2015, India introduced local content and forced data localization requirements as part of its national telecom and machine-to-machine policy. In May 2015, India launched a new National Telecom Machine-to-Machine Roadmap for the development and deployment of Internet of Things (“IOT”) technologies. While the roadmap contains many impressive elements, it unfortunately extends discriminatory policies to government procurement and the “Make in India” initiative. Specifically, India used the Roadmap to introduce local content requirements in telecommunications equipment by linking to the Indian government’s procurement initiative—the Preferential Market Access (“PMA”) plan. The Roadmap calls for devices, such as sensors and microchips, to be included in the PMA, which aims to have local manufacturers produce 60 percent of ICT products procured by the Indian public sector by 2017, rising to 80 percent in 2020.2

The Roadmap also introduces the possibility of India’s first forced local data storage requirement. The plan requires that all IoT gateways and application servers that supply customers in India be located in India.3 In proposing this policy, the Modi Government has used the need for national security as justification, but the notion that data must be stored locally to protect privacy or be secure is patently false, and has been disproven by a range of experts.4

India also maintains local content requirements for solar energy projects. In 2015, India implemented local content requirements for firms bidding on some projects related to the Jawaharlal Nehru National Solar Mission (“JNNSM”). India has allocated $1.4 billion to the JNNSM, which aims to construct 100 gigawatts of solar power by 2022. In March 2015, India announced phase II of the JNNSM. In subsequent tender documents, the Indian government stated that it would evaluate current market conditions and decide on the share of the projects to be reserved for domestically manufactured solar cells and modules. For the June 2015 tender, India offered to contract for 2,000 megawatts of grid-connected photovoltaic solar power by 2017. Of this, 250 megawatts are to be reserved for domestic content providers.

The United States filed a dispute settlement case at the World Trade Organization (“WTO”) arguing that these domestic content requirements were inconsistent with India’s obligations under Article III:4 of the General Agreement on Tariffs and Trade (“GATT”), which establishes the national treatment obligation; Article 2.1 of the Agreement on Trade-Related Investment Measures (“TRIMs”); and under the Agreement on Subsidies and Countervailing Measures (“SCM”), specifically Article 5(c) of the SCM Agreement as the measures provide a subsidy for use of Indian origin goods prejudicing U.S. interests.5 In August 2015, the WTO dispute panel reportedly found in a confidential preliminary ruling that India had in fact violated

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2 Government of India, National Telecom M2M Roadmap (New Delhi: Government of India, Ministry of Communication and Information Technology, Department of Telecommunications, 2015).
3 Id.
5 Id.
its WTO obligations.\textsuperscript{6} India has continued its policies despite this ruling and reportedly plans to appeal the decision.

II. Forced Transfer of Technology

A. Continued Lack of Test Data Protection

Protection of undisclosed test and other data remains a serious problem for AFTI and its members, as India fails to effectively protect against unfair commercial use of undisclosed test data and other data generated to obtain marketing approval for pharmaceutical and agrochemical products. AFTI and its members have highlighted this issue extensively in previous Special 301 and National Trade Estimate submissions, and are very concerned that in the National IPR Policy leaked in April 2015, NITT has categorically ruled out the possibility of regulatory data protection (data exclusivity) for clinical test data, in contradiction to India’s requirements under the TRIPS Agreement. Specifically, the National IPR Policy sets out as an area of study “[p]rotection of undisclosed information,” but intentionally excludes “data exclusivity” as an area for future policy development.\textsuperscript{7} Regulatory data protection, or data exclusivity, is an important protection mandated by TRIPS Article 39.3. India’s ongoing failure to ensure that there is not unfair commercial use of an innovator’s time- and resource-intensive regulatory data by a follow-on manufacturer for a fixed term is inconsistent with this obligation. Moreover, it strongly disadvantages innovative foreign companies, as valuable test data submitted by innovator companies to regulatory authorities can be used by companies producing generics as a basis for the approval of their products.

In its 2015 National Trade Estimate 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 and agricultural products.”\textsuperscript{8} AFTI and its members urge India to do so, as well. As the WTO Secretariat noted in its 2015 Trade Policy Review of India, there is no specific legislation protecting test data submitted for obtaining regulatory approval of pharmaceuticals.\textsuperscript{9} The Drugs and Cosmetics Act of 1940 regulates the manufacture and marketing approvals for drugs and traditional medicines, while the Insecticides Act of 1968 addresses the manufacture and marketing approvals for agricultural chemicals (such as insecticides, fungicides and weedicides). However, there is no statute in place in India for the protection of pharmaceutical, agrochemical and traditional medicine-related data against disclosure and reliance by third parties. Such test data is said to be protected under the Official Secrets Act. However, and as noted by the WTO Secretariat, it is unclear how India implements the second obligation under Article 39.3 of the


\textsuperscript{7} Department of Industrial Policy and Promotion, \textit{Draft of the National Intellectual Property Rights Policy}, April 2015, pg 13.


TRIPS Agreement, which is in addition to the obligation to provide protection against disclosure, namely, protection of such data against unfair commercial use.\(^{10}\)

B. Continued Lack of Trade Secret Protection

AFTI and its membership continue to believe that India does not provide adequate protection for trade secrets, and the limited protection that is available is insufficient. Based on its WTO obligations, India is required to protect trade secrets. Under TRIPS Article 39.2, innovators are entitled to protection for their trade secrets and must be allowed “to prevent information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices.”\(^ {11}\) To qualify as a trade secret, the information: (1) must be secret; (2) must have commercial value because it is a secret; and (3) must have been subject to reasonable steps by the rightful holder of the information to keep it secret.\(^ {12}\)

India does not have a national law to protect information that qualifies as a trade secret under international law. While India’s 2008 National Innovation Bill includes language that, on its face, appears promising for the protection of trade secrets, the measure falls short. Chapter VI of the National Innovation Bill, Articles 8 through 10 pertain to confidentiality, confidential information, and remedies. A review of such provisions shows, however, that India has completely missed the mark and fails to protect trade secrets.\(^ {13}\) In actuality, the Act merely “reaffirm[s] the existing legal position of protection of trade secrets through common law actions of breach of confidence, contractual obligations and principles of equity.”\(^ {14}\) It does not mandate the protection of trade secrets. Further, India’s Contract Act imposes a heavy burden on innovators to show that the information is “highly confidential” before they may be entitled to an imperfect remedy. Complicating matters further, 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.\(^ {15}\)

Given that there is no specific legislation regulating the protection of trade secrets and hence no enforcement measures/penalties for violations of trade secrets, companies in India must resort to contract law to obtain protection for their trade secrets. However, India’s legal code does not provide sufficient remedies to enforce such contractual provisions. Moreover, and as the WTO Secretariat noted in its report following India’s Trade Policy Review, “[i]t is not clear precisely how India protects against disclosure of trade secrets by third parties not party to any

\(^{10}\) Id.


\(^{12}\) Id.


formal or informal contracts or confidence.”16 The inadequacy of India’s system continues to stand as a barrier to U.S. trade and investment.

III. Patents

AFTI and its members were encouraged by Prime Minister Modi’s April 2015 remarks in which he called for India to align its patent laws with international standards in order to encourage foreign investment. Specifically, Prime Minister Modi stated that, “India must also work on intellectual property rights guidelines to match global standards. If we don’t work towards bringing our intellectual property rights at par with global parameters, then the world will not keep relations with us. If we give confidence to the world on IPR, then we can become a destination globally for their creative work.”17 Despite these comments, several longstanding issues and concerns remain that serve as significant barriers to U.S. trade and investment.

A. Compulsory Licensing

India’s compulsory licensing practices remain troubling to AFTI as they continue to evidence intent to benefit domestic Indian industries to the detriment of U.S. exporters. On December 12, 2014, the Indian Supreme Court rejected Bayer’s appeal of a July 2014 Bombay High Court decision refusing to revoke a compulsory license (“CL”) issued to Indian drug maker Natco Pharma Ltd. (“Natco”).18 This CL was initially granted in March 2012 by the Indian Controller General of Patents (the “Controller General”) 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.

In light of the Indian Supreme Court’s ruling, AFTI and its members remain very concerned with the Nexavar decision, its underlying rationale, and its potential use as a tool for the furtherance of Indian industrial policy. Specifically, the Controller General based its grant of the CL to Natco in part on Bayer’s failure to “work” the Nexavar patent in India because it imported its products, rather than manufacturing them in India. On appeal, the IPAB modified the Controller General’s reasoning to clarify that “in some cases” the “working” requirement could be met solely by importation. However, the IPAB rejected Bayer’s explanation that economic factors prevented manufacturing in India, stating that, “the patentee must show why it could not be locally manufactured. A mere statement to that effect is not sufficient there must be evidence.”19 In its decision, the IPAB did not clarify the circumstances under which the “working” requirement would be met without manufacturing in India. Moreover, when asked

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18 Andrew Ward and Amy Kazin, Bayer Loses Bid to Block Cheap Version of Cancer Drug in India, FINANCIAL TIMES, Dec. 12, 2014.
multiple times within its Trade Policy Review at the WTO to clarify the idea behind the requirement that technology must be worked in India, the government of India simply responded by citing the IPAB decision, adding no further clarity to the issue.20

As highlighted by USTR in its 2015 Special 301 Report, this decision could be used to inappropriately pressure innovators outside of India – including those in sectors well beyond pharmaceuticals, such as green technology and information and communications technology – to manufacture in India in order to avoid being compelled to license an invention to third parties.21 Moreover, the legal basis for the Nexavar decision is very likely in violation of India’s WTO obligations, specifically TRIPS Article 27.1, as set forth in AFTI’s 2014 Special 301 submission.22 AFTI and its members have, however, been heartened by two recent decisions by the Controller General to reject applications for compulsory licenses applied for in the last year, one for AstraZeneca’s patented anti-diabetic drug Onglyza, the other for Bristol-Myers Squibb’s cancer drug Sprycel.

B. Section 3(d)

AFTI’s membership has expressed longstanding concern with Section 3(d) of India’s Patents Act, concern that has, thus far, gone unaddressed by the Modi government. Specifically, Section 3(d) of India’s Patents Act denies American companies – particularly those in the biopharmaceutical and agricultural chemicals sectors – market access in a manner that is likely in violation of WTO agreements. In enacting onerous and WTO non-compliant standards for patentability, Indian authorities appear to have intentionally created an additional hurdle for protection of foreign biopharmaceuticals and chemicals, with the aim of benefitting India’s domestic industries.

In structuring Section 3(d) as it is drafted, India has created a fourth condition for patentability. Specifically, India has added a requirement that inventions constituting a “new form of a known substance” must also “result in the enhancement of the known efficacy of that substance” in order to be patentable. In doing so, India requires that in order to receive a patent, a “new form of a known substance” be i) new; ii) involve an inventive step; iii) be capable of industrial application; and iv) demonstrate enhanced efficacy. This addition of a fourth criterion for patentability is inconsistent with TRIPS Article 27.1, which mandates that patents be available for any inventions that are “new, involve an inventive step and are capable of industrial application.”

Section 3(d) still looms as a very real threat to patent protection, as evidenced by several recent patent rejections and revocations. On January 13, 2015, Gilead’s patent application for a key compound within its drug Sovaldi was rejected by the Indian Patent Office under Section

21 Office of the U.S. Trade Representative, 2015 Special 301 Report, pg. 50.
22 Article 27.1 establishes that, where national legislation imposes a local working requirement, as it does in India, patent holders should be able to satisfy such requirement by demonstrating that they have imported the patented product. Put another way, Article 27.1 does not allow for the issuance of a compulsory license merely because the patentee does not produce the relevant patented goods locally.
3(d). Gilead’s patent application was challenged by Indian generic drug maker Natco, along with a U.S.-based non-profit group called the Initiative for Medicines, Access and Knowledge. The Patent Office ruled that the active compound in Sovaldi was not sufficiently different to a previously-known molecule to merit patent protection. This decision was overturned on January 30, 2015 by the Delhi High Court. Although there has been criticism of Sovaldi’s cost in some western countries, Gilead is poised to make the drug available for far less in India through a voluntary licensing agreement announced in September 2014 with seven Indian generic manufacturers.

In March 2015, the Indian Patent Office revoked Boehringer Ingelheim’s patent on Spiriva on the grounds that it lacks an inventive step, and fails to demonstrate therapeutic efficacy under the requirements of Section 3(d). Similarly, in July 2015 the Indian Patent Office revoked Roche’s patent for Valcyte, an anti-retroviral drug used for the treatment of CMV disease. The patent was also revoked based on the grounds that it lacks an inventive step and was a known substance under Section 3(d). These decisions continue to underscore the very real threat Section 3(d) still presents to patent protection for American companies.

V. Copyright

India’s lack of robust and enforceable copyright policies results in the denial of effective protection of intellectual property rights for U.S. and Indian companies alike, and presents a significant barrier to U.S. exports of goods and services, and to U.S. foreign direct investment. Copyright infringement is a historic and consistent problem in India. While there have been some positive developments, there has been no improvement in addressing infringement, and unfortunately the problem appears to be growing. Spanning multiple industries, copyright infringements particularly hinder innovation and creative growth for companies related to music and film production, as well as publications and software. While the Indian government has taken some notable actions, it has failed to rein in a problem that badly undermines the market for Indian and U.S. right holders alike.

India is ranked second to last in the International IP Index created by the Global Intellectual Property Center of the U.S. Chamber of Commerce, and scored a 1.47 out of a possible six for copyright protections in 2015—the same score as the previous two years. This shows a lack of progress on the part of the Indian government. The problem is daunting. Piracy of movies, music and illegal downloads in India is estimated to have cost the music and entertainment industry approximately $4 billion dollars per year, the bulk of which affects local content. Unfortunately, with the continuing growth of interconnectedness via the internet, piracy of music and movies has become instant and widespread, growing the illegal practice of distributing creative products. Due to the high rate of piracy, weak IPR protections, and poor

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enforcement, industry groups in India and abroad shy away from innovating new products and investing more in India.  

Finally, the Copyright Act amendments passed in 2012 have proven over the last three 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, an area that will continue to grow as access to the Internet expands in India.  

The amendments also failed to provide adequate tools to address the widespread copyright infringements affecting the country, and failed to introduce much needed anti-camcording legislation, despite its status as a longstanding nuisance to foreign and domestic film industries.  The Act also provides multiple exceptions for personal use and for personal reproduction, many of which are unwarranted and loosely-worded.  Moreover, in order to ensure compliance with the provisions of the Act, the Indian government provided assurances that it would establish a permanent Copyright Board.  This body has not yet been formed, making many provisions of the Act inoperable.  

A.  Internet piracy and illegal downloading  

Illegal downloading, including peer-to-peer (“P2P”) filesharing and illegal streaming is rampant in India.  A recent study tracking downloading of IP addresses on P2P networks for film and television content found India to be in the top ten Internet piracy countries in the world.  

One digital research firm approximated that as of May 2013, the total online video consumption had doubled since 2011—up to 3.7 billion videos per month.  

One popular Indian film, Kaminey, was illegally downloaded over 350,000 times in India and abroad. The illegal downloading and distribution of music also remains a concern.  While losses are difficult to calculate, the U.S. music industry alone estimated a total loss of $431 million in 2012, mostly attributed to mobile and internet piracy.  

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27 Utpal Borpujari, India Major Online Film Piracy Hub, Deccan Herald, January 30, 2014.  


29 Id.  

With the increasing number of internet users in India, the problem is likely only growing, not receding.\(^{31}\) The growth of mobile devices has skyrocketed, with the addition of over a half a billion subscribers from just 2006 (there are now an estimated 900 million mobile phone users).\(^ {32}\) Due to the rise of smart phones, these copyright infringements are particularly nefarious because pirated materials are now being instantly shared via a mobile device.\(^ {33}\)

**B. Camcording piracy**

The illegal recording of cinema in India continues to represent one of the worst cases in the world, affecting local and foreign distributors alike.\(^ {34}\) While AFTI and its members applaud the Obama Administration and Modi Government for discussing the issue during the October 2015 meeting of the U.S.-India Trade Policy Forum, unauthorized camcording remains a severe problem.\(^ {35}\) 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.\(^ {36}\) That number dropped to 43 incidents in 2013, and dropped again to 40 in 2014.\(^ {37}\) Though a positive trend, the number does not include unauthorized camcording of local Indian, foreign, or independent films. The latest arrest of camcorder pirates happened on October 11, 2015, but it is hardly scratching the surface. As already mentioned, the 2012 Copyright Act amendments, while a positive intent on the part of the government, fail to include effective protections to prevent the copying of movies in theaters. The export of this problem to other markets in the region adds to the gravity of the poor enforcement in India, and shows that India needs to secure, exercise and enforce the rights related to the copyright protection in the film industry in particular.

**C. Illegal copying of books and written publications**

The use and distribution of photocopied books, journals and other written documents remains a major challenge to publishers in India, and is another example of the denial of adequate and effective intellectual property rights serving as a trade barrier to U.S. industry.\(^ {38}\) The growing use of the internet across the country allows for pirated books to be retrieved, copied, and distributed more easily than ever before—both physically and electronically. The dissemination of unlicensed scanned copies of academic materials has become a particularly large problem, and is often done at the prompting of, or just outside the campuses of, Indian

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\(^{31}\) *Why the US Fears India’s Internet Boom*, LIVEMINT, May 21, 2015.


\(^{33}\) *4G Roll-Out Fans Increase Film Piracy Fears*, LIVEMINT, Aug. 21, 2015.

\(^{34}\) *India, China the Problem Areas in Camcorder Piracy Cases*, Hollywood Reporter, Dec. 8, 2014.


\(^{36}\) *Id.*


\(^{38}\) *Id.*
academic institutions. American industry groups continue to push for 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.

It is estimated that nearly a quarter of books in India are pirated. Not only is India one of the biggest perpetrators of the 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.

VI. Conclusion

One year ago, in its Special 301 submission, AFTI and its members applauded the Obama administration for recognizing the opportunity presented by the new Modi government for re-engagement on important issues within the bilateral economic relationship. The value of such engagement is, however, ultimately judged by concrete trade and investment outcomes. To date, few if any such outcomes have been achieved. Therefore, we call on the Obama administration, in its remaining year in office, to use its available leverage to address the issues we have outlined above.

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