Ms. Susan F. Wilson  
Director for Intellectual Property and Innovation  
Office of the U.S. Trade Representative  
600 17th Street, N.W.  
Washington, D.C. 20508

Dear Ms. Wilson:

The Alliance for Fair Trade with India (“AFTI”) was launched in June 2013 in support of increased action to address the erosion of intellectual property rights (“IPR”) in India. AFTI’s diverse membership is comprised of organizations representing a range of U.S. industries adversely impacted by India’s troubling and frequently discriminatory policies, including manufacturing, agriculture, telecommunications, pharmaceuticals and beyond. In light of its mandate, AFTI submits to the Office of the United States Trade Representative (“USTR”) this report which calls on USTR, under Section 182 of the Trade Act of 1974, to designate India a Priority Foreign Country (“PFC”) in its annual Special 301 Report.

The annual Special 301 Report provides USTR with one of its key tools for reviewing intellectual property protection and market access practices worldwide, and for identifying those countries whose practices are damaging to U.S. industry. As we detail below, India’s intellectual property practices are among the most damaging in the world, and clearly rise to the statutory threshold required for a PFC determination. Moreover, in the last year India has reached an inflection point both in the egregiousness of its domestic policies and in the belligerence of its international statements, in a manner that not only merits, but necessitates a PFC determination. Some of the most egregious policies and practices highlighted in the report include:

- **India’s compulsory licensing and forced tech transfer policies.** In addition to being WTO non-compliant, India’s approaches to compulsory licensing and the forced transfer of technology are clearly intended as tools of industrial policy, to be wielded against foreign companies for the benefit of domestic Indian enterprises. The direct beneficiaries of such policies are companies in industries in which India has become, or aspires to be, a global player, including in pharmaceuticals, green technology, telecommunications, and semiconductors. Since the Indian Controller General’s decision to grant a compulsory license for Nexavar in March 2012, but particularly over the last twelve months, it has become apparent that the Indian government intends to use CL’s as a tool for bolstering domestic innovation.

- **Rampant copyright infringement.** Copyright infringement has long been problematic in India, and India’s position as a haven for the illegal downloading and distribution of music, movies, and books has become particularly worrisome for U.S. industry.

- **India’s lengthy history as a bad actor with regard to IPR.** Since the inception of the Special 301 process, India has been featured prominently in every one of USTR’s annual reports, either as a Priority Watch List Country or a Priority Foreign Country. Moreover, fourteen years after its first mention in the Special 301 Report, India has still failed to
implement WTO-compliant regulations to protect confidential test and other data. Additionally, as an extension of the protection that has been requested for confidential test and other data, AFTI requests that USTR demand the same protections for trade secrets from India that it has requested from China in past years. This request is in-line with the Obama Administration’s recently published Strategy on Mitigating the Theft of U.S. Trade Secrets. As discussed below, the challenges that India presents vis-à-vis trade secrets are sufficiently urgent to be considered a national security concern.

- Failure to take productive steps to remedy concerns in bilateral and multilateral forums. Despite longstanding concerns expressed by the U.S. and other governments, India has made very little progress within bilateral and multilateral forums in remedying an array of IP-related issues. Equally as troubling, some of these discriminatory IP practices have begun to be emulated by other developing countries, as India has publicly advocated that other countries adopt its discriminatory IP policies. This is a trend which will continue unless the U.S. government takes appropriate action.

For these and other reasons set forth below, AFTI calls upon USTR to identify India as a Priority Foreign Country, and to take requisite action, both on the bilateral and multilateral stages, to encourage India to remedy the policies and practices at issue.

Sincerely,

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I. Legal Threshold

Section 182(a)(1) of the Trade Act of 1974 ("Trade Act") (19 U.S.C. 2242), requires the United States Trade Representative ("USTR") to identify those countries that (a) deny adequate and effective protection of intellectual property rights or (b) deny fair and equitable market access to U.S. persons who rely on intellectual property protection. As defined under Section 182, a foreign country denies "adequate and effective protection of intellectual property rights" if the foreign country:

Denies adequate and effective means under the laws of the foreign country for persons who are not citizens or nationals of such foreign country to secure, exercise, and enforce rights relating to patents, process patents, registered trademarks, copyright and mask works.

Furthermore, under Section 182, a foreign country denies "fair and equitable market access" if the country:

Effectively denies access to a market for a product protected by a copyright or related right, patent, trademark, mask work, trade secret, or plant breeder’s right, through use of laws, procedures, practices, or regulations which (A) violate provisions of international law or international agreements to which both the United States and the foreign country are parties, or (B) constitute discriminatory nontariff trade barriers.

a. Priority Foreign Country Determination

Under Section 182(a)(2) of the Trade Act, USTR has the authority to declare a country identified under Section 182(a)(1) as a Priority Foreign Country if it is a country:

- That has the most onerous or egregious acts, policies, or practices that (i) deny adequate and effective intellectual property rights, or (ii) deny fair and equitable market access to United States persons that rely upon intellectual property protection;

- Whose acts, policies, or practices have the greatest adverse impact (actual or potential) on the relevant United States products; and

- That is not (i) entering into good faith negotiations, or (ii) making significant progress in bilateral or multilateral negotiations, to provide adequate and effective protection of intellectual property rights.

As set forth in the sections below, we believe that India clearly meets this threshold.

II. Patents

a. Overview
In 1991, USTR identified India as a Priority Foreign Country, on the grounds that it “provide[d] an inadequate level of patent protection, including too short a term of protection and overly broad compulsory licensing provisions.”

More than twenty years later, these same concerns regarding India’s patent regime remain. Several other troubling policies and practices have, however, emerged in recent years that stand as evidence of a continued and egregious denial of adequate and effective protection of IP. These include the revocation of numerous patents by the Indian Controller General of Patents and the Intellectual Property Appellate Board, the denial of patent applications as well as the approval of generic drugs during a patent’s term, the granting of a compulsory license, narrow standards for patentability, pre-grant opposition procedures that are prone to abuse by patent challengers, and burdensome patent application requirements under Section 8 of the Indian Patents Act. For U.S. industry, two of the most troubling of these are India’s approach to compulsory licensing and its narrow standards for patentability, specifically Section 3(d) of the Indian Patents Act, both of which are discussed in greater detail below.

b. Compulsory Licensing

India’s compulsory licensing practices clearly rise to the statutory threshold established for identification of a trading partner as a Priority Foreign Country. The Indian government’s decision in March 2012 to grant a compulsory license (“CL”) to an Indian pharmaceutical company to allow it to manufacture a generic copy of Nexavar, an anti-cancer medicine manufactured by Bayer, both i) denies Bayer adequate and effective protection of its intellectual property rights; and ii) denies Bayer fair and equitable market access in a manner that is in violation of India’s WTO commitments. Moreover, this decision, and the egregious approach to

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3 In the most recent and troubling instance of a patent application denial, in April 2013, the Indian Supreme Court denied an appeal challenging the rejection of a patent for Gilvec, an anti-cancer medication. The Court held that the drug showed no new invention and did not satisfy the criteria under section 3(d) of the Patents Act. In the most recent instance of generic approval during a patent term, Indian drug maker Glenmark launched a generic version of Merck’s patented diabetes medicine Januvia after obtaining approval from an Indian regulatory body. Glenmark entered the Indian market in disregard of Merck’s compound patent on Januvia. See Soutik Biswas, Novartis: India rejects patent plea for cancer drug Glivec, BBC, Apr. 1, 2013, http://www.bbc.co.uk/news/business-21991179; Kaustubh Kulkarni & Tom Pfeiffer, Merck unit sues India’s Glenmark over diabetes drug, REUTERS, Apr. 2, 2013, http://www.reuters.com/article/2013/04/02/us-india-merck-glenmark-idUSBRE9310L420130402.
compulsory licensing that it presents, will adversely impact U.S. companies far beyond the pharmaceutical sector as it will serve as a key tool for implementing Indian industrial policy. In fact, it appears as if the Indian government is poised to replicate the decision in a variety of other sectors to benefit domestic Indian innovation to the detriment of U.S. industry.

1. India’s March 2012 Compulsory License

The Indian Controller General of Patents (“Controller General”) granted its first CL under the amended Patents Act in March of 2012. The CL related to a patent covering a product to treat liver and kidney cancer called Nexavar, produced by Bayer Group, a German-based drug company with extensive facilities in the U.S. The Controller General granted the right to produce and sell Nexavar in India to the Indian generics producer Natco Pharma Ltd. (“Natco”). Bayer had initially extended its patent application to India for Nexavar in 2001, and had received a grant of registration in March 2008. Bayer did not sell any quantities of the drug in India in 2008, but did make sales in 2009 and 2010. All sales of Nexavar in India were of imported drugs, as Bayer chose not to manufacture in country given the initially low quantity of the drug being sold domestically.

In issuing its compulsory license for Nexavar, the Controller General relied on Section 83 of the Patent Act, which states that:

Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by the Chapter, regard shall be had to the following general considerations, namely, (a) that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay; and (b) that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article.

Specifically, in its decision the Controller General explained that, in reading Section 83 it “becomes amply clear...that mere importation cannot amount to working of a patented invention.” The Controller General went on to explain that a patentee could achieve compliance with Section 83, only “by either manufacturing the product in India or by granting a license to any other person for manufacturing in India.” With regard to Nexavar, Bayer did neither. Thus, the Controller General essentially found that only through local production of Nexavar, or by granting licensing rights for local production purposes, could Bayer prevent issuance of a compulsory license.

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4 CONTROLLER OF PAT. MUMBAI, APPLICATION FOR COMPULSORY LICENSE UNDER SEC. 84(1) OF THE PAT. ACT, 970 IN RESPECT OF PAT. NO. 215758, (ISSUED MAR. 9, 2012).
7 CONTROLLER OF PAT. MUMBAI, APPLICATION FOR COMPULSORY LICENSE UNDER SECTION 84(1) OF THE PAT. ACT, 970 IN RESPECT OF PAT. NO. 215758, 43 (ISSUED MAR. 9, 2012).
8 Id.
2. **Local Working Requirements and Contravention of TRIPS Article 27.1**

The Controller General’s decision to grant a compulsory license based on its interpretation of the Patent Act’s local working requirement is in violation of India’s WTO obligations, and specifically in violation of TRIPS Article 27.1.

Within the context of the WTO, compulsory licensing is governed by Article 31 of TRIPS, along with Article 5(A) of the Paris Convention, which has been incorporated into the TRIPS Agreement. Article 5(A)(2) of the Paris Convention provides the basis for the right to grant compulsory licenses, as it provides that states shall have the right to pass legislative measures providing for the granting of compulsory licenses in order to prevent any abuse of patent rights. Article 5(A)(1), though not directly related to compulsory licensing, does tangentially provide guidance on local working requirements as it states that importation of patented products by the patent owner does not entail the forfeiture of the patent. Article 31 of TRIPS then sets out procedural and substantive conditions relating to a country’s right to issue a compulsory license. Despite these extensive conditions, Article 31 neither defines the circumstances under which a compulsory license may be granted, nor does it explicitly mention failure to work as grounds for issuing of a compulsory license.

In making compulsory licensing decisions, the WTO has established that WTO members must read and interpret Article 31 together with Article 27.1. Specifically, the WTO Panel’s decision in *Canada-Patent Protection of Pharmaceutical Products*, states that it is an “acknowledged fact that the Article 31 exception for compulsory licenses and government use is understood to be subject to the non-discrimination rule of Article 27.1” Article 27.1 states, in relevant part, that:

> “patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.”

(Article 27.1 thus 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 require that a patent be locally produced. This language is critical to understanding the limitations of local working requirements.

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12 Art. 31 is a lengthy provision, and should be read in full, but states, in relevant part, that compulsory licenses “may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.” TRIPS AGREEMENT, ART. 31(b), available at [http://www.wipo.int/treaties/en/ip/paris/trtdocs_wo020.html#P123_15283](http://www.wipo.int/treaties/en/ip/paris/trtdocs_wo020.html#P123_15283).


not allow for the issuance of a compulsory license merely because the patentee does not produce the relevant patented goods locally. This is the exact justification provided by the Controller General in his March 2012 decision, thus placing India squarely in violation of its WTO obligations under TRIPS.

3. **Prior U.S. Government Opposition to Local Working Requirements**

The U.S. government has previously taken issue with local working requirements similar to those seen in India. In 2000 the Permanent Mission of the U.S. filed a request for consultation at the WTO challenging the TRIPS compliance of Article 68 of Brazil’s Law No. 9,279 of May 14, 1996, which established a local working requirement for patents that could only be satisfied by local production. The complaint was withdrawn and a settlement reached between the two governments, but not before the U.S. Government committed itself to “aggressively engage other countries that impose or maintain such [local working] requirements.”

AFTI and its members therefore call on the U.S. government to follow through on that commitment to engagement, and name India a Priority Foreign Country. India’s policies vis-à-vis compulsory licenses are legitimately egregious—in addition to being WTO non-compliant—as India stands virtually alone among WTO Member States in asserting that importation is not a means of satisfying local working requirements. A review of national legislation of a selection of WTO Member States, including Ghana, Jordan, Mexico, the Philippines, South Africa, and Uruguay, shows that the patent laws in each of these countries explicitly provides for importations as a means of satisfying local working requirements. Moreover, even in Brazil importation can satisfy local working requirements where there is a lack of economic feasibility for the local manufacture of a patented invention.

4. **Compulsory Licensing as Industrial Policy**

The March 2012 Controller General decision is not an isolated incident. In fact, it is one of several recent acts, policies, or practices initiated by the government of India that indicate a commitment to usage of compulsory licensing as a tool for bolstering domestic Indian innovation. The Indian Ministry of Health (“MoH”) appears poised to grant compulsory licenses for several other drugs manufactured by foreign—including American—pharmaceutical companies. Moreover, there is indication that other parts of the Indian government are contemplating using the rationale applied in the Nexavar decision to advance the interests of Indian companies in non-health-related industries. Among those industries likely targeted are green technology and semiconductors, two areas in which U.S. companies do significant business in India. Thus, it is apparent that compulsory licensing is now viewed as a tool of Indian industrial policy, to be wielded against foreign companies for the purpose of spurring domestic innovation and production.

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The March 2012 Nexavar decision appears to have opened the door for other compulsory licensing grants in the pharmaceutical sector, with some particularly troubling developments over the last year. In December 2012, the MoH recommended the issuance of a compulsory license for the manufacture of Bristol-Myers Squibb’s (“BMS”) anti-cancer drug Sprycel under Section 92 of the Patent Act, which allows for Government-issued CLs in the case of a public emergency, and which would allow for granting of the CL without any notice to BMS. Sprycel remains under consideration for a section 92 CL. Following this recommendation, in March 2013, BDR Pharmaceuticals, an Indian drug company, applied for a compulsory license to manufacture Sprycel under Section 84 of the Patent Act. In April 2013, the MoH again recommended the issuance of a compulsory license, this time for Herceptin, a breast cancer treatment manufactured by Roche. Subsequent to the recommendation, and in apparent acknowledgement of the inevitability of a grant of a CL, Roche abandoned its patent for Herceptin in India.

Although defenders of the Indian government’s compulsory licensing of pharmaceuticals argue that the practice is motivated by a commitment to patient access, several pieces of evidence belie this claim. First, India’s per capita government expenditure on health care is among the lowest in the world. In 2011 per capita government health spending at an average exchange rate was $18.30, placing it on par with Burkina Faso (at $18.70), and slightly below Haiti (at $25.20). This limited appropriation of government resources for health purposes, along with a range of limitations that the Indian government places on the private health insurance sector, strongly draws into question the government’s alleged commitment to patient access. Moreover, recent public statements by the chairman of India’s largest pharmaceutical company, Cipla, indicate that he and other members of that industry view compulsory licensing as a mechanism for achieving global growth, not advancing patient interests. In his 2012 address at Cipla’s annual general meeting, the Chairman and Managing Director, Dr. Y. K. Hamied, laid out his vision for his company and the rest of the Indian pharmaceutical industry, explaining that the “current aim” of the industry was “to make a determined thrust and expand in the U.S. market as well as in the emerging markets that include Brazil, China, India, Indonesia, Russia, South Africa.” Within the context of Dr. Hamied’s global vision, the Indian market is almost an afterthought, as he explained that Cipla’s goal and that of the domestic industry is to “expand our international business” to accomplish “a mission of globalization.” The main mechanism for achieving this mission—compulsory licensing. In advocating for an aggressive CL regime, Hamied explains that “there should be an automatic license of right and the patent holder of valid

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21 As the WHO website explains, this is a core indicator of health financing systems, and also serves as a key metric for understanding the relative level of public spending on health to the beneficiary population. WORLD HEALTH ORGANIZATION, HEALTH FINANCING: HEALTH EXPENDITURE PER CAPITA BY COUNTRY, http://apps.who.int/gho/data/view.main.1920ALL?lang=en, (last visited Feb. 4, 2014)
23 Id.
patents should receive a reasonable royalty of 4% on net sales.\textsuperscript{24} In recommending such an approach Hamied is calling for the granting of CL’s without consultation with the patent holder, a move that is \textit{prima facie} commercially unreasonable, and thus likely in violation of TRIPS Article 31(b).\textsuperscript{25} Thus, significant evidence indicates that India’s compulsory licensing policies vis-a-vis pharmaceuticals are driven by industrial policy considerations, not by patient access concerns.

Numerous U.S. companies and industry associations have also expressed their concern about the potential usage of compulsory licenses in non-pharmaceutical contexts.\textsuperscript{26} Only one of more than a dozen grounds provided within the Patent Act for compulsory licensing is health related, thus leaving ample space for non-health CL’s.\textsuperscript{27} Moreover, the same reasoning applied in the Nexavar decision could be used to grant compulsory licenses for technologies in other industry sectors, and could serve as the foundation for other efforts to promote domestic innovation at the expense of American companies.

Recent policy statements by the Indian government support these fears. In 2011, the Government of India issued its National Manufacturing Policy (“NMP”) which encourages compulsory license grants for the “latest patented green technology” when a right holder refuses to license on reasonable terms or is not working the patent in India.\textsuperscript{28} This commitment to compulsory licensing in the green tech industry coincided with a significant jump in spending on domestic green tech and sustainability initiatives, from $35 billion in 2010 to a projected $70 billion in 2015.\textsuperscript{29} Moreover, several Indian companies have recently become global players in the green tech space, among them the Suzlon Group, which is the world’s fifth largest wind turbine supplier, and has operations in more than 30 countries.\textsuperscript{30} Similar concerns surrounding potential CL grants exist within America’s semiconductor industry. American semiconductor companies have made significant investments in India in recent years, and as of late-2013, 18 of

\textsuperscript{24} Id.

\textsuperscript{25} TRIPS Article 31(b) states that, “[S]uch use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.” TRIPS AGREEMENT, ART. 31(b), available at \url{http://www.wto.org/english/docs_e/legal_e/27-trips.pdf}.


\textsuperscript{30} SUZLON COMPANY PROFILE, \url{http://www.suzlon.com/about_suzlon/2.aspx?l1=1&l2=1} (last visited Feb. 4, 2014)
the top 20 U.S. semiconductor companies had built design centers in India.\textsuperscript{31} This, however,
makes these companies particularly vulnerable to Indian industrial policies. In its 2013 Special
301 submission, the Semiconductor Industry Association expressed its concern with the potential
usage of CL’s as a mechanism for forced technology transfer in India, explaining that, “it is well
known that India is currently seeking to build and operate a domestic semiconductor fab to
enable the implementation of some of its industrial policies that provide preferences for local IP,
R&D and manufacturing of ICT products.”\textsuperscript{32}

In another troubling policy shift, the Controller General now requires every patentee and
licensee to furnish annual statements that include significant details of how they are working
each patented invention on a commercial basis in India, or, if not worked, the reasons why and
the steps being taken to work the invention.\textsuperscript{33} This requirement is extremely onerous for
technology products that are often based on hundreds if not thousands of patents, and is a
requirement that is not found in any other major patent system in the world.\textsuperscript{34} Furthermore, the
apparent intention of the requirement is to create a database of information that can then be used
to justify future compulsory licenses.

b. Section 3(d) of India’s Patents Act

Section 3(d) of India’s Patents Act also rises to the threshold established for a country to
be identified as a Priority Foreign Country, as it denies American companies—particularly those
in the pharmaceutical and agricultural chemicals sectors—of 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 pharmaceuticals and chemicals, with the aim of benefitting India’s domestic
industries.

Section 3(d) of the Patent Act states that:

the mere discovery of a new form of a known substance which does not result in the
enhancement of the known efficacy of that substance or the mere discovery of any...new
use for a known substance or of the mere use of a known process, machine or apparatus
unless such known process results in a new product or employs at least one new reactant
is not an invention within the meaning of this Act.\textsuperscript{35}

\begin{itemize}
\item[]\textsuperscript{31} Meera Siva, \textit{Fab Opportunity}, THE HINDU, Nov. 1, 2013,
\textcolor{blue}{http://www.thehindu.com/features/education/careers/fab-opportunity/article5304852.ece.}
\item[]\textsuperscript{32} SEMICONDUCTOR INDUS. ASS’N, WRITTEN COMMENTS TO THE OFFICE OF THE U.S. TRADE REP. IN
RESPONSE TO FED. REG. NOTICE REGARDING 2013 SPECIAL 301 REVIEW: IDENTIFICATION OF COUNTRIES UNDER
\item[]\textsuperscript{33} The Controller’s demands are based on INDIA PATENTS ACT, 1970, Sec. 146(2), available at
\textcolor{blue}{http://www.ipindia.nic.in/ipr/patent/patent_Act_1970_28012013_book.pdf.}
\item[]\textsuperscript{34} SEMICONDUCTOR INDUS. ASS’N, WRITTEN COMMENTS TO THE OFFICE OF THE U.S. TRADE REP. IN
RESPONSE TO FED. REG. NOTICE REGARDING 2013 SPECIAL 301 REVIEW: IDENTIFICATION OF COUNTRIES UNDER
\item[]\textsuperscript{35} INDIA PATENTS ACT, 1970, Sec. 3(d), available at
\textcolor{blue}{http://www.ipindia.nic.in/ipr/patent/patent_Act_1970_28012013_book.pdf.}
\end{itemize}
Section 3(d) of the Patents Act is inconsistent with Article 27.1 of TRIPS as it adds an additional condition precedent for patentability—enhanced efficacy—to the requirements of TRIPS Article 27.1. The text and context of TRIPS Article 27.1 make clear that WTO members “shall” treat the three criteria of “new,” “inventive step,” and “capable of industrial application” as sufficient for granting patents. Such language clearly establishes that WTO members should make patents available to inventions that satisfy the three listed substantive criteria. The text of the provision does not leave parties any discretion as to whether to grant a patent if the substantive three criteria are met and does not contemplate any right to add additional criteria. Furthermore, Article 27.1 directs that patents must be made available for “any inventions” in “all fields of technology” that meet the three TRIPS criteria.

In structuring Section 3(d) as it is drafted, India has created a fourth condition precedent 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 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 in order to receive a patent. This addition of a fourth condition precedent for patentability is inconsistent with TRIPS Article 27.1, which, as discussed above, mandates that patents be available for any inventions that are “new, involve an inventive step and are capable of industrial application.”

III. Forced Transfer of Technology

a. Protection of Trade Secrets and Confidential Data

As early as 2000, and every year thereafter, USTR’s Special 301 Report notes that India has failed to implement TRIPS-compliant regulations to protect trade secrets, confidential test and other data. India’s TRIPS Article 39 obligations to protect trade secrets and confidential information, including test data, are rooted in Article 10bis of the Paris Convention for the Protection of Industrial Property, which assures nationals of signatory countries that they will receive effective protection against “unfair competition,” which is defined as “[a]ny act of competition contrary to honest practices in industrial or commercial matters.” In addition, India is required to “protect confidential information… [and] ensure that it has procedures to protect such information” with regard to certain pharmaceutical or products of modern biotechnology, specifically living modified organizations. Further, India must “not use such information for a commercial purpose, except with...written consent.” India’s failure to provide data protection subjects U.S. companies to unfair competition and violates India’s

39 Id.
obligations under multiple agreements, and thus constitutes a practice that rises to the threshold established for identification of a trading partner as a “Priority Foreign Country.”

Fourteen years after its first mention in the Special 301 Report, India still has not fulfilled its obligation to provide the requisite legal protections. India has not provided a structure to protect undisclosed test data submitted for the marketing approval of new chemical entities and has no statutory, regulatory, or other legal protection for trade secrets.

1. No Protection for Trade Secrets

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.” 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. India does not have a national law to protect information that qualifies as a trade secret under international law.

India does not provide adequate protection for trade secrets, and the limited protection that is available is insufficient. 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. 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; however, a review of such provisions shows that India has completely missed the mark and fails to protect trade secrets. 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.” 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.

The Obama Administration’s new Strategy on Mitigating the Theft of U.S. Trade Secrets recognizes “emerging trends” that indicate “the pace of economic espionage and trade secret theft against U.S. corporations is accelerating” according to the Office of the National

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41 Id.
Counterintelligence Executive (“ONCIX”).45 Moreover, this theft is occurring through “multiple vectors of attack for persons and government seeking to steal trade secrets.”46 Those who would steal include “[f]oreign competitors of U.S. corporations, some with ties to foreign governments,”47 as discussed in detail at Section III(a)5.

To combat this real threat to the competitive advantage of U.S. companies in foreign markets, the Administration has pledged to target weaknesses in trade secret protection through “enhanced use of the Special 301 Report...and, where appropriate, act upon information about the adequacy and effectiveness of trade secret protection by U.S. trading partners.”48

The trade secrets of U.S. companies are valuable and must be protected. Accordingly, AFTI urges USTR to exercise its enhanced use of the Special 301 Report to spur real IPR reform in India and prompt it to protect investments in innovation made by U.S. companies.

2. **No Protection for Test Data**

According to USTR’s most recent National Trade Estimate Report, “India also continues to lack effective protection against unfair commercial use of undisclosed test and other data generated to obtain marketing approval for pharmaceutical and agrochemical products.”49 In fact, Dr. Satwant Reddy and Dr. Gurdial Singh Sandhu, prominent officials from India’s Ministry of Chemicals & Fertilizers, write that “[i]n India, there is no separate legislation to protect the undisclosed test data in the case of pharmaceuticals and agrochemicals submitted to the regulatory authorities.”50 India is, however, required, under TRIPS Article 39.3, to protect against unfair commercial use of undisclosed test or other data “when requiring [submission of such data] as a condition of approving the marketing of pharmaceutical or agricultural chemical products which utilize new chemical entities.”51 In this regard, India does not meet its obligations and denies U.S. companies “adequate and effective” protection of their intellectual property rights.

As contemplated by the TRIPS Agreement, the Indian government requires U.S. companies to submit extensive and valuable information to India’s Central Drugs Standard Control Organization (“CDSCO”) under the Ministry of Health and Family Welfare (“MoH” and

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46 Id.

47 Id.

48 Id.


“FW”) for evaluation, before bringing a product to market. Such data submitted by pharmaceutical and agricultural chemical companies seeking market approval include (1) information relating to a product’s quality, safety and efficacy and (2) information regarding the composition and physical and chemical characteristics of the product. Such undisclosed data may also qualify as “trade secrets” that represent information of value to U.S. companies. It is at this stage that data protection is critical; however, the data collected by Indian regulatory agencies that is developed by U.S. companies remains unprotected.

In the pharmaceuticals 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. PhRMA, a trade association representing the leading biopharmaceutical researchers and biotechnology companies, sets the average cost to develop a drug (including the cost of failures) at $1.2 billion (up from $900 million in the late 1990s), while acknowledging recent studies that have estimated costs to be much higher. 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 dollars and approximately 10 years, while plant biotechnology products cost nearly $136 million dollars and require over 13 years. These significant investments on the part of U.S. companies deserve to be protected, and a failure to do so by the Indian government is a denial of adequate and effective protection of intellectual property rights.

3. No Data Exclusivity

Beyond the base level of protection, India has failed to grant exclusive rights to producers of critical technologies to effectively protect against unfair commercial use. That is, India fails to protect innovators from use of these data by competing manufacturers. TRIPS Article 39.3 must be interpreted to “require the protection of data against use by the competitors for some period of time.” BIO echoes these sentiments on market exclusivity, explaining, for

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53 Id.


59 A non-profit organization with a membership of more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in all 50 States and a number of foreign countries.

example that India currently allows for the “unfair commercial use of such data by makers of
generic copies of innovator products (i.e., products that must be shown for the first time to be
safe and effective, or to not cause significant risk to the environment).” 61 India’s failure to
ensure data exclusivity has adversely impacted U.S. companies.

4. **Longstanding Negative Impact**

India’s longstanding unfavorable posture with regard to protection for test data and trade
secrets, and the related impact, was not unforeseen. As early as 2000, India noted that
“[f]acilitating the access to developing countries of technologies selected by them as appropriate
to their requirements constitutes one of the key elements in accelerating the pace of their
economic and social development.” 62 India’s statement focuses on the needs of developing
countries as India was and remains concerned that the TRIPS Agreement might “tempt IPR
holders to charge exorbitant and commercially unviable prices for transfer or dissemination of
technologies held through such IPRs,” and that technology transfer should be “fair and
reasonable.” 63

These statements reveal that India did and still does not ideologically support the TRIPS
Agreement and accept that IPRs are a necessary ingredient to spur technological advancement.
Thus, India resorts to forced technology transfers, compulsory licensing and does not provide the
 protections that are mandated. For a greater discussion of India’s discriminatory and troubling
compulsory licensing policies, please see Section II.a.

Today, countries that offer strong data protection are attractive destinations for
investments from businesses that consider their data to be critical, including database producers
and pharmaceutical and agrochemical manufacturers. At the same time, countries with lax IPR
regimes and weaker protection are attractive to businesses that rely on the proliferation of low
cost or free data. India serves as a haven for data pirates due to its lack of data protection and
will continue as such if USTR does not intervene.

5. **India’s Offensive National Policies**

designates information and communications technology (“ICT”) and civilian and dual-use
technologies, including the clean energy and healthcare/pharmaceuticals sectors as areas of focus
for foreign collectors of U.S. trade secrets. 64 Not surprisingly, AFTI’s concerns are focused
around data protection in these same sectors and areas of sensitivity that are highlighted by U.S.
intelligence agencies, particularly highly regulated industries where the Indian government

61 *Id.*

62 WORLD TRADE ORGANIZATION: COUNCIL FOR TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY

63 WORLD TRADE ORGANIZATION: COUNCIL FOR TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY

64 OFFICE OF THE NAT’L COUNTERINTELLIGENCE EXEC., *FOREIGN SPIES STEALING US ECONOMIC SECRETS IN
maintains major equity stakes in competing commercial enterprises. For example, related to certain policies listed below, USTR’s 2013 National Trade Estimate references the Indian government’s ownership in large Indian telecommunication companies, including Mahanagar Telephone Nigam Limited (“MTNL”), Bharat Sanchar Nigam Limited (“BSNL”), and Videsh Sanchar Nigam Ltd. (“VSNL”), now Tata Communications Limited. As described further, with each of the measures highlighted below, the Indian government either (a) denies adequate and effective protection of intellectual property rights or (b) denies fair and equitable market access to U.S. persons who rely on intellectual property protection.

b. Forced Third Party Access

India’s Committee of the Ministry of Corporate Affairs is in the process of drafting a National Competition Policy to foster competition, promote efficiency, institute consumer protection, foster social welfare, reduce inflation, accelerate increased employment and develop entrepreneurs.

One of the problematic features of India’s competition policy is the requirement that dominant infrastructure and IPR owners grant third party access to “essential facilities” on “agreed reasonable and nondiscriminatory terms” at Section 5.1(vi), as shown below.

“Third party access to ‘essential facilities’, i.e. requiring dominant infrastructure and intellectual property right owners to grant access to third parties their essential infrastructure and platforms (e.g., electricity, communications, gas pipe lines, railway tracks, ports, IT equipment et) on agreed reasonable and non-discriminatory terms and conditions aligned with competition principles.”

This policy would lead to consequences that are incongruent with the policy’s stated goals of spurring innovation and increasing competition. Rather, the application of the antitrust “essential facilities” doctrine forces companies to allow access to their data and trade secrets, with the apparent goal of benefitting Indian enterprise. While the final National Competition Policy is pending and Section 5.1(vi) may be reviewed prior to finalization, the troubling policy development illustrates the negative trending and suggests that India’s IPR environment will likely become more adverse to U.S. businesses over time unless USTR acts.

c. Testing and Forced Access to Proprietary Information

The Indian government issued a series of new telecommunications license amendments, in 2011 and subsequently, that require the testing of all “telecommunications equipment” that are determined to pose security risks. These license amendments require the domestic testing of products exported to India and fail to adopt an internationally accepted criterion or allow for the testing of products in an accredited lab, whether that lab is located in India or otherwise. This overly broad and narrowly drawn policy evidences a thinly veiled agenda, wrought by the Indian

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government, to gain access to the trade secrets of multinational companies that choose to do business within its borders. The regulations and overarching policies, such as the National Cyber Security Policy,\textsuperscript{67} deviate from global practice and require clarification to avoid consequences during implementation.

d. **Requirement that Licensed Telecommunications Equipment Vendors\textsuperscript{68} Test Imported ICT Equipment in Indian Labs\textsuperscript{69}**

The Indian Department of Telecommunication (“DoT”) requires the security certification of all imported telecom equipment, mandating licensees to comply with the following measure:\textsuperscript{70}

\textit{Induct only those network elements into his telecom network, which have been got tested as per relevant contemporary Indian or International Security Standards e.g. IT and IT related\textsuperscript{71} elements against ISO/IEC 15408 standards, for Information Security Management System against ISO 27000 series Standards, Telecom and Telecom related elements against 3GPP security standards, 3GPP2 security standards etc from any international agency/labs of the standards e.g. Common Criteria Labs in case of ISO/IEC 15408 standards until 31st March 2013. \textbf{From 1st April 2013 the certification shall be got done only from authorized and certified agencies/labs in India.} The copies of test results and test certificates shall be kept by the licensee for a period of 10 years from the date of procurement of equipment.[sic]}

The measure extends the period for “Security Certification of Telecom Equipment” within India for “security related concerns” through July 1, 2014, subject to further extensions.

This requirement is an extra burden for U.S. companies operating in India. The fact that the regulation differentiates between imported and domestically produced telecommunications equipment violates India’s obligations under the WTO’s Agreement on Technical Barriers to Trade (“TBT”) and Article III of the General Agreement on Tariffs and Trade (“GATT”) 1994. These standards-related trade barriers are significant and stand in the way of U.S. exporters and other U.S. government initiatives that are designed to neutralize the impact of such barriers.

\textsuperscript{67} The National Security Policy of 2013, which regulates the action of “the whole spectrum of ICT users and providers including home users and small, medium and large enterprises and Government & non-Government entities”, includes the following goal: “To improve visibility of the integrity of ICT products and services by establishing infrastructure for testing & validation of security of such products.” \textit{MINISTRY OF COMM. AND INFO. TECH., NAT’L CYBER SEC. POLICY – 2013 (2013), available at http://www.dsci.in/sites/default/files/National%20Cyber%20Security%20Policy%20.pdf.}

\textsuperscript{68} The requirement applies to (1) Unified Access Service Licensees and Basic Service Licensees; (2) “cellular Mobile Telephone Service Licensee(s) in Telecom Circle Service Areas/Metro Service Areas to whom CMTS Licenses were issued prior to 2001”; (3) all Cellular Mobile Telephone Service Licensee(s) including BSNL and MTNL to whom CMTS Licenses were issued in 2001 or thereafter; and (4) all Unified Licensees.


\textsuperscript{70} \textit{GOV. OF INDIA: MINISTRY OF COMM. & INFO. TECH., EXTENSION OF TIME FOR SEC. CERTIFICATION (2013).}

\textsuperscript{71} \textit{Id.}
e. **Impending Expansion of Products to be Tested**

Press reports indicate that the Indian DoT is considering requiring the testing of all information technology products before they are used in mobile networks.\(^72\) DoT has argued that the local screening of all IT products and traditional network gear before use in India is necessary for national security reasons. “When an IT product is used in a telecom network, it should be treated as a telecom network element and not as an IT product alone since it is being deployed in a critical information infrastructure,” according to an internal DoT note seen by the Economic Times of India.\(^73\) Like the DoT measure to test imported products, this policy would be overbroad and burden U.S. companies, while providing Indian laboratories with access to U.S. trade secrets and confidential information.

f. **Requirement for Inspection of a Vendor’s Manufacturing Facilities and Supply Chain\(^74\)**

U.S. and other foreign vendors of telecommunications equipment must permit Indian telecom service providers (“TSPs”), the Indian Department of Telecommunications, or other designees/designated agencies, to “inspect the hardware, software, design, development, manufacturing facility and supply chain” and must allow software to be subjected to audit or security checks at any time.\(^75\) Mandatory exposure of such extensive aspects of a commercial enterprise, without adequate data protections, denies fair and equitable market access to U.S. telecommunications vendors.

Ironically, the Telecom Sector Roadmap for Innovation 2010-2020 references the problematic testing requirements. Having benefited from the lack of adequate and effective protection of IPR afforded to foreign telecom vendors, India’s telecommunications sector has experienced impressive growth. However, as is described in the report regarding growth, as “[m]uch as these achievements look impressive, they have been attained primarily with the help of imported technology and products.”\(^76\)

g. **Requirement that Only Resident Trained Indian Nationals Be Responsible for Security Cases**

One of the preferred methods for trade secret misappropriation is through employees. It is worth repeating the ONCIX warning that “[f]oreign competitors of U.S. corporations, some with ties to foreign governments, have increased their efforts to steal trade secret information through


the recruitment of current or former employees.” In India, companies are required to hire Indian nationals for sensitive positions that maintain access to confidential information.

Under the Amendment to Unified Access Licenses, the licensees, including U.S. companies, “may only employ Resident trained Indian Nationals as (a) Chief Technical officer/s (b) Chief Information Security Officer (c) Nodal Executives for handling interception and monitoring cases and (iv) In charge of GMSC, MSC, Softswitch, Central Database and System Administrators.”

Both ONCIX and the Indian government’s Telecom Sector Innovation Council reference China’s approach to the technology transfer and innovation. For example, the Telecom Sector Innovation Council has written that:

In state support for innovations, we have the example of other economies like China, [which]... has placed the full force of the state behind the indigenous innovation. They coined words like co-innovation and re-innovation to lay claims on the technology developed in the west. The lure of a huge market was used to invite transnational companies into the parlour and part with their technology.”

India, in its reverence of China as a model of national innovation policies, closes the loop with the requirement that only Indian trained nationals hold certain positions within telecommunications companies. This requirement facilitates technology transfer in a troubling way. For example, ONCIX indicates that:

The growing interrelationships between Chinese and US companies—such as the employment of Chinese-national technical experts at US facilities and the off-shoring of US production and R&D to facilities in China—will offer Chinese Government agencies and businesses increasing opportunities to collect sensitive US economic information.

India’s recent regulations raise the same concerns as China’s well-developed practices. U.S. companies that must comply with the regulations necessarily open themselves up to the potential drain of confidential information and trade secrets. The requirements described above are a significant part of India’s industrial policy arsenal and denies both adequate and effective IPR protection to U.S. companies and may be seen as the denial of fair and equitable market access to U.S. persons.


78 GOV. OF INDIA: MINISTRY OF COMM. & INFO. TECH., AMENDMENT TO THE UNIFIED ACCESS SERVICE LICENSE AGREEMENT FOR SECURITY RELATED CONCERNS OR EXPANSION OF TELECOM SERVICES IN VARIOUS ZONE OF THE COUNTRY (2011).


IV. Copyright

a. Overview

India’s lack of robust and enforceable copyright policies results in the denial of adequate and effective protection of intellectual property rights. Copyright infringement is a historic and consistent problem that has not led to any real improvement in policy and unfortunately 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 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 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 2013—the same score from two years prior.\(^81\) This shows a lack of progress and an unwillingness on the part of the Indian government to discard its antiquated policies. 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.\(^82\)

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, lacking IPR protections, and poor enforcement, industry groups in India and abroad remain inhibited from innovating new products and investing more in India.\(^83\)

Finally, while lauded as a major step forward for IPR protections in India, the Copyright Act amendments in 2012 failed to adequately address a 21\(^{st}\) century economy that relies heavily on e-commerce and digital products. Although the amendments offered more protection 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, and other data files—an area which will continue to grow as India becomes more interconnected via the worldwide web.\(^84\) The amendments failed to provide adequate tools to address the widespread copyright infringements affecting the country, and also failed to introduce much needed anti-camcording legislation, despite its status as a longstanding nuisance to foreign and domestic film

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industries. The Act also provides multiple exceptions for personal use and for personal reproduction. Thus, enforcement remains spotty and ineffective.85

b. Internet piracy and illegal downloading

Illegal downloading, including peer to peer (“P2P”) filesharing and illegal streaming is rampant in India. By almost any global measure, India remains at the top of the list for major illegal piracy in film, music and other black-market goods like software.86 According to a 2012 report by the Entertainment Software Association, India ranked sixth in the world in terms of P2P connections and filesharing, and many expect this to expand commensurate with the growing amount of broadband users in India.87 In film, 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.88 One popular Indian film, Kaminey, was downloaded over 350,000 times in India and abroad.89 The illegal downloading and distribution of music is no better. The Digital Music Index ranked India as the 8th biggest torrent downloading country in 2012, which included the piracy of approximately 71 million songs in just the first half of the year.90 While losses are difficult to calculate, the music industry alone estimated a total loss of $431 million in 2012, mostly attributed to mobile and internet piracy.91

The aforementioned amendments added to the Copyright Act do not provide the enforcement mechanisms necessary to stem this tide of internet piracy, and as such Indian legislation does not provide for adequate enforcement against websites providing access to infringing materials.92 With the increasing amount of internet users in India, the problem is likely only growing, not receding.93 The growth of mobile devices has skyrocketed, with the

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89 Id.


addition of over a half a billion subscribers from just 2006 (there is now an estimated 900 million mobile phone users). Due to the rise of smart phones, these copyright infringements are particularly nefarious because pirated materials can now be instantly shared via a mobile device.

c. Camcording piracy

The illegal recording of cinema in India continues to represent one of the worst cases in the world, affecting local distributors and foreign ones alike. With a rise in camcording incidents in India in 2012, India accounts for at least 53 percent of all forensic matches of illegally distributed films in the Asia Pacific region. From 2009 through 2011, there were 155 matches traced to Indian origin. This is significant because it reveals that the practice does not just serve the domestic market, but contributes significantly to the international one as well, hindering U.S. businesses in markets well beyond India. Due to the robust domestic film industry, there have been several industry-led awareness initiatives in order to drive down the practice, including the breakup of a major syndicate illegally stealing and selling film. Unfortunately, these local efforts have not been matched by robust federal initiatives.

Despite calls for greater action, the historic problem illegal camcording has played in the country, and the documented abuses, the government only has a handful of related arrests—7 in 2012. As already mentioned, the Copyright Act amendments, while a positive step on the part of the government, fail to include effective protections to prevent the copying of movies in theaters. Due to the lack of anti-camcording legislation, we believe India clearly denies adequate and effective means to protect intellectual property rights. The export of this problem to other markets in the region adds to the gravity of the poor enforcement in India, and shows that it is unable to secure, exercise and enforce the rights related to the copyright protection in the film industry in particular.

d. 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. 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 Indian 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.

Furthermore, these counterfeit books are not staying in India, but are instead being sold in Africa, the European Union and the United States. Rather than speak out against the practice, the Indian government has instead announced it would work to make the copy of academic books and journals completely legal in the country. This is an extremely troubling precedent, as it would deny publishers and authors abroad the royalties for high-end text books and other publications, and would result in furthering an anti-competitive environment. Indian publishers will no doubt only find encouragement to continue this act if legislation that condones it is enacted.

The magnitude of pirated books and resources, including the variety of ways in which they are created and distributed, rise to the standard of denying adequate and effective means of IPR protection to American authors and publishers. This is particularly problematic for U.S. authors, as American titles are frequently copied and sold for a fraction of the bookstore price. The fact that these books are then distributed widely outside of India only underscores the problem as one of denying market access to U.S. publishers globally, as opposed to just India—a major market in and of itself—and extends to the EU and others.

V. Innovation


India’s “innovation mercantilist” policies and regulations promote the goal of expanding domestic Indian industry to the detriment of the intellectual property rights of U.S. companies. On account of this industrial bias and recent surge of protectionism, India is seen as less open than other emerging market economies.\(^{107}\) India’s current problematic orientation is deeply rooted in India’s anti-innovative history and is shown in the country’s positions on IPR within multilateral/bilateral forums on IP issues, including within the WTO and other multilateral mechanisms. This history and current practice warrant India’s designation as a “Priority Foreign Country” on account of its denial of adequate and effective protection of intellectual property rights along with its failure to allow fair and equitable market access to U.S. companies.

a. India’s History of Anti-Innovation Policy

India has been featured prominently in USTR’s Special 301 Report, either as a Priority Watch List (“PWL”) country or a Priority Foreign Country (“PFC”), since the inception of the Special 301 process. The Special 301 reports related to India, throughout the years, read with almost identical language showing that the myriad U.S. concerns related to India’s grant of IPR to rights holders have been ignored, year after year, or not adequately addressed. For twenty-five years, India has been listed. In refusing to make the requested changes to its IPR regime, the Indian government has denied the necessary protections that U.S. industry requires to enter and safely exist in the country’s growing market.

b. India’s Anti-Innovation Policies on Display in the International Forum

India continues to take IP-impairing positions within international forums. India signed the TRIPS Agreement in 1994, thus, accepting the obligation to strengthen and protect intellectual property rights and amend certain of its laws within a permissive period of 10 years and grant of specific and limited exceptions. However, despite the accommodation for developing countries, India’s decision to sign the TRIPS Agreement has been controversial within India’s domestic industries; for example, among Indian producers of generics. Five years after signing TRIPS, India communicated that the TRIPS agreement is “not about harmonization of standards but about minimum standards of intellectual property rights” – we place added emphasis on the word “minimum.”\(^{108}\) Indian officials, through the years, have taken stances evidencing a view that IPR presents a burden or an impediment to trade and growth – unfortunately, this race-to-bottom mentality is dangerous because it has an impact on other developing nations that may adopt India’s approach to IPR.

India’s anti-innovative history, informs its current support of anti-innovative IPR policies in international forums, as seen below with a few examples of how India has historically and continues to play a leading role in driving an IP weakening agenda at the WTO, UNFCCC, and WIPO.


1. **WTO: India – Patents (US)**

In November 1996, the United States requested the composition of a WTO panel to challenge India’s failure to fulfill its international obligations with regard to patent protection. The Panel ruled that India create a “mailbox” allowing for the filing of patent applications for pharmaceutical and agricultural chemical products and that such products could be granted exclusive marketing rights, a ruling which India appealed. The Appellate Body upheld the Panel’s finding that India’s patent regime was inconsistent with its obligations under (1) Article 70.8(a) of the TRIPS Agreement for failing to create a “mailbox” filing system for patent applications with regard to pharmaceutical and agricultural chemical products, as such had not yet been afforded patent protection; and (2) Article 70.9 for failure to provide a mechanism that would allow for the grant of exclusive marketing rights for pharmaceutical and agricultural chemical products.

2. **WTO: India – Certain Measures Relating to Solar Cells and Solar Modules**

India continues to adopt laws and regulations that evidence its misapplication of global IPR standards and WTO rules. Last year at the WTO, the U.S. challenged India’s use of subsidies and “buy local” rules in its domestic solar program. On February 6, 2013, the U.S. requested consultations with India at the WTO regarding India’s domestic content requirements under the Jawaharlal Nehru National Solar Mission (“NSM”) affecting solar cells and solar modules. The U.S. holds that these domestic content requirements, as evidenced in the U.S. request for consultations, are 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 Articles 3.1(b), 3.2, 5(c), 6.3(a), and 6.3(c) of the SCM Agreement as the measures provide a subsidy for use of Indian origin goods prejudicing U.S. interests.

3. **WTO – Information Technology Agreement Negotiations**

India decided not to participate in the on-going negotiations over the expansion of products covered by the WTO’s Information Technology Agreement (“ITA”), which has approximately 70 participants, including India and the United States. The agreement allows

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112 Id.
113 Id.
for the elimination of tariffs on certain high-tech products and electronics. However, because the ITA was first signed approximately 16 years ago, the ITA does not cover many “newer” technologies, like DVDs and GPS technology, among others. Historically, industry associations have found the ITA to be one of the most commercially successful trade agreements in the WTO, noting that the ITA has driven innovation, accelerated productivity, increased employment, and lowered consumer prices – all values held by India.

Last year’s discussions on the ITA in Geneva were aimed at expanding the list to cover items in additional sectors – this broadening is estimated to lead to an increase of $190 billion in global GDP, and increased revenues for U.S. ICT technology and an associated 60,000 jobs.\(^\text{115}\)

India has benefitted tremendously from the ITA. Since its signing, India’s export growth for related ICT goods has outpaced imports 3 to 1. Yet India still holds closely to its mercantilist values, and has not truly supported the ITA, citing the “national interest” as its reason for not engaging.\(^\text{116}\) This refusal to engage illustrates that India is not entering into good faith negotiations to provide adequate and effective protection of intellectual property rights.

4. **World Intellectual Property Organization (“WIPO”)**

India is part of a group of developing countries that focus on broadening exceptions and limitations to IPR instead of broadening protection and increasing enforcement. India actively obstructs the daily business of WIPO both in collaboration with these governments and often alone to even further extremes. The Indian delegation at WIPO stalls discussions, openly accuses rights holders of abuse, focuses exclusively on exceptions and limitations, and otherwise refuses to engage in a real way in the discussion at hand. They have tried repeatedly to block any work on quality from going forward by insisting that there is no agreed definition of quality. Further, they describe the patent system as being about public interest, not private interests.

Of note, India has not signed on to the WIPO “Internet Treaties” – it is the only BRIC country not to have signed.\(^\text{117}\) WIPO’s “Internet Treaties” include the WIPO Copyright Treaty (“WCT”) and the WIPO Performances and Phonograms Treaty (“WPPT”), which opened for signature in the mid-1990’s. These treaties are “designed to update and supplement the existing international treaties on copyright and related rights” and incorporate certain provisions of the TRIPS Agreement that were not already explicitly covered by the WIPO treaties.\(^\text{118}\)

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India’s stance on the “Internet Treaties” is not surprising given the government’s failure to provide adequate and effective protection for intellectual property rights holders whose rights are infringed online. For example, as argued by the International Intellectual Property Alliance (“IIPA”), a coalition of trade associations representing U.S. copyright-based industries, in India

[i]illegal downloading sites, P2P filesharing, BitTorrent trackers and indexes, ii streaming sites, deep linking sites, blogs, forums, and social network sites directing users to infringing files, cyberlockers used to advertise massive amounts of infringing materials, and piracy through auction sites all continue to plague right holders in India.”119

Further, and as noted in Section IV.b., IIPA points to a Motion Picture Distributors Association (“MPDA”) study, which lists India as one of the top ten countries in the world for Internet piracy, where pirated films reach the Internet from India in approximately 3.15 days.120 Of concern to the U.S., Peer Media Technologies reported that, during 2011, unauthorized copies of popular U.S. movie titles were downloaded/uploaded approximately 25 million times via P2P filesharing sites in India.121

India’s refusal to join the WIPO “Internet Treaties” in the nearly twenty years since the agreements opened for signature, stands as evidence of the country’s intention to continue profiting off of piracy and theft while denying adequate and effective protection of intellectual property rights.

5. United Nations Framework Convention on Climate Change (“UNFCCC”)

Within the UNFCCC India has called for “compulsory licensing” (as discussed above in Section III.a.) and other permissive exceptions for clean technologies or Environmentally Sound Technologies (“ESTs”). Moreover, India has portrayed the grant of IPR as a burden on the technology transfer process, though empirical evidence supports the adoption of IPR for the promotion of growth.

6. Failure to Meaningfully Engage - Discrimination

In many sectors within the Indian economy, American companies are disadvantaged due to India’s failure to engage with the United States on a comprehensive trade agreement. Though the United States is India’s top economic partner, India has already enacted or is in the process of negotiating trade agreements with the European Union, Japan, Singapore, the India-ASEAN, Agreement on South Asia Free Trade Area (“SAFTA”) with Afghanistan, Bangladesh, Bhutan, and the Maldives; the India-Thailand FTA; the Regional Comprehensive Economic Partnership (“RCEP”) Agreement among ASEAN + 6; the India - EU Broad Based Trade and Investment Agreement (“BTIA”); the Global System of Trade Preferences (“GSTP”) and agreements with

120 Id.
121 Id.
other partners – except for the United States. These actual and impending trade agreements with other major trading partners place U.S. companies on unequal footing. Furthermore, India has not engaged in the Trans-Pacific Partnership. India’s preferential agreements with nearly all the U.S.’s major competitors place American firms at a distinct disadvantage.

India is not making significant progress in bilateral or multilateral negotiations to provide adequate and effective protection of intellectual property rights.

c. India’s “Notorious Markets”

India hosts a number of markets considered by USTR in previous Special 301 Out-of-Cycle Reviews of Notorious Markets. The Report for 2012 names Nehru Place, located in New Delhi, India, as “one of the many markets in major cities throughout India that are known for dealing in large volumes of pirated software, pirated optical media containing movies and music, and counterfeit goods.” Nehru Place has been on the list for years and is one of thousands of markets that showcase trademark counterfeiting and copyright piracy operating on a commercial scale. Trade associations like MPAA and IIPA have argued that the following Indian markets “deal in infringing goods and services, facilitating and sustaining global piracy and counterfeiting”:

- **Chennai**: Richie Street, Censor Plaza and Burma Bazaar
- **Kolkata**: Bara Bazaar
- **Delhi**: Chandini Chowk, Palika Bazaar and Sarojini Nagar Market
- **Ghaziabad**: Navyuk Market Ambedkar Road and Nehru Nagar Market
- **Ahmedabad**: Kallupur Market and Laldarwajah
- **Indore**: Jail Road and Rajwada
- **Mumbai**: Manish Market, Lamington Road, Dadar Train Station, Andheri Station Market, Borivili Train Station and Thane Station Market

As seen in the egregious nature of India’s policies and lack of enforcement of internationally agreed upon rules of engagement on intellectual property issues, particularly those in the sectors addressed in this petition, India continues to deny adequate and effective intellectual property rights to U.S. citizens and companies in the creative industries.

d. India’s Protectionist Policies Have Precedent Setting Potential

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123 Id.


Three years into India’s “Decade of Innovation,” India has developed a state-by-state innovation mechanism that aims to protect domestic innovators. Regardless of whether this national innovation policy is WTO-consistent, the initiative reflects the inward focus that has been a hallmark of India’s IPR, trade and competition policies – particularly where these policies overlap.

India’s widely publicized and highly protectionist innovation policies have set a negative precedent in countries where there is a push to develop national policies to bolster domestic capacity. Government ministers from BRIC countries frequently consult each other for advice on how to handle persistent or emerging issues; for example, India, Brazil, and South Africa have been working together as the IBSA Trilateral for more than a decade. Recently, the Trilateral has considered intellectual property rights. Many point to the new draft South African IP policy as an example of the influence and adoption of India’s IP policy.\(^{126}\)

In 2013, the United States urged India to “resist imposing discriminatory policies or other counterproductive measures in pursuit of [it’s domestic manufacturing] objective[s] at the expense of adequate and effective protection of IPR.”\(^{127}\) We ask that USTR renew this request and with vigor by designating India as a Priority Foreign Country; thus, sending a message to other nations who are adopting and will adopt a similar approach to intellectual property protection using India as an example.

VI. India as a Priority Foreign Country

The Administration identified India as a Priority Foreign Country for the first time in 1991, within USTR’s Special 301 Report for that year. The report explained that “[d]espite progress in negotiating mutually acceptable solutions to our intellectual property problems in many countries around the world, the lack of adequate and effective intellectual property protection and market access has remained particularly acute in some of our trading partners.”\(^{128}\) Today, though India has signed on to a number of intellectual property related agreements, the country fails to provide adequate and effective intellectual property protection.

In 1991, India was identified as a Priority Foreign Country, because it “provide[d] an inadequate level of patent protection, including too short a term of protection and overly broad compulsory licensing provisions.”\(^{129}\) India remained on the Priority Foreign Country list in 1992 because of the “patent problems which led to the 1991 decision [had] not been addressed [and] [i]n general, the US [was] concerned about the overall protection accorded pharmaceuticals and


129 Id.
other patent provisions.”130 Today, India continues to fall short of its obligation to provide an adequate level of patent protection, and its current compulsory licensing practices, discussed in Section III.a., continue to disregard India’s international obligations and deny protection of IPR for U.S. companies.

Further, in 1991, USTR found that India had a “total lack of protection” for certain types of inventions, including particularly pharmaceuticals. USTR also found that many “U.S. patented products [were] widely pirated,” and that “[c]opyrighted materials including books, videos, sound recordings, and computer software, [were] also pirated.”131 Though in the 1992 report USTR acknowledges that India had “made substantial commitments to address piracy of copyrighted materials including books, videos, sound recordings, and computer software, as well as with respect to market access for motion pictures,” these efforts were not sufficient to save the country from a designation.132 India’s “denial of adequate and effective patent protection” was found to be unreasonable, and, as detailed above in Section IV, piracy by all measures remains rampant today.

VII. Conclusion

The simple reality is that India stands at an inflection point with regard to its discriminatory IP policies. Practices that have long adversely impacted U.S. companies by denying them adequate and effective IP protection have, over the last twelve months, reached crisis levels. Actions and statements by the Indian government in the last year with regard to their approaches to compulsory licensing and forced tech transfer, in particular, have placed U.S. industry on notice; while the Indian government may hide behind claims of “patient access” and “public interest” in justifying certain actions and measures, the very transparent motive is to benefit domestic Indian innovation and industry.

The annual Special 301 Report provides USTR with a key tool for reviewing intellectual property protection and market access practices worldwide, and for identifying those countries whose practices are damaging to U.S. industry. As we have set forth in the above, India’s practices grow more damaging with each day they go unaddressed, as the Indian government feels more emboldened to expand them to other industries, and advocate them to other countries. Thus, a Priority Foreign Country determination is not only merited, but required, in order to stem this tide.