Alliance for Fair Trade with India

October 29, 2014

The Honorable Michael Froman
United States Trade Representative
Office of the United States Trade Representative
600 17th Street NW
Washington, DC 20508

RE: Comments Regarding Foreign Trade Barriers To U.S. Exports for 2015 Reporting, Docket Number USTR-2014-0014 (Request for Public Comments To Compile the National Trade Estimate Report on Foreign Trade Barriers, 79 Fed. Reg. 48292) (Aug. 15, 2014)

Dear Ambassador Froman:

The Alliance for Fair Trade with India ("AFTI") was launched in June 2013 in support of increased action to resolve discriminatory trade practices in India. AFTI's diverse membership is comprised of organizations representing a range of U.S. industries adversely impacted by India's policies and discriminatory trade barriers. In light of its mandate, AFTI provides to the Office of the United States Trade Representative ("USTR") the attached comments for the 2015 National Trade Estimate Report on Foreign Trade Barriers ("NTE"). The comments set forth the manner in which India's imposition of certain discriminatory tariffs, its failure to protect intellectual property rights ("IPR"), and its forced transfer of technology, serve as significant barriers to our membership, to U.S. exports of goods and services, and to U.S. foreign direct investment in India.

While AFTI welcomes USTR's recent Special 301 Report calling for further evaluation of India's intellectual property regime during an "out of cycle" review, we have yet to see any real movement on the part of the Indian government with regard to IP protections. When he took office, Prime Minister Narendra Modi promisingly declared India "open for business," and committed to incentivize investment and "give the world a favorable opportunity" to trade with India. Our membership was initially encouraged by these statements, and by the announcement of the formation of an annual high-level Intellectual Property Working Group. Such rhetoric must, however, translate into concrete action. Thus far this has not been the case.

In particular, the Modi government has further abrogated the commitment India made at the World Trade Organization Ministerial in Bali in December 2013, thereby blocking the implementation of a global trade facilitation agreement previously agreed to unanimously by all 160 members of the WTO. This is a move that threatens to undermine the global rules-based trading system. Moreover, the new Indian government has raised tariffs and imposed new burdensome testing requirements on information and communication technology products from the United States and other countries. These and other recent and continued concerns are set forth in greater detail in the attached.

Thank you for your continued efforts and leadership in ensuring non-discriminatory market access for U.S. companies and investors in India and around the world. We hope our comments are helpful in facilitating U.S. efforts to reduce or eliminate trade barriers with India, enforce U.S. trade laws, and strengthen a rules-based system with our trading partners.

The Alliance for Fair Trade with India

I. 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 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 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 2014—the same score as the year prior.[1] 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.[2]

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.[3]

Finally, the Copyright Act amendments passed in 2012 have proven over the last two years inadequate in addressing the realities of a 21st 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.[4] The amendments also failed to provide adequate tools to address the

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[1] GLOBAL INTELL. PROP. CTR., CHARTING THE COURSE: GIPC INTERNATIONAL IP INDEX (2014), *available at* http://www.theglobalipcenter.com/wp-content/themes/gipc/map-index/assets/pdf/Index_Map_Index_2ndEdition.pdf.

[2] ERNST & YOUNG, THE EFFECTS OF COUNTERFEITING AND PIRACY ON INDIA'S ENTERTAINMENT INDUSTRY (2008), *available at* http://infojustice.org/wp-content/uploads/2011/02/Ernst-Young-PIracy-report-India-2009.pdf.

[3] INT'L CHAMBER OF COM., COUNTERFEITING, PIRACY AND SMUGGLING IN INDIA—EFFECTS AND POTENTIAL SOLUTIONS (2013), *available at* http://www.iccwbo.org/Data/Documents/Bascap/International-engagement-and-advocacy/Country-Initiatives/India/Download-India-report/.

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

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. 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, as well as Copyright Enforcement Agency Council. Neither body has been formed, making many provisions of the Act inoperable.[5]

b. 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.[6] 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.[7] One popular Indian film, *Kaminey*, was illegally downloaded over 350,000 times in India and abroad.[8] 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.[9]

With the increasing amount of internet users in India, the problem is likely only growing, not receding.[10] The growth of mobile devices has skyrocketed, with the addition of over a half a billion subscribers from just 2006 (there is now an estimated 900 million mobile phone users).[11] 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 and foreign distributors alike. Despite some improvements,

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

[6] Utpal Borpujari, *India Major Online Film Piracy* Hub, Deccan Herald, January 30, 2014.

[7] Gouri Shah, *TV Channels set to compete with illegal internet downloads*, LIVEMINT, Sept. 23, 2013, http://www.livemint.com/Consumer/x9vORU1c6cXRZmFLXtQnSO/TV-channels-gear-up-to-compete-with-illegal-Internet-downloa.html.

[8] *Id.*

[9] *A Tangle of Trade Barriers: How India's Industrial Policy is Hurting U.S. Companies Before the H. Comm. on Energy and Com., Subcomm. on Com., Mfg. and Trade*, 113th Cong. (2013) (statement of Mark Elliot, Exec. V.P., Global Intell. Prop. Ctr., U.S. Chamber of Com.), *available at* http://aftindia.org/wp-content/uploads/2013/06/MTE-testimony-India-EC-06-27-2013-for-submission-FINAL.pdf.

[10] INT'L FED'N OF THE PHONOGRAPHIC INDUS., IFPI DIGITAL MUSIC REPORT (2013), *available at* http://www.ifpi.org/content/library/dmr2013.pdf.

[11] INT'L FED'N OF THE PHONOGRAPHIC INDUS., IFPI DIGITAL MUSIC REPORT (2013), *available at* http://www.ifpi.org/content/library/dmr2013.pdf.

unauthorized camcording remains a severe problem.[12] 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.[13] That number dropped to 43 incidents in 2013. Though a positive trend, the number does not include unauthorized camcording of local Indian, foreign, or independent films. 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. 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.

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 serving as a trade barrier to U.S. industry.[14] 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.[15] 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.[16]

It is estimated that nearly a quarter of books in India are pirated.[17] 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. [18] Even Indian authors largely accept the copying of their own work, and police are hesitant to enforce copyright law.[19]

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[12] INT'L INTELL. PROP. ALLIANCE, INDIA: 2013 SPECIAL 301 REPORT ON COPYRIGHT PROTECTION AND ENFORCEMENT (2014).

[13] *Id.*

[14] *Id.*

[15] Shamnad Basheer, *Why students need the right to copy*, THE HINDU, Apr. 26, 2013, http://www.thehindu.com/opinion/op-ed/why-students-need-the-right-to-copy/article4654452.ece.

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

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

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

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

Furthermore, these counterfeit books are not staying in India, but are instead being sold in Africa, the European Union and the United States.[20] 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.[21] This is particularly problematic for U.S. authors, as American titles are frequently copied and sold for a fraction of the bookstore price.[22] 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.

II. Telecommunications

India is the second largest telecommunications market in the world behind China, with over 900 million telephone subscribers as of December 2013.[23] Unfortunately, the Indian government still maintains strict policies that favor Indian telecommunications firms, local equipment providers, and other domestic industry over U.S. and other foreign companies. Through limiting foreign investment, creating multiple local content requirements for related equipment, and providing a difficult and confusing tax regime for imported products, India uses many tools in its arsenal to prop up domestic industry at the expense of foreign companies.[24]

India's investment laws and restrictions vis-à-vis the telecommunications sector provide clear advantage to Indian firms, while hurting American and other foreign entities. Most recently in July of this year, the Indian government imposed a ten percent customs duty on the importation of a broad range of telecommunication equipment, likely in violation of India's Information Technology Agreement (ITA) commitments. The Indian government appears to incorrectly use evolving technologies as a rationale to identify products as not being covered by the ITA. The notification that implemented the 10 percent duty includes a variety of technologies rather than specific products including, Voice over Internet Protocol ("VoIP"),

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

[21] Basant Kumar Mohanty, *India to seek photocopy right for students*, THE TELEGRAPH INDIA, Sept. 21, 2013, http://www.telegraphindia.com/1130921/jsp/nation/story_17374550.jsp#.Uu_YuvldVVY.

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

[23] *Press Release on Telecom Subscription Data as of 31st December 2013*, Telecom Regulatory Authority of India, http://www.trai.gov.in/WriteReadData/PressRealease/Document/PR-TSD-Dec,%2013-17022014.pdf

[24] One clear example is a burdensome licensing fee of approximately $500,000 per service, or up to $2.7 million for an India Universal license, according to the U.S. Trade Representative's National Trade Estimate Report on Foreign Trade Barriers. This fee acts as a barrier to entry particularly for small and medium sized enterprises. OFFICE OF THE U.S. TRADE REP., NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS, INDIA (2014), *available at* http://www.ustr.gov/sites/default/files/2014%20NTE%20Report%20on%20FTB%20India.pdf.

various types of optics-based technologies, multiple input/multiple output ("MIMO"), and long term evolution ("LTE").[25] Established WTO precedent suggests that ITA coverage is based on the product and its function as included in the ITA and not based on the evolving technologies that underlie the functionality of the products.

Of further concern to foreign investors is the government's equity in three highly competitive telecommunications firms. The firms include: VSNL, in which the government holds a 26 percent stake; MTNL, in which the government holds a 56 percent stake; and BSNL, in which the government holds a 100 percent stake. Due to the high level of ownership, many foreign companies are concerned that governmental policies regarding the growing telecommunications sector will favor these three companies in a discriminatory manner.[26] In one recent and troubling example, the Indian government awarded wireless spectrum to BSNL and MTNL without first going through a competitive bidding process.[27]

Another predominant concern among U.S. companies operating within the sector lies in the onerous licensing requirements for telecom equipment provided by foreign suppliers. Starting in 2009 (through July of 2010), India issued a series of requirements for telecommunications equipment and service providers in order to maintain the integrity and security of the sector, stressing that the strength of India's telecommunications structures and equipment constituted a national security concern.[28] These requirements, which only applied to imported products, imposed overly burdensome regulations that led to transfer of technology requirements, and included the requirement that Indian nationals be employed as network engineers.[29] According to the 2013 Section 1377 Review, "On Compliance with Telecommunications Trade Agreements," released by the Office of the U.S. Trade Representative, these amendments were offered "to impose an inflexible and unworkable security approval process" and as such encouraged the forced transfer of technology to Indian firms.[30] In response to wide-spread criticism, several of these regulations were suspended, and subsequently improved upon with the issuance of updated licensing in May of 2011.

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[25] Government of India, Ministry of Finance, Department of Revenue Notification 11/2014-Customs, available at http://www.cbec.gov.in/customs/cs-act/notifications/notfns-2014/cs-tarr2014/cs11-2014.pdf

[26] OFFICE OF THE U.S. TRADE REP., NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS, INDIA (2013).

[27] *Id.*

[28] TELECOMMUNICATIONS INDUSTRY ASSOCIATION, 2013 SUBMISSION TO THE SPECIAL 301 COMMITTEE (2013), *available at* http://www.tiaonline.org/sites/default/files/pages/TIA%201377%20Comments%20-%2001-03-14%20-%20Final.pdf.

[29] *Id.*, pg. 12.

[30] OFFICE OF THE U.S. TRADE REP., 2013 SECTION 1377 REVIEW: ON COMPLIANCE WITH TELECOMMUNICATIONS TRADE AGREEMENTS (APRIL 2013), *available at* http://www.ustr.gov/sites/default/files/04032013%202013%20SECTION%201377%20Review.pdf, Pg. 19.

Unfortunately, companies in the United States and elsewhere still believe the revised license amendments of 2011 do not adequately rise to global standards.[31] As articulated in the 2014 Section 1377 report, the unresolved licensing issues include:

- The requirement for telecommunications equipment vendors to test all imported information and communication technology ("ICT") equipment in labs in India;

- The requirement to allow telecommunications service providers and government agencies to inspect a vendor's manufacturing facilities and supply chain; and perform security checks for the duration of the contract; and

- The imposition of strict liability and possible blacklisting of a vendor for taking inadequate precautionary security measures without the right to appeal.[32]

U.S. industry has expressed its hopes that the Indian government will quickly and effectively respond to the key concerns articulated above.[33]

Such policies and practices reveal India's unwillingness to work with foreign companies, and make investment by the United States and other entities difficult. This volatile and onerous environment has clearly affected foreign direct investment ("FDI") in the telecommunications sector. According to a report published by the Indian government on FDI equity into the Indian market, the telecoms sector has experienced a precipitous drop over the course of only a few years. In fiscal year 2011-12, FDI equity inflows into India in the telecoms sector stood at almost $2 billion. By the next reporting period, that number fell by over 80 percent to only $304 million. In the most recent reporting period, FY 2013-14, FDI equity inflows in the telecommunications sector fell again to only $82 million.[34]

III. Patents

a. Overview

India has a long and troubled history with regard to discriminatory patent policies. In 1991, USTR identified India in its annual Special 301 Report 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."[35] More than twenty years later, similar concerns regarding India's patent regime have resurfaced, as the 2014 Special 301

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[31] OFFICE OF THE U.S. TRADE REP., 2013 SECTION 1377 REVIEW: ON COMPLIANCE WITH TELECOMMUNICATIONS TRADE AGREEMENTS (APRIL 2014), *available at:* http://www.ustr.gov/sites/default/files/2013-14%20-1377Report-final.pdf.

[32] *Id*., Pgs. 16-17.

[33] TELECOMMUNICATIONS INDUSTRY ASSOCIATION, 2013 SUBMISSION TO THE SPECIAL 301 COMMITTEE (2013), *available at* http://www.tiaonline.org/sites/default/files/pages/TIA%201377%20Comments%20-%2001-03-14%20-%20Final.pdf. pg. 12.

[34] DEPARTMENT OF INDUSTRIAL POLICY AND PROMOTION, *Sectors Attracting Highest FDI Equity Inflows*, updated Dec. 2013, pg. 3.

[35] OFFICE OF THE U.S. TRADE REP., USTR ANNOUNCES SPECIAL 301, TITLE VII REVIEWS (1992), available at http://keionline.org/sites/default/files/ustr_special301_1992.pdf.

Report concluded that, "[r]ecent actions by the Government of India with respect to patents…have raised serious concerns about the innovation climate in India and risk hindering India's progress towards an innovation-focused economy."[36]

The simple reality is that several troubling patent-related policies and practices have emerged in recent years that serve as significant barriers to U.S. exports of goods, services, and U.S. foreign direct investment to India. These include the revocation of numerous patents by the Indian Controller General of Patents and the Intellectual Property Appellate Board,[37] the denial of patent applications as well as the approval of generic medicines during a patent's term,[38] the granting of a compulsory license and the ongoing consideration of others, narrow standards for patentability that are inconsistent with international standards, 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 damaging 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. These policies, and the uncertainty that they have created for foreign industry, have had a clearly detrimental impact on investment decisions, most acutely in the biopharmaceutical sector. Moreover, they have caught the eye of the U.S. Government, as the 2014 version of the National Trade Estimate Report explains that it views these developments with "heightened . . . concerns."[39] We encourage USTR to sustain such scrutiny, as there have been no improvements over the course of the last year.

b. Compulsory Licensing

India's compulsory licensing practices evidence intent to benefit domestic Indian industries, to the detriment of U.S. exporters. The Indian government's decision in March

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[36] OFFICE OF THE U.S. TRADE REP., USTR ANNOUNCES SPECIAL 301 (2014), available at http://www.ustr.gov/sites/default/files/USTR%202014%20Special%20301%20Report%20to%20Congress%20FINAL.pdf.

[37] There have been several prominent cases of patent revocation in the last year. In February 2013, the Indian Controller General of Patents revoked a patent on a cancer drug produced by Pfizer using a "hindsight" analysis. In August 2013, IPAB revoked patents for Ganfort and Combigan, both produced by Allergan, on the grounds that the inventions were obvious, and Allergan failed to comply with the requirements of Section 8 of the Patents Act. *See* Runman Ahmed, Pfizer India: Patent for Cancer Drug Sutent Revoked, THE WALL STREET JOURNAL, Oct. 5, 2012, http://online.wsj.com/news/articles/SB10000872396390444223104578038111744300822; Kaustubh Kulkarni, India revokes patents on Allergan eye drugs Ganfort and Combigan, REUTERS, Aug. 8, 2013, http://www.reuters.com/article/2013/08/08/us-allergan-india-idUSBRE97712020130808.

[38] 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.

[39] OFFICE OF THE U.S. TRADE REP., NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS, INDIA (2014), *available at:* http://www.ustr.gov/sites/default/files/2014%20NTE%20Report%20on%20FTB.pdf.

2012[40] 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, denied Bayer adequate and effective protection of its intellectual property rights to the direct benefit of Indian drug maker Natco Pharma Ltd. ("Natco"). Moreover, this decision, and the approach to compulsory licensing that it presents, could adversely impact U.S. companies far beyond the biopharmaceutical sector, as it has the potential to 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.[41] 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 United States.[42] The Controller General granted the right to produce and sell Nexavar in India to the Indian generics producer 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 medicine in India in 2008, but did make sales in 2009 and 2010. All sales of Nexavar in India were of imported medicines, as Bayer chose not to manufacture in country given the initially low quantity of the medicine 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.[43]

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

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[40] This decision was affirmed by the Intellectual Property Appellate Board on March 4, 2013, and subsequently upheld by the Bombay High Court in July 2014. *See* Khushboo Narayan, *Bombay HC Upholds IPAB Order on Nexavar's Generic Copy*, LIVE MINT, July 15, 2014, http://www.livemint.com/Companies/feivYXISXb6XBMhELJD6LJ/Bombay-HC-upholds-Nexavar-compulsory-licensing-decision.html.

[41] 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).

[42] As of December 31, 2012, Bayer employed more than 15,000 employees in North America. BAYER: PROFILE AND ORGANIZATION, http://www.bayer.com/en/Profile-and-Organization.aspx (last visited Feb. 4, 2014).

[43] INDIA PATENTS ACT, 1970, ART. 83(b), *available at* http://www.ipindia.nic.in/ipr/patent/patent_Act_1970_28012013_book.pdf.

invention."[44] 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."[45] 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.

Bayer appealed the March 2012 decision, and in March 2013, the Intellectual Property Appellate Board ("IPAB") affirmed the Controller General's grant of a compulsory license. This decision was subsequently upheld by the Bombay High Court in July 2014.[46] Interestingly, in its opinion IPAB acknowledged India's commitment under the TRIPS Agreement barring the forfeiture of a patent for lack of manufacturing.[47] Just a few lines later, however, IPAB affirmed the rationale cited by the Controller General in its grant, 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."[48] The Controller General's decision, and IPAB's subsequent affirmation, to grant a compulsory license based on its interpretation of the Patent Act's local working requirement was in violation of India's WTO obligations, and specifically in violation of TRIPS Article 27.1.

2. 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 to the detriment of U.S. exports. The Indian Ministry of Health ("MoH") has considered or is considering granting compulsory licenses for several other medicines manufactured by foreign—including American—biopharmaceutical 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. AFTI members fear 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.

The March 2012 Nexavar decision appears to have troublingly opened the door for other compulsory licensing grants in the biopharmaceutical sector. In December 2012, the MoH

[44] 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).

[45] *Id.*

[46] Khushboo Narayan, *Bombay HC Upholds IPAB Order on Nexavar's Generic Copy*, LIVE MINT, July 15, 2014, http://www.livemint.com/Companies/feivYXISXb6XBMhELJD6LJ/Bombay-HC-upholds-Nexavar-compulsory-licensing-decision.html.

[47] The opinion stated that, "the prohibition of discrimination in the grant of patent under the International Conventions which bar forfeiture of patent for no manufacturing will not come in the way of the Controller granting a compulsory license." INTELLECTUAL PROPERTY APPELLATE BOARD, ORDER NO. 45 OF 2013. (ISSUED MAR. 4, 2013).

[48] *Id.*

recommended the issuance of a compulsory license for the manufacture of Bristol-Myers Squibb's ("BMS") anti-cancer medicine 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.[49] Sprycel remains under consideration for a Section 92 CL, as indicated by an August 2014 letter from the MoH to the Department of Industrial Policy and Promotion, in which the MoH claimed there was an "urgent need" to allow generic copies of the drug.[50] The MoH has also advocated for the issuance of a compulsory license for Herceptin, a breast cancer treatment manufactured by Roche.[51] 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.[52]

Numerous U.S. companies and industry associations have also expressed their concern about the potential usage of compulsory licenses in non-biopharmaceutical contexts.[53] 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.[54] 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 the invention or is not working the patent in India.[55] 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.[56] 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

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[49] *India Recommends Compulsory License for Anti-Cancer Drug*, WORLD IP REV., Dec. 9, 2013, http://www.worldipreview.com/news/india-recommends-compulsory-licence-for-anti-cancer-drug.

[50] *Indian Health Ministry Seeking Compulsory License for BMS' Sprycel*, THE PHARMA LETTER, Aug, 18, 2014, http://www.thepharmaletter.com/article/indian-health-ministry-seeking-compulsory-license-for-b-ms-sprycel.

[51] Caroline Copley & Tom Pfeiffer, *Roche Gives Up on India Patent for Breast Cancer Drug*, REUTERS, Aug. 16, 2013, http://www.reuters.com/article/2013/08/16/us-roche-herceptin-india-idUSBRE97F08220130816.

[52] Amy Kazmin, *Roches Drops Patent for Herceptin in India*, FIN. TIMES, Aug. 13, 2013, http://www.ft.com/cms/s/0/b8c9cf06-0676-11e3-9bd9-00144feab7de.html.

[53] LETTER FROM INTEL CORP TO STANFORD K. MCCOY, U.S. TRADE REP.'S 2013 SPECIAL 301 REV. SUBMISSION BY INTEL CORP. REGARDING INDIA (FEB. 8, 2013); 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 SEC. 182 OF THE TRADE ACT OF 1974 (2013).

[54] INDIA PATENTS ACT, 1970, ART. XIV, *available at* http://www.ipindia.nic.in/ipr/patent/patent_Act_1970_28012013_book.pdf.

[55] GOV. OF INDIA MINISTRY OF COM. & INDUS., NAT'L MFG. POLICY, SEC. 4.4.1-3 (2011), *available at* http://dipp.nic.in/English/policies/National_Manufacturing_Policy_25October2011.pdf.

[56] Rajesh Kurup, *Indian Green IT and Sustainability Spending to Reach $70 bn by 2015*, THE HINDU, Oct. 2, 2013, http://www.thehindubusinessline.com/industry-and-economy/info-tech/indian-green-it-and-sustainability-spending-to-reach-70-bn-by-2015-gartner/article3958216.ece.

supplier, and has operations in more than 30 countries.[57] 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 the top 20 U.S. semiconductor companies had built design centers in India.[58] This, however, makes these companies particularly vulnerable to Indian industrial policies. In its 2014 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, stating that, "the Government of India is experimenting with broad compulsory licensing as a way to accelerate technology transfer."[59]

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.[60] 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.[61] Furthermore, the apparent intention of the requirement is to create a database of information that can then be used to justify future compulsory licenses.

c. Section 3(d) of India's Patents Act

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.

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

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[57] SUZLON COMPANY PROFILE, http://www.suzlon.com/about_suzlon/l2.aspx?l1=1&l2=1 (last visited Feb. 4, 2014).

[58] Meera Siva, *Fab Opportunity*, THE HINDU, Nov. 1, 2013, http://www.thehindu.com/features/education/careers/fab-opportunity/article5304852.ece.

[59] SEMICONDUCTOR INDUS. ASS'N, WRITTEN COMMENTS TO THE OFFICE OF THE U.S. TRADE REP. IN RESPONSE TO FED. REG. NOTICE REGARDING 2014 SPECIAL 301 REVIEW: IDENTIFICATION OF COUNTRIES UNDER SEC. 182 OF THE TRADE ACT OF 1974 (2014), *available at* http://www.semiconductors.org/clientuploads/Trade%20and%20IP/SIA%202014%20Special%20301%20Submission-%20Final.pdf.

[60] The Controller's demands are based on INDIA PATENTS ACT, 1970, Sec. 146(2), *available at* http://www.ipindia.nic.in/ipr/patent/patent_Act_1970_28012013_book.pdf.

[61] 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 SEC. 182 OF THE TRADE ACT OF 1974 (2013).

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.[62]

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.[63] 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."

IV. Forced Transfer of Technology

India's failure to enforce global intellectual property laws seem less about the government's inability to address the issue and more part of a deliberate strategy and policy to "shift the highest value goods from other economies into the country."[64] The policy, which mirrors China's approach, in essence, acts as "the largest industrial subsidy in the world, and brilliantly, it costs the [Indian government] nothing."[65] In India, domestic companies rely on globally competitive companies and the confidential information and test data they develop to operate their businesses without paying. The forced transfers of technology profiled below

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[62] INDIA PATENTS ACT, 1970, SEC. 3(d), *available at* http://www.ipindia.nic.in/ipr/patent/patent_Act_1970_28012013_book.pdf.

[63] *Novartis v. India*, Nos. 2706-2716 (Sup. Ct. of India Apr. 1, 2013), ¶¶ 95-96 (hereinafter "Glivec"). The Indian Supreme Court held in Glivec that "if the product for which patent protection is claimed is a new form of a known substance with known efficacy, then the subject product must pass, in addition to clauses (j) and (ja) of section 2(1) [which define "invention" and "inventive step" respectively] the test of enhanced efficacy as provided in section 3(d) read with its explanation." Glivec, ¶ 192 (emphasis added).

[64] *See infra* Carl Roper, Trade Secret Theft, Industrial Espionage, and the China Threat http://books.google.com/books?id=TXtcAgAAQBAJ&pg=PA67&lpg=PA67&dq=trade+secret+subsidy&source=bl&ots=BRY7zBpjxo&sig=e1R8gNskkbff42Vxk7eM4RyGom4&hl=en&sa=X&ei=a2AnU7qLPIaM0AGV2IHQDQ&ved=0CFAQ6AEwBjgU#v=onepage&q=trade%20secret%20subsidy&f=false.

[65] *Id*.

discriminate against a wide-range of U.S. industries, and serve as a significant barrier to the export of U.S. goods and services, as well as to U.S. foreign direct investment.

a. Protection of Trade Secrets and Confidential Data

As early as 2000,[66] 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 10*bis* 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."[67] In addition, India is required to "protect confidential information… [and] ensure that it has procedures to protect such information" with regard to certain biopharmaceutical or products of modern biotechnology, specifically living modified organizations.[68] Further, India must "not use such information for a commercial purpose, except with...written consent."[69] India's failure to provide data protection subjects U.S. companies to unfair competition and violates India's obligations under multiple agreements.

Fourteen years after its first mention in USTR's 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."[70] 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.[71] India does not have a national law to protect information that qualifies as a trade secret under international law.

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[66] *Hearing on U.S.-India Trade Relations: Opportunities and Challenges Before the H. Comm. on Ways and Means, Subcomm. on Trade,* 113th Congr. (2013) (written testimony of Roy F. Waldron, Chief Intell. Prop. Counsel, Pfizer Inc.), *available at* http://waysandmeans.house.gov/uploadedfiles/pfizer_testimony31313.pdf. ("India was required to prevent unfair commercial use of pharmaceutical regulatory data through the grant of generic marketing approval based on the innovator's data by January 1, 2000. They still have not done so.")

[67] TRIPS AGREEMENT, ART. 39, *available at* http://www.wto.org/english/docs_e/legal_e/27-trips.pdf.

[68] CARTAGENA PROTOCOL ON BIOSAFETY, ART. 21 (2000), *available at* http://bch.cbd.int/protocol/text/.

[69] *Id.*

[70] TRIPS AGREEMENT, ART. 39.2, *available at* http://www.wto.org/english/docs_e/legal_e/27-trips.pdf.

[71] *Id.*

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. A review of such provisions shows, however, that India has completely missed the mark and fails to protect trade secrets.[72] 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."[73] 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.[74]

2. No Protection for Test Data

According to USTR's 2014 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."[75] 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."[76] 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 of agricultural chemical products which utilize new chemical entities."[77] In this regard, India does not meet its obligations.

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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[72] THE NATIONAL INNOVATION ACT OF 2008, Art. 8-10, *available at* http://www.dst.gov.in/draftinnovationlaw.pdf.

[73] Anuradha Salhotra, *Protection of Trade Secrets in India*, MODERN PHARMACEUTICALS, June 2012, *available at* http://issuu.com/infomedia18/docs/modern_pharmaceuticals_june_2012/65.

[74] THE INDIAN CONTRACT ACT, 1872, ACT No. 9 OF 1872 1 *available at* http://www.indiankanoon.org/doc/171398/.

[75] OFFICE OF THE U.S. TRADE REP., NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS, INDIA (2014), *available at* http://www.ustr.gov/sites/default/files/2014%20NTE%20Report%20on%20FTB.pdf

[76] SATWANT REDDY & GURDIAL SINGH SANDHU, REPORT ON STEPS TO BE TAKEN BY GOVERNMENT OF INDIA IN THE CONTEXT OF DATA PROTECTION PROVISIONS OF ARTICLE 39.3 OF TRIPS AGREEMENT (2007), *available at* http://chemicals.nic.in/DPBooklet.pdf.

[77] TRIPS AGREEMENT, ART. 3.2, *available at* http://www.wto.org/english/docs_e/legal_e/27-trips.pdf.

"FW") for evaluation, before bringing a product to market.[78] Such data submitted by biopharmaceutical 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.[79] 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 biopharmaceuticals context, U.S. companies spend an average of 10 to 15 years investing in research and development ("R&D") for a new product, at a tremendous cost. PhRMA, a trade association representing the leading biopharmaceutical researchers and biotechnology companies, sets the average cost to develop a medicine (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.[80] Some have estimated that "[t]he development of test data typically represents more than sixty percent of the R&D costs of new drugs."[81] 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.[82]

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.[83] 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."[84] BIO[85] echoes these sentiments on market exclusivity,[86] noting that "effective market exclusivity for regulated pharmaceutical and agriculture chemical products would contribute significantly to providing adequate and effective protection of intellectual property

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

[79] *Id.*

[80] PHRMA, 2013 PROFILE BIOPHARMACEUTICAL RESEARCH INDUSTRY (2013), *available at* www.phrma.org/sites/default/files/pdf/PhRMA%20Profile%202013.pdf.

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

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

[83] WORLD HEALTH ORGANIZATION, PROTECTION OF DATA SUBMITTED FOR THE REGISTRATION OF PHARMACEUTICALS: IMPLEMENTING THE STANDARDS OF THE TRIPS AGREEMENT, 2002, *available at* http://apps.who.int/medicinedocs/en/d/Jh3009ae/11.html.

[84] WORLD HEALTH ORGANIZATION, REPORT OF AN ASEAN WORKSHOP ON THE TRIPS AGREEMENT AND ITS IMPACT ON PHARMACEUTICALS (2000). *available at* http://apps.who.int/medicinedocs/pdf/h1459e/h1459e.pdf.

[85] 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.

[86] BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO), SPECIAL 301 SUBMISSION, (2014), *available at* http://www.bio.org/sites/default/files/2014%20BIO%20Submission.pdf.

rights in India…[however] India has not yet implemented any meaningful protection for the data that must be generated."[87]

4. India's Offensive National Policies

The Office of the National Counterintelligence Executive ("ONCIX") report titled, *Foreign Spies Stealing US Economic Secrets in Cyberspace*, designates information and communications technology ("ICT") and civilian and dual-use technologies, including the clean energy and healthcare/biopharmaceuticals sectors as areas of focus for foreign collectors of U.S. trade secrets.[88] 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 maintains major equity stakes in competing commercial enterprises. For example, related to certain policies listed below, USTR's 2014 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.[89] As described further, with each of the measures highlighted below, the Indian government either (a) denies adequate protection of intellectual property rights or (b) denies fair and equitable market access to U.S. persons who rely on intellectual property protection thus warping the competitive relationship between U.S. and foreign industries, and creating an unfair trade barrier for U.S. industry.

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

[87] *Id.*

[88] OFFICE OF THE NAT'L COUNTERINTELLIGENCE EXEC., FOREIGN SPIES STEALING US ECONOMIC SECRETS IN CYBERSPACE (2011), *available at* http://www.ncix.gov/publications/reports/fecie_all/Foreign_Economic_Collection_2011.pdf.

[89] OFFICE OF THE U.S. TRADE REP., NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS, INDIA (2014), *available at* http://www.ustr.gov/sites/default/files/2014%20NTE%20Report%20on%20FTB.pdf.

tracks, ports, IT equipment et) on agreed reasonable and non-discriminatory terms and conditions aligned with competition principles.[90]

While the essential facilities doctrine was first developed in United States law, the implementation of such within India will likely have different consequences due to India's lack of protection for trade secrets. Rather, the application of the antitrust "essential facilities" doctrine in India forces companies to allow access to their data and trade secrets, with the apparent goal of benefitting Indian enterprise. Thus, this policy could lead to consequences that are incongruent with the policy's stated goals of spurring innovation and increasing competition. 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.

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. After several extensions, these testing requirements went in to effect July 1 of this year.[91] This heavy handed policy suggests a government agenda 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,[92] deviate from global practice and require clarification to avoid negative consequences during implementation.

d. Requirement that Licensed Telecommunications Equipment Vendors[93] Test Imported ICT Equipment in Indian Labs[94]

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[90] GOVERNMENT OF INDIA: MINISTRY OF CORPORATE AFFAIRS, NATIONAL COMPETITION POLICY 2011 (2011), *available at* http://www.mca.gov.in/Ministry/pdf/Revised_Draft_National_Competition_Policy_2011_17nov2011.pdf.

[91] R. Jai Krishna, *India Extends Deadline for Telecom-Gear Certification*, Nov. 5, 2013, THE WALL STREET JOURNAL, *available at*: http://online.wsj.com/articles/SB10001424052702303482504579179503235494152.

[92] 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." 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.

[93] 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.

[94] OFFICE OF THE U.S. TRADE REP., NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS, INDIA (2014), *available at* http://www.ustr.gov/sites/default/files/2014%20NTE%20Report%20on%20FTB.pdf.

The Indian Department of Telecommunication ("DoT") requires the security certification of all imported telecom equipment, mandating licensees to comply with the following measure:[95]

> [I]nduct 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[1] 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. From 1st April 2013 the certification shall be got done [sic] 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.

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.[96]

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.

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.[97] 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 *Times of* India.[98] 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.

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[95] GOV. OF INDIA: MINISTRY OF COMM. & INFO. TECH., EXTENSION OF TIME FOR SEC. CERTIFICATION (2013) *available at* http://www.dot.gov.in/sites/default/files/DOC011113-002.pdf; *see also* OFFICE OF THE U.S. TRADE REP., NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS, INDIA (2014), *available at* http://www.ustr.gov/sites/default/files/2014%20NTE%20Report%20on%20FTB.pdf.

[96] R. Jai Krishna, *India Extends Deadline for Telecom-Gear Certification*, Nov. 5, 2013, THE WALL STREET JOURNAL, *available at*: http://online.wsj.com/articles/SB10001424052702303482504579179503235494152.

[97] Kalyan Parbat, *DoT wants overhauling of telecom laws to give more teeth to India's security agencies*, ECON TIMES, Oct. 23, 2013, http://articles.economictimes.indiatimes.com/2013-10-23/news/43326447_1_national-information-board-telecom-security-policy-indian-telecom-networks.

[98] Kalyan Parbat, *DoT to test all products used in mobile networks*, Dec. 30, 2013, THE TIMES OF INDIA, *available at* http://articles.timesofindia.indiatimes.com/2013-12-30/telecom/45708710_1_dot-products-telecom-department.

f. Requirement for Inspection of a Vendor's Manufacturing Facilities and Supply Chain[99]

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.[100] 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."[101]

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."[102] 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."[103]

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[99] OFFICE OF THE U.S. TRADE REP., NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS, INDIA (2013), *available at* http://www.ustr.gov/sites/default/files/2013%20NTE%20India%20Final.pdf.

[100] GOV. OF INDIA: MINISTRY OF COMM. & INFO. TECH., LETTER TO ALL UNIFIED ACCESS SERVICE LICENSEES AMENDING LICENSE CLAUSE 41.6A, (2011).

[101] CTR. FOR DEV. OF TELEMATICS, REPORT ON TELCOM SECTOR ROADMAP FOR INNOVATION 2010-2020, *available at* http://www.cdot.com/tsic.pdf.

[102] OFFICE OF THE NAT'L COUNTERINTELLIGENCE EXEC., FOREIGN SPIES STEALING US ECONOMIC SECRETS IN CYBERSPACE (2011), *available at* http://www.ncix.gov/publications/reports/fecie_all/Foreign_Economic_Collection_2011.pdf.

[103] 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).

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.[104]

India's requirement that only Indian trained nationals hold certain positions within telecommunications companies 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.[105]

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.

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[104] CTR. FOR DEV. OF TELEMATICS, REPORT ON TELCOM SECTOR ROADMAP FOR INNOVATION 2010-2020, *available at* http://www.cdot.com/tsic.pdf.

[105] OFFICE OF THE NAT'L COUNTERINTELLIGENCE EXEC., FOREIGN SPIES STEALING US ECONOMIC SECRETS IN CYBERSPACE (2011), *available at* http://www.ncix.gov/publications/reports/fecie_all/Foreign_Economic_Collection_2011.pdf.