



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

Re: 2017 Special 301 Review, Docket Number USTR–2016–0026

Dear Ms. Peterson:

The Alliance for Fair Trade with India (“AFTI”) is comprised of a diverse group of organizations that support increased action to address the barriers to trade and investment U.S. companies are facing in India. These barriers include the erosion of intellectual property rights (“IPR”), and AFTI represents a range of U.S. industries adversely impacted by India’s IPR policies and practices.

In light of this mandate, AFTI submits to the Office of the U.S. Trade Representative (“USTR”) this report which calls on USTR, under Section 182 of the Trade Act of 1974, to again place India on its Priority Watch List. In addition, USTR in its 2016 Special 301 Report noted its obligation under the Trade Facilitation and Trade Enforcement Act of 2015 to develop “action plans” for each country that USTR identifies as a Priority Watch List country and that has been on the Priority Watch List for at least one year.<sup>1</sup> The Act also instructs USTR to consider whether foreign countries provide “adequate and effective means for U.S. persons to secure, exercise and enforce their rights relating to trade secrets.”<sup>2</sup> As discussed in detail throughout this submission, there is strong evidence that the Indian Government has not made meaningful efforts to emerge from its current status under the Priority Watch List, or made efforts to protect IPR holders’ interests with respect to trade secrets. Therefore, we urge USTR to provide an opportunity for a meaningful assessment of India’s IP regime through an Out-of-Cycle Review (“OCR”) so that the Trump Administration can evaluate progress on these important issues. The OCR will also provide a basis for USTR to dedicate the required bilateral attention necessary to develop a robust “action plan” to ensure that India’s commitments are translated into substantive and real policy change.

The last OCR on India occurred three years ago, before India finalized its new National IPR Policy in 2016, and focused on process and engagement rather than substance. AFTI members believe an OCR is now warranted to document the lack of meaningful progress on the substance of India’s IPR policies since 2014.

In its 2016 Special 301 Report, USTR recognized as a positive development the Government of India’s recognition of the need for reform in IPR protection but identified several serious challenges that remain:

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<sup>1</sup> USTR 2016 Special 301 Report at 1-2.

<sup>2</sup> *Id.* at 2.

India has also not taken the opportunity to address longstanding challenges that represent significant IPR regime deficiencies compared to other markets. The pharmaceutical industry in particular faces a host of challenges related to IPR. These include irregularities in the application of Section 3(d) of India's Patents Act; the lack of an effective system for protecting against unfair commercial use, as well as the unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products; lack of clarity on standards for Sections 85 and 92 compulsory licenses and revocation under Section 66; and the lack of an effective system for notifying interested parties of marketing approvals for generic pharmaceuticals in a manner that would allow for the early resolution of potential patent disputes. For industries that create and supply content, high levels of piracy and unpredictability in the market undermine a vibrant and competitive sector for Indian and U.S. companies. Brand owners also face delays and challenges in obtaining trademarks, and rampant counterfeit products in the market. India has yet to develop legislation that would ensure trade secrets are adequately protected against misappropriation. Further, India has not yet joined important international IPR treaties, such as the WCT, the WPPT, and the Singapore Treaty.<sup>3</sup>

In May 2016, The Indian Department of Industrial Policy and Promotion ("DIPP") finalized its new National IPR Policy. The National IPR Policy references several of the suggestions contained in the 2015 Special 301 Report, and AFTI views the final draft of the Policy as a significant improvement over the draft that was leaked in April 2015 with better language on a few specific areas of IPR such as increasing capacity in IPR agencies and process reforms to boost enforcement. While AFTI welcomes the efforts of the Government of India embodied in the National IPR Policy, the policy does not address meaningfully several outstanding issues where India continues to fall short of its international obligations, as discussed in further detail below. Moreover, AFTI believes that significant efforts will be needed to ensure that the concepts contained in the National IPR Policy translate into concrete policy measures.

In this respect, AFTI encourages and expects that India will continue to engage with the United States through the various channels of dialogue developed between the countries in recent years, including the Strategic and Commercial Dialogue and the U.S.-India Trade Policy Forum. Such dialogues have allowed U.S. government officials to engage the Indian government on a broadening array of concerns, generating better conversations on these issues and broad, high-level statements. Despite the positive atmosphere surrounding these dialogues, and resulting encouraging statements, these engagements have not resulted in substantive and measurable improvements. AFTI therefore urges the new administration to take the proactive step to initiate an OCR to ensure that the Government of India follows through with its positive commitments and takes further measures to ensure the protection of U.S. IPR holders in compliance with India's international obligations and global standards.

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

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<sup>3</sup> *Id.* at 39.

## I. Forced Localization

Forced localization continues to be a chronic issue facing U.S. IPR holders in India. The Modi Administration has done little to step away from protectionist forced localization policies clearly aimed at favoring domestic IP holders at the expense of goods, services, and IP from the United States other countries.

India's local content requirements for solar energy projects were most recently subject to dispute settlement at the World Trade Organization ("WTO"). In February 2013, the United States requested consultations with India concerning certain domestic content requirements relating to the Jawaharlal Nehru National Solar Mission ("JNNSM"), including tender documents stating that a share of the projects were to be reserved for domestically-manufactured solar cells and modules. In August 2015, a WTO panel found that India had in fact violated Article III:4 of the General Agreement on Tariffs and Trade ("GATT") and Article 2.1 of the Agreement on Trade-Related Investment Measures ("TRIMs"), which establishes the national treatment obligation.<sup>4</sup> In September 2016, the Appellate Body affirmed the panel's ruling, rejecting all of India's defensive arguments.<sup>5</sup> AFTI urges India to bring its measure in full compliance with the Appellate Body's rulings and recommendations.

India's forced localization measure in the solar industry is not an isolated case. While discussion about the importance of manufacturing in India driven by the "Make in India" initiative is not a bad thing, greater discussion about forced localization measures to achieve those goals is. India continues to maintain localization requirements contained in its Machine-to-Machine Roadmap for the development and deployment of Internet of Things ("IOT") technologies, launched in 2015. The measure introduces local content requirements in telecommunications equipment by linking to the Indian government's the Preferential Market Access ("PMA") plan, a 2011 information technology industry policy to promote local production whose scope was eventually limited to government procurement after considerable pushback from numerous stakeholders. The Roadmap calls for devices, such as sensors and microchips, to be included in the PMA, which aims to have local manufacturers produce 60 percent of ICT products procured by the Indian public sector by 2017, rising to 80 percent in 2020.<sup>6</sup> The Roadmap also introduces the possibility of India's first forced local data storage requirement by requiring that all IOT gateways and application servers that supply customers in India be located in India.<sup>7</sup>

It is worth noting that the draft National IPR Policy released in 2015 recommended that certain patent applications be examined on an expedited basis of given assurance that the manufacturer has either started manufacturing the invention in India or undertakes to do so within two years from the date of filing of the request for expedited examination. AFTI

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<sup>4</sup> Panel Report, *India – Certain Measures Relating to Solar Cells and Solar Modules*, WT/DS456/R (Feb. 24, 2016).

<sup>5</sup> Appellate Body Report, *India – Certain Measures Relating to Solar Cells and Solar Modules*, WT/DS456/AB/R (Sept. 16, 2016).

<sup>6</sup> Government of India, *National Telecom M2M Roadmap* (New Delhi: Government of India, Ministry of Communication and Information Technology, Department of Telecommunications, 2015).

<sup>7</sup> *Id.*

expressed concern that such policy would favor Indian businesses with pre-existing domestic operations and discriminate against IPR holders who are unable or unwilling to establish manufacturing operations in India. The final version of the National IPR Policy stepped back from the language in its draft form, but it nonetheless retains a recommendation for the exploration of “the possibility of expedited examination of patent applications to promote manufacturing in India.” Therefore, the National IPR Policy does little to assuage concerns or to suggest that India is taking notable actions to address this longstanding issue.

## II. Lack of Regulatory Data Protection

AFTI and its members continue to find that India does not provide adequate protection of regulatory data. The lack of protection appears to violate Article 39.3 of TRIPS, which requires countries to protect “undisclosed test or other data, the origination of which involves a considerable effort” against unfair commercial use, when such data is required as a condition of approving the marketing of pharmaceutical or agricultural chemical products that utilize new chemical entities.

AFTI raises particular concern with the lack of protection afforded under India’s laws and regulations with respect to undisclosed tests. In fact, India does not have any specific legislation protecting data that has been submitted for obtaining regulatory approval of pharmaceuticals or agricultural chemical products.<sup>8</sup> Such test data is said to be protected under the Official Secrets Act. However, as noted by the WTO Secretariat in its Trade Policy Review of India in 2015, it is unclear how India implements the second obligation under Article 39.3 of the TRIPS Agreement, which is in addition to the obligation to provide protection against disclosure, namely, protection of such data against unfair commercial use.<sup>9</sup>

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 under the Ministry of Health and Family Welfare for evaluation, before bringing a product to market.<sup>10</sup> 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.<sup>11</sup> 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 from theft or disclosure.

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<sup>8</sup> WTO Trade Policy Review, *Report by the Secretariat*, WT/TPR/S/313/Rev. 1 (Apr. 28, 2015). The Drugs and Cosmetics Act of 1940 regulates the manufacture and marketing approvals for drugs and traditional medicines, while the Insecticides Act of 1968 addresses the manufacture and marketing approvals for agricultural chemicals (such as insecticides, fungicides and weedicides). However, there is no statute in place in India for the protection of pharmaceutical, agrochemical and traditional medicine-related data against disclosure and reliance by third parties.

<sup>9</sup> *Id.*

<sup>10</sup> CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, GUIDANCE FOR INDUSTRY, *available at* <http://www.ayushmuhs.in/public/Guidelines/CDSCO.pdf>.

<sup>11</sup> *Id.*

Test data protections are crucial to a variety of U.S. industries. 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 and an AFTI member, sets the average cost to develop a medicine (including the cost of failures) at \$2.6 billion (up from \$900 million in the late 1990s), while acknowledging recent studies that have estimated costs to be much higher.<sup>12</sup> Some have estimated that “[t]he development of test data typically represents more than sixty percent of the R&D costs of new drugs.”<sup>13</sup> 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.<sup>14</sup>

The initiatives taken by the Modi government do not appear to contain any efforts to improve the regulatory framework for data protection. In its 2016 Special 301 Review Comments, AFTI expressed concern that the draft National IPR Policy set out as an area of study “[p]rotection of undisclosed information,” but intentionally excluded “data exclusivity” as an area for future policy development.<sup>15</sup> The final version of the National IPR Policy removes any language suggesting further study and includes no mention of undisclosed information whatsoever.

In its 2016 Special 301 Report, USTR reiterated the concerns expressed in its 2015 National Trade Estimate report, urging India “to provide an effective system for protecting against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products.”<sup>16</sup> Despite these repeated urgings, India continues to provide inadequate protection for IP holders, in violation of its international obligations and global IP standards.

### III. Continued Lack of Trade Secret Protection

Theft of trade secrets is a serious issue that undermines companies’ ability to compete in the global market place. A recent report from the Congressional Research Service notes that U.S. companies suffer billions of dollars in losses resulting from the theft of trade secrets annually.<sup>17</sup> The report also calls out India as an emerging economy with very weak laws and enforcement practices.<sup>18</sup>

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<sup>12</sup> PhRMA, 2016 PROFILE BIOPHARMACEUTICAL RESEARCH INDUSTRY (2016), available at <http://www.phrma.org/sites/default/files/pdf/biopharmaceutical-industry-profile.pdf>.

<sup>13</sup> 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](http://www.iprsonline.org/unctadictsd/bellagio/docs/Correa_Bellagio4.pdf).

<sup>14</sup> 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](http://www.croplife.org/view_document.aspx?docId=4057).

<sup>15</sup> Department of Industrial Policy and Promotion, *Draft of the National Intellectual Property Rights Policy*, April 2015, p. 13.

<sup>16</sup> USTR 2016 Special 301 Report, at 43.

<sup>17</sup> Protection of Trade Secrets: Overview of Current Law and Legislation, Congressional Research Services (April 22, 2016), available at: <https://fas.org/sgp/crs/secrecy/R43714.pdf>.

<sup>18</sup> *Id.*

India does not have legislation that specifically protects information that qualifies as a “trade secret” under international law. Rather, India has relied on contract and common law to provide trade secret protection.<sup>19</sup> However, India’s legal code does not provide sufficient remedies to enforce such contractual provisions. Moreover, as the WTO Secretariat noted in its report following India’s Trade Policy Review, “[i]t is not clear precisely how India protects against disclosure of trade secrets by third parties not party to any formal or informal contracts or confidence.”<sup>20</sup>

In 2008, India passed the National Innovation Bill, which includes language pertaining to confidentiality, confidential information, and remedies.<sup>21</sup> While this language appears to suggest some protection of confidential information, the bill does not mandate the protection of trade secrets, but 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.”<sup>22</sup> 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.<sup>23</sup> Such restrictions make it difficult for domestic and foreign companies alike to protect their trade secrets adequately.

The lack of trade secret protection in India is inconsistent with India’s obligations under TRIPS Article 39.2, which requires Members to allow persons 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 so long as such information: (a) is secret . . . ; (b) has commercial value because it is a secret; and (3) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.<sup>24</sup>

India’s national laws fail to meet this standard and imposes significant uncertainties on trade secret holders. Moreover, the National IPR Policy does not indicate that the protection of trade secrets is of any concern for the Modi government. Compared to the complete absence of any specific legislation for the protection of trade secrets, and the repeated identification of the issue, the National IPR Policy only contains a passing mention of trade secrets, simply identifying “protection of trade secrets” as one of many “important areas of study and research for future policy development.”

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<sup>19</sup> *Id.*

<sup>20</sup> WTO Trade Policy Review, *Report by the Secretariat*, WT/TPR/S/313/Rev. 1 (Apr. 18, 2015).

<sup>21</sup> 2008 National Innovation Bill, Chapter VI, <http://www.dst.gov.in/draftinnovationlaw.pdf>.

<sup>22</sup> Anuradha Salhotra, *Protection of Trade Secrets in India*, MODERN PHARMACEUTICALS, June 2012, available at [http://issuu.com/infomedia18/docs/modern\\_pharmaceuticals\\_june\\_2012/65](http://issuu.com/infomedia18/docs/modern_pharmaceuticals_june_2012/65).

<sup>23</sup> THE INDIAN CONTRACT ACT, 1872, ACT No. 9 OF 1872 1 available at <http://www.indiankanoon.org/doc/171398/>.

<sup>24</sup> AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS, Art. 39.2.

## IV. Patents

In its 2016 Special 301 Comments, AFTI expressed optimism with respect to Prime Minister Modi's April 2015 remarks calling for India to align its patent laws with international standards in order to encourage foreign investment. While there has been some positive gestures – notably the removal of the expedited examination procedures for manufacturing in India from the final Patents (Amendment) Rules published on May 16, 2016 – such examples are unfortunately all too rare. Unfortunately, Prime Minister Modi's stated commitments have yet to come to fruition, and several longstanding issues and concerns remain that serve as significant barriers to U.S. trade and investment.

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

In its 2017 NTE submission, AFTI raised concerns and provided specific recommendations to strengthen the Final CRI Guidelines released by the Indian Government in February 2016. Specifically, AFTI noted that:

Section 3(k) of the India Patents Act (1970) specifically excludes “a mathematical or business method or a computer programme per se or algorithms” from patentable subject matter. AFTI notes that while patents are not usually awarded for code, computer-related inventions are patent eligible subject matter. Specifically, patent claims involving computer software operating in conjunction with corresponding hardware may be granted if the requisite conditions are satisfied, namely novelty, inventive step, and industrial applicability. In addition, AFTI recommends providing more examples of what would be considered patentable subject matter under Section 3(k) of the India Patents Act (1970) in the Final CRI Guidelines for greater clarity.<sup>25</sup> AFTI continues to urge the Indian Government take these recommendations into account. In particular, during the 2016 Trade Policy Forum, Indian Minister of Commerce and Industry Sitharaman noted that India has set up a Committee to re-examine the guidelines on examination of CRI patent applications, and expressed hope that a final decision would be taken soon in this regard consistent with Indian law.<sup>26</sup> AFTI urges the Indian Government to follow through with these commitments in a timely manner. These efforts should include modification of Section 5(3) of the Guidelines to permit examination of patentability for inventions that make contributions in both the computer program and the known hardware, if the invention could bring further technical effect.

AFTI also continues to view that any discrimination against categories of inventions in the Final CRI Guidelines is inconsistent with TRIPS Article 27.1, which requires 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.”

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<sup>25</sup> AFTI 2017 NTE Submission at 8.

<sup>26</sup> India and United States Joint Statement on the Trade Policy Forum, October 20, 2016, *available at* <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2016/october/%E2%80%8BIndia-US-Joint-Statement-TPF>.

## B. Compulsory Licensing

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

India’s compulsory licensing practices remain troubling to AFTI as they continue to evidence intent to benefit domestic Indian industries to the detriment of U.S. companies. In one notorious example, on December 12, 2014, the Indian Supreme Court rejected Bayer’s appeal of a July 2014 Bombay High Court decision refusing to revoke a compulsory license (“CL”) issued to Indian drug maker Natco Pharma Ltd. (“Natco”).<sup>27</sup> This CL was initially granted in March 2012 by the Indian Controller General of Patents (the “Controller General”) under the amended Patents Act, and granted Natco the right to produce and sell Bayer’s anti-cancer drug Nexavar in India. Despite significant international scrutiny, this decision (the “Nexavar decision”) was subsequently affirmed by the Intellectual Property Appellate Board (the “IPAB”) in March 2013.

In light of the Indian Supreme Court’s ruling, AFTI and its members remain very concerned with the Nexavar decision, its underlying rationale, and its potential use as a tool for the furtherance of Indian industrial policy. Specifically, the Controller General based its grant of the CL to Natco in part on Bayer’s failure to “work” the Nexavar patent in India because it imported its products, rather than manufacturing them in India. On appeal, the IPAB modified the Controller General’s reasoning to clarify that “in some cases” the “working” requirement could be met solely by importation. However, the IPAB rejected Bayer’s explanation that economic factors prevented manufacturing in India, stating that, “the patentee must show why it could not be locally manufactured. A mere statement to that effect is not sufficient there must be evidence.”<sup>28</sup> In its decision, the IPAB did not clarify the circumstances under which the “working” requirement would be met without manufacturing in India. Moreover, when asked multiple times within its Trade Policy Review at the WTO to clarify the idea behind the requirement that technology must be worked in India, the government of India simply responded by citing the IPAB decision, adding no further clarity to the issue.<sup>29</sup>

As highlighted by USTR in its 2016 Special 301 Report, this decision could be used to inappropriately pressure innovators outside of India – including those in sectors well beyond pharmaceuticals, such as green technology and information and communications technology – to manufacture in India in order to avoid being compelled to license an invention to third parties.<sup>30</sup> Moreover, the legal basis for the Nexavar decision is very likely in violation of India’s WTO

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<sup>27</sup> Andrew Ward and Amy Kazin, *Bayer Loses Bid to Block Cheap Version of Cancer Drug in India*, FINANCIAL TIMES, Dec. 12, 2014.

<sup>28</sup> Decision of the Intellectual Property Appellate Board, Chennai, March 4, 2013, OA/35/2012/PT/MUM, Paragraph 52.

<sup>29</sup> WTO Trade Policy Review, India: Minutes of the Meeting, WT/TPR/M/313/Add.1., at 35, 47, 104, 202.

<sup>30</sup> USTR 2016 Special 301 Report, at 43.

obligations, and specifically in violation of TRIPS Article 27.1, as set forth in AFTI's 2016 Special 301 submission.<sup>31</sup>

AFTI notes that the number of compulsory licenses issued over the past year has dropped, as the Indian government seems to have tackled these issues more carefully. While AFTI welcomes such a more careful approach to this complex issue, it notes at the same time that this shift does not resolve the broader concerns with India's compulsory licensing regime. The policy tools that allow Indian government agencies to issue such licenses remain in place, and could be used again in the future.

### **C. Section 3(d)**

It is of great concern to AFTI and its members that India continues to maintain Section 3(d) of the Indian Patents Act in apparent violation of Article 27 of the TRIPS Agreement. Article 27 of TRIPS requires Members to make patents available for any inventions, "in all fields of technology," as long as they meet three criteria: (1) the invention is new; (2) the invention involves an inventive step; and (3) the invention is capable of industrial application.

In addition to the three criteria outlined in TRIPS, Section 3(d) adds a fourth condition for patentability – inventions constituting a "new form of a known substance" must also "result in the enhancement of the known efficacy of that substance." The addition of this fourth requirement is blatantly inconsistent with TRIPS Article 27.

Section 3(d) also explains that, "[f]or the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy." Thus, Section 3(d) appears to target the pharmaceutical and agricultural chemical sectors, possibly resulting in an additional violation of Article 27. Specifically, Article 27 requires Members to ensure patentability "in all fields of technology" as long as the three criteria are met. Thus, the imposition of an additional fourth requirement to targeted industries results in an additional violation of TRIPS Article 27.

USTR in its 2016 Special 301 Report recognized that "unpredictable application of Section 3(d) of the Patents Act has led to additional rejections of patent applications for innovative pharmaceutical products."<sup>32</sup> Since the 2016 Special 301 Report, the Indian Patent Office has continued to reject applications for pharmaceutical products relying on Section 3(d). For example, in November 2016, the Indian Patent Office denied a patent to Xtandi, claiming that the invention is "not patentable under section 3(d)."<sup>33</sup> Thus, the Modi Administration is

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<sup>31</sup> Article 27.1 establishes that, where national legislation imposes a local working requirement, as it does in India, patent holders should be able to satisfy such requirement by demonstrating that they have imported the patented product. Put another way, Article 27.1 does not allow for the issuance of a compulsory license merely because the patentee does not produce the relevant patented goods locally.

<sup>32</sup> USTR 2016 Special 301 Report, at 39.

<sup>33</sup> Healthworld, "Patent denied, price of prostate cancer drug may go down," available at: <http://health.economicstimes.indiatimes.com/news/pharma/patent-denied-price-of-prostate-cancer-drug-may-go-down/55344613>.

continuing to ignore repeated calls to rectify this onerous and WTO non-compliant standard for patentability, to the detriment of both foreign and Indian IP holders.

## V. Copyright

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

India is ranked third to last of the forty-five countries listed in the International IP Index created by AFTI member 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 2017—the same score as the previous four years.<sup>34</sup> This shows a lack of progress on the part of the Indian government. The problem is daunting. Piracy of movies, music and illegal downloads in India is estimated to have cost the music and entertainment industry approximately \$4 billion dollars per year, the bulk of which affects local content. Unfortunately, with the continuing growth of interconnectedness via the internet, piracy of music and movies has become instant and widespread, growing the illegal practice of distributing creative products. Due to the high rate of piracy, lacking IPR protections, and poor enforcement, industry groups in India and abroad remain inhibited from innovating new products and investing more in India.<sup>35</sup>

### A. Copyright Act Amendments

The Copyright Act amendments passed in 2012 have proven over the last four years inadequate in addressing the realities of a 21<sup>st</sup> century economy that relies heavily on e-commerce and digital products. Although the amendments offered remunerative rights for composers and songwriters whose products are used in film, the legislation did not lay out adequate protections to guard against the illegal internet downloads of music, movies, software and other data files. The problem will only continue to grow as India becomes more interconnected via the worldwide web.<sup>36</sup> The amendments also failed to provide adequate tools to address the widespread copyright infringements affecting the country and failed to introduce

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<sup>34</sup> Global Intellectual Property Center, *The Roots of Innovation: U.S. Chamber International IP Index* (2017), available at [http://www.theglobalipcenter.com/wp-content/uploads/2017/02/GIPC\\_IP\\_Index\\_2017\\_Report.pdf](http://www.theglobalipcenter.com/wp-content/uploads/2017/02/GIPC_IP_Index_2017_Report.pdf).

<sup>35</sup> 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/>.

<sup>36</sup> 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>.

much needed anti-camcording legislation, despite its status as a longstanding nuisance to both foreign and domestic film industries. The Act further provides multiple unwarranted and loosely-worded exceptions for personal use and for personal reproduction. The Indian government provided assurances that it would establish a permanent Copyright Board to ensure compliance with the provisions of the Act, but this body has not yet been formed, making many provisions of the Act inoperable.<sup>37</sup>

## **B. Internet Piracy and Illegal Downloading**

Illegal downloading, including peer-to-peer (“P2P”) filesharing and illegal streaming, is rampant in India. India is often cited as one of the top ten Internet piracy countries in the world.<sup>38</sup> One digital research firm approximated that total online video consumption had doubled from 2011 to 2013, up to 3.7 billion videos per month.<sup>39</sup> A recent report from May 2016 stated that online video consumption has doubled yet again since 2013, to 7 billion views per month.<sup>40</sup> One popular Indian film, *Kaminey*, was illegally downloaded over 350,000 times in India and abroad.<sup>41</sup> 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 2011, mostly attributed to mobile and internet piracy.<sup>42</sup>

With the increasing amount of internet users in India, the problem is likely only growing, not receding.<sup>43</sup> The growth of mobile devices has skyrocketed, with the number of mobile phone users surpassing one billion in October 2015.<sup>44</sup> Due to the rise of smart phones, these copyright infringements are particularly nefarious because pirated materials are now being instantly shared via mobile device.<sup>45</sup>

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<sup>37</sup> 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/>.

<sup>38</sup> See, e.g., Utpal Borpujari, *India Major Online Film Piracy Hub*, Deccan Herald, January 30, 2014.

<sup>39</sup> 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>.

<sup>40</sup> Rajdeep Chatterjee, *State of Digital: India 2016*, LinkedIn, May 2, 2016.

<sup>41</sup> Utpal Borpujari, *India Major Online Film Piracy Hub*, Deccan Herald, January 30, 2014.

<sup>42</sup> *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*, 113<sup>th</sup> 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>.

<sup>43</sup> *Why the US Fears India’s Internet Boom*, LIVEMINT, May 21, 2015.

<sup>44</sup> Bhuma Shrivastava, *India Becomes Mobile-Phone Market With a Billion Subscribers*, Bloomberg Technology, December 30, 2015, available at <https://www.bloomberg.com/news/articles/2015-12-30/india-becomes-second-phone-market-to-cross-1-billion-subscribers>.

<sup>45</sup> *4G Roll-Out Fans Increase Film Piracy Fears*, LIVEMINT, Aug. 21, 2015.

### 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.<sup>46</sup> 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.<sup>47</sup> After slightly decreasing from 43 incidents in 2013 to 41 incidents in 2014, the number significantly dropped to 19 incidents in 2015.<sup>48</sup> Though a positive trend, the number does not include unauthorized camcording of local Indian, foreign, or independent films. The latest arrest of camcorder pirates happened on October 11, 2015, but it is hardly scratching the surface. As already mentioned, the 2012 Copyright Act amendments, while a positive intent on the part of the government, fail to include effective protections to prevent the copying of movies in theaters. The export of this problem to other markets in the region adds to the gravity of poor enforcement in India and shows that India needs to enforce rights related to 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. It is yet another example of the denial of adequate and effective intellectual property rights serving as a trade barrier to U.S. industry.<sup>49</sup> The growing use of the internet across the country allows pirated books to be retrieved, copied, and distributed more easily than ever before, both physically and electronically. The dissemination of unlicensed scanned copies of academic materials has become a particularly large problem and is often done at the prompting of, or just outside the campuses of, Indian academic institutions.<sup>50</sup> In September 2016, the Delhi High Court rejected a copyright infringement petition brought under the Copyright Act by international publishers against a bookstore on the Delhi University campus, which had been selling photocopied sections of copyrighted textbooks. The judge found that photocopying equated to copying by hand.<sup>51</sup> One commentator in India called the judgment “a bold articulation of the principles of equitable access to knowledge — and one that deserves to be emulated globally.”<sup>52</sup> American industry groups continue to push for the Ministry of Human Resource Development without success to

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<sup>46</sup> *India, China the Problem Areas in Camcorder Piracy Cases*, Hollywood Reporter, Dec. 8, 2014.

<sup>47</sup> *Id.*

<sup>48</sup> INT’L INTELL. PROP. ALLIANCE, INDIA: 2016 SPECIAL 301 REPORT ON COPYRIGHT PROTECTION AND ENFORCEMENT (2016), available at <http://www.iipawebiste.com/rbc/2016/2016SPEC301INDIA.PDF>.

<sup>49</sup> *Id.*

<sup>50</sup> 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>.

<sup>51</sup> <http://www.thehindu.com/news/cities/Delhi/University-copying-books-for-teaching-is-not-copyright-violation-Delhi-HC/article14984190.ece>

<sup>52</sup> <http://www.thehindu.com/opinion/lead/A-blow-for-the-right-to-knowledge/article14987252.ece>

issue a statement or circular to academic and research institutions to combat the illegal use of photocopied and scanned materials.<sup>53</sup>

It is estimated that nearly a quarter of books in India are pirated.<sup>54</sup> 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.<sup>55</sup> Even Indian authors largely accept the copying of their own work, and police are hesitant to enforce copyright law.<sup>56</sup>

## VI. Conclusion

For the foregoing reasons, AFTI requests that USTR once again place India on its Priority Watch List, where it has been placed – except for the few years it was listed as a Priority Foreign Country – since the first Special 301 Report in 1989. AFTI further requests that USTR institute an OCR for India so that the Trump Administration can have full information to develop an “action plan” to ensure that India is meeting its obligations and trade commitments to the United States on intellectual property.

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<sup>53</sup> 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>.

<sup>54</sup> Ariel Bogle, *The World of India Book Piracy*, MELVILLE HOUSE, Jan. 7, 2013, <http://www.mhpbooks.com/the-world-of-indian-book-piracy/>.

<sup>55</sup> *Hearing on U.S.-India Trade Relations: Opportunities and Challenges Before the H. Comm. On Ways and Means*, 113<sup>th</sup> 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](http://waysandmeans.house.gov/uploadedfiles/iipa_statement_for_the_record_sc_trade_india_hearing_march_13_2013.pdf).

<sup>56</sup> 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](http://www.nytimes.com/2013/01/06/books/review/the-book-boys-of-mumbai.html?_r=0).