Alliance for Fair Trade with India

October 31, 2014

Susan Wilson
Director for Intellectual Property and Innovation
Office of the United States Trade Representative
600 17th Street NW
Washington, DC 20508

RE: 2014 Special 301 Out-of-Cycle Review of India

Dear Ms. Wilson,

The Alliance for Fair Trade with India ("AFTI") welcomes the opportunity to submit these comments on USTR's Special 301 "Out-of-Cycle Review" ("OCR") of India. AFTI was launched in June 2013 in support of increased action to resolve discriminatory trade practices in India, including the erosion of intellectual property rights ("IPR"), and to serve as a mechanism for engaging with U.S. policymakers on such issues. AFTI's diverse membership is comprised of organizations representing a range of U.S. industries adversely impacted by India's IPR policies, and in light of these concerns, our membership provided a lengthy submission to USTR earlier this year for its annual Special 301 review.

AFTI welcomed USTR's decision in its Special 301 Report to conduct an OCR of the Indian Government's IPR practices and policies. We remain concerned about the lack of any concrete steps on the part of India to remedy several longstanding issues. USTR's request for comments asks for information relating to the quality of the Government of India's engagement on IPR issues of concern and the quality of engagement interested parties have experienced with the Government of India on IPR issues. AFTI believes an inquiry into the ability to engage with the Government of India in a meaningful fashion on IPR issues of concern should be an important element of the OCR. But to be of real value to AFTI's members and the broader U.S. business community, the OCR should be about substance in addition to process.

Given AFTI's mandate and its focus on educating and working with U.S. policymakers, AFTI itself cannot provide significant insight on recent engagement with the Government of India, although several AFTI members are planning to submit their own comments on the OCR. AFTI can, however, speak to the substantive issues that are of concern to its members, and whose resolution AFTI believes should be a focus of the OCR. These issues include:

- India's compulsory licensing and forced tech transfer policies. In addition to very likely being WTO non-compliant, India's approaches to compulsory licensing and the forced transfer of technology are clearly intended as tools of industrial policy, to be used against foreign companies for the benefit of domestic Indian enterprises.

- Copyright infringement. Copyright infringement has long been problematic in India, and remains a point of major concern for AFTI. India's position as a haven for the illegal downloading and distribution of music, movies, and books is particularly worrisome.

- Protection of confidential data. Fourteen years after its first mention in the Special 301 Report, India has still failed to implement WTO-compliant regulations to protect confidential test and other data. India has not provided a structure to protect undisclosed test data submitted for the marketing approval of new chemical entities.

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 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 on the substantive concerns highlighted below.

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

The Alliance for Fair Trade with India

I. Copyright

a. AFTI Concerns

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. 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. 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.

Moreover, 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 theInternet. The amendments also failed to provide adequate tools to address the widespread copyright infringements affecting the country, and failed to introduce much needed anti-camcording legislation, despite its status as a longstanding problem for foreign and domestic film industries. The Act also provides multiple exceptions for personal use and for personal reproduction. In order to ensure compliance with the provisions of the Act, the Indian government committed to establishing a permanent Copyright Board. Despite assurances over the last year, this body has yet to be formed making many provisions of the Act inoperable.

b. AFTI Recommendations

In light of the above persisting issues, AFTI encourages the Modi Government and the Obama Administration to pursue greater bilateral public sector engagement on copyright issues, and specifically recommends the establishment of a copyright working group within the U.S.-India Trade Policy Forum in order to facilitate cooperation and exchange at the technical level between copyright protection and enforcement experts in the U.S. and Indian governments. Moreover, AFTI's membership calls for the inclusion of specific anti-camcording provisions in the draft Cinematograph Bill, pursuant to recent public statements by the Ministry of Information and Broadcasting.

II. Compulsory Licensing

a. AFTI Concerns

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 2012 to grant a compulsory license ("CL") to an Indian pharmaceutical company to allow it to manufacture a generic copy of Nexavar, an anti-cancer medicine manufactured by Bayer, denied Bayer adequate and effective protection of its intellectual property rights to the direct benefit of Indian drug maker Natco Pharma Ltd. ("Natco"). Despite significant international concern and scrutiny, this decision was affirmed by the Intellectual Property Appellate Board ("IPAB") in March 2013, and subsequently upheld by the Bombay High Court in July 2014. This series of decisions, and the approach to compulsory licensing that it represents, 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.

b. AFTI Recommendations

The AFTI membership calls on the Modi Government to make a public commitment to refrain from granting any additional compulsory licenses unless it is to meet genuine health emergencies as anticipated by the Doha Declaration on TRIPS and Public Health. Moreover, we call for publication by the Intellectual Property Appellate Board of a document clarifying the circumstances under which the "working" requirement under Section 84 of India's Patent Act would be met without manufacturing in India. Without such clarification, IPAB's March 4, 2013 decision could inappropriately pressure innovators outside of India to manufacture in India in order to avoid being compelled to license an invention to third parties.

III. Other Patent Issues

a. AFTI Concerns

India has a long and troubled history with regard to discriminatory patent policies, outside of compulsory licensing. 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." More than twenty years later, similar concerns regarding India's patent regime have resurfaced, as the 2014 Special 301 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."

The simple reality is that several troubling patent-related policies and practices have emerged in recent years that serve to discriminate against U.S. industry. These include the revocation of numerous patents by the Indian Controller General of Patents and the Intellectual Property Appellate Board, the denial of patent applications as well as the approval of generic medicines during a patent's term, pre-grant opposition procedures that are prone to abuse by

patent challengers, burdensome patent application requirements under Section 8 of the Indian Patents Act, the aforementioned granting of a compulsory license and the ongoing consideration of others, and narrow standards for patentability that are inconsistent with international standards.

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

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

b. AFTI Recommendations

AFTI calls on the Modi Government to cease imposing additional patentability criterion, such as the above-discussed "enhanced efficacy" requirement contained in Section 3(d). Moreover, we call on the Modi Government to establish a mechanism for confirming whether an item about to be manufactured is under patent. In light of recent cases such as *Merck v. Glenmark* and *Cipla v. Roche* we believe there needs to be greater regulatory coordination between officials in the state and central governments to confirm whether or not an item is under patent. Finally, our membership believes that U.S. industry would benefit from the Establishment of a patent working group within the U.S.-India Trade Policy Forum in order to facilitate technical collaboration between patent authorities in both countries that would facilitate more timely examination of patent applications.

IV. Protection of Confidential Test Data

a. AFTI Concerns

As early as 2000, and every year thereafter, USTR's Special 301 Report notes that India has failed to implement TRIPS-compliant regulations to protect confidential test and other data. India's TRIPS Article 39 obligations to protect 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." 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. Further, India must "not use such information for a commercial purpose, except with...written consent." India's failure to provide data protection subjects U.S. companies to unfair competition and violates India's obligations under multiple agreements.

b. AFTI Recommendations

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. For this reason, AFTI and its membership call on the Modi Government to amend the draft National Innovation Act such that it provides for data protection for pharmaceuticals and agro-chemicals in line with India's obligation under TRIPS Article 39.