



**The impact of competition
stemming from Indian
generics?**

**The price of medicines to
treat diseases such as HIV, TB
and cancer are down by **more
than 90%****

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our medicines**

**PERSISTENT US ATTACKS ON INDIA'S PATENT LAW & GENERIC COMPETITION
JANUARY 2015**

SUMMARY: Attacks by the US government and industry on India's patent laws began to intensify after India issued a compulsory licence in March 2012. These attacks – which aim to undermine generic competition – further amplified after the Indian Supreme Court's landmark April 2013 decision to uphold the rejection of a patent for a life-saving leukaemia drug.*

In 2014, this pressure continued through the US Trade Representative (USTR)'s unilateral Special 301 Report and Out-of-Cycle Review, two US International Trade Commission (USITC) investigations at the request of US Congress. This pressure has continued through multiple avenues of bilateral engagement on IP through the existing US-India Trade Policy Forum and the creation of a new high-level IP working group announced jointly by President Obama and Prime Minister Modi in September. These activities and interventions represent a concerted, years-long effort by the US to pressure the Indian government and judiciary to change its patentability standards and practices, and to limit the use of public health legal safeguards.

In spite of responses by Indian government officials that India's patent laws are compliant with international rules,¹ there is reason to be concerned that this pressure may be having an effect. The new government has delayed a decision to allow generic production of an exorbitantly-priced patented anti-cancer medicine that is unaffordable for patients in the country, in spite of a recommendation by a Health Ministry expert committee. Just before Prime Minister Modi's visit to the US, India announced the development of a national intellectual property rights (IPR) policy to 'clarify' existing IP laws, the drafting of which was tasked to a think tank with worrying potential conflicts of interest.²

BACKGROUND: India has long been considered the 'pharmacy of the developing world' due to the country's critical role as a producer of affordable, quality generic versions of life-saving medicines relied upon by developing countries and international donor-funded treatment programmes alike. For example, more than 80 percent of donor-funded HIV treatments in developing countries are sourced from Indian generic manufacturers.³ India continues to be a source for more affordable generics in part because of a patent law that applies legal safeguards for public health that comply with international trade rules outlined in the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS

* See full timeline of events here:

http://www.msfaaccess.org/sites/default/files/MSF_assets/IP/Docs/IP_Timeline_US%20pressure%20on%20India_Sep%202014_0.pdf

Agreement). However, in recent years, including throughout 2014, these legal safeguards have repeatedly come under attack by the US government and industry.

Key IP rules targeted in the persistent attacks on India's law throughout 2014, despite these measures being compliant with international trade rules, include:

1. **Patentability criteria:** India's law is strict about what does and does not deserve a patent, reserving patents for new drugs and discouraging secondary patenting i.e. new forms of known drugs and ensuring that patent claims on medicinal compounds meet the inventive step criteria. This means that some patents awarded in countries such as the US do not merit patents in India.
2. **Patent oppositions (pre-grant and post-grant):** Additional public health safeguards allow any interested party to oppose a patent if they deem a given drug ineligible for a patent under India's law, before (pre-grant) or after (post-grant) a patent has been granted.
3. **Compulsory licences:** All signatory countries to the WTO TRIPS Agreement, including India and the US, have the right to allow a third party to produce a generic version of the drug in question by granting a compulsory licence; for example, if that drug is deemed unaffordable or unavailable by the Patent Controller or the government.⁴ A 'compulsory licence' issued by the Patent Controller in 2012 for an unaffordable cancer drug brought its price down by 97% almost instantly.
4. **Discretion for injunctive relief:** In patent infringement cases, some courts have refused to automatically hand out injunctive relief that bans the availability of a generic product in the market. Such injunctive relief can be sought as a remedy by multinational pharmaceutical companies against generic producers. Much like US courts,⁵ Indian courts have argued that they must weigh the public interest, including the potential risk of denying patients access to life-saving medicines, in determining the appropriate remedy.
5. **TRIPS plus measures:** There is persistent pressure on India to adopt patent term extension and data exclusivity, measures not required under the TRIPS agreement (therefore called 'TRIPS plus') and considered a threat to the production, registration and supply of affordable medicines from India.

KEY EVENTS IN THE TIMELINE OF US PRESSURE ON INDIA IN 2014

First US International Trade Commission (USITC) investigation of India's trade and investment policies

September 2013 – December 2014

The USITC launched an investigation into trade policies in India at the request of the Senate Committee on Finance and the House Committee on Ways and Means in September 2013.⁶ Multiple pharmaceutical representatives as well as civil society representatives, including MSF,⁷ participated in a USITC hearing for the investigation held in February 2014.

The result of this investigation was released in a report on 22 December 2014.⁸ Not surprisingly, the report concluded that a wide range of restrictive Indian policies have adversely affected US companies doing business in India. Among the various key policy barriers, treatment of intellectual property (IP) was found to have large negative effects on specific US industries. The report further suggested that if tariff and investment restrictions were fully eliminated and standards of IP protection were made comparable to US and Western European levels, US exports to India would rise by two thirds.

US Trade Representative (USTR)'s Special 301 Report on intellectual property (IP) names India on Priority Watch List

February 2014 - April 2014

The USTR released the 2014 Special 301 Report⁹ on 30 April 2014 after more than 100 submissions on multiple issues and countries, including MSF's own submission highlighting India's crucial role as the 'pharmacy of the developing world.'¹⁰ India has been named on a warning list in this report every year, and for the second consecutive year, India was named on the Priority Watch List. This year's report specifically noted concerns with Section 3(d), pre-grant oppositions and compulsory licences.

In a bid to hike up the pressure, the report also called for an Out-of-Cycle Review (OCR) for India in the last quarter of 2014 to evaluate the ongoing engagement on issues of concern with respect to India's environment for IP protection and enforcement as a 'tool' to 'encourage progress on IP rights (IPR) issues of concern.' [See OCR entry below.]

Second US International Trade Commission investigation of India's trade and investment policies **September 2014 – September 2015**

A request for a second ITC investigation on India's trade practices was made by US Congress on 24 September 2014.¹¹ This investigation is in addition to the USITC investigation into India's trade and investment policies requested by the same lawmakers in August 2013, the results of which were reported in December 2014. The results of the second investigation are requested by 24 September 2015.

Development of national IPR Policy in India **September 2014 – January 2015 (and beyond)**

The Indian Commerce & Industry Minister Nirmala Sitharaman under the newly elected government announced the framing of a National Intellectual Property Rights (IPR) Policy to safeguard national interest and bring clarity to the existing patent law on 9 September 2014.¹² An IP Think Tank was announced the following month to draft the new National IPR Policy and to advise the department on issues related to IP.¹³

In December 2014, the Department of Industrial Policy and Promotion (DIPP) released a draft IPR Policy¹⁴ and solicited comments from stakeholders, due 30 January 2015.¹⁵ First draft of the policy recently released is alarming. The draft emphasises patent monopolies as the key driver of innovation, when such claims have been refuted by numerous studies, and experts at the World Health Organization, which have found IP to be a barrier to both access to affordable medicines, and innovation for medicines desperately needed by developing countries for diseases such as TB.

Opportunities for US pressure on India through additional bilateral fora **September 2014 – ongoing**

Following the visit of the new Prime Minister to the US, a joint statement was released on 30 September 2014 by the leaders of both governments. The statement included a "*commitment to establish an annual high-level Intellectual Property (IP) Working Group with appropriate decision-making and technical-level meetings as part of the Trade Policy Forum.*"¹⁶ A few days later the Department of Intellectual Property and Promotion (DIPP) issued a clarification on the establishment of high level IP working group between the US and India highlighting the existence of a bilateral trade policy forum since 2010, affirming that India's IPR legal regime is fully TRIPS compliant, and rejecting any unilateral pressure by the US, for example through the Special 301 Report.

In November 2014, the US-India Trade Policy Forum met for the first time in four years during which US Trade Representative Michael Froman "extensively highlighted" IPR concerns, specifically naming compulsory licences among the challenging issues, noting "*the US is watching closely.*"¹⁷

USTR 2014 Out-of-Cycle Review (OCR) for India **October 2014 – December 2014**

On 14 October 2014 the USTR launched the OCR for India, as recommended in the April 2014 Special 301 Report, to evaluate the government of India's engagement on IPR issues of concern.¹⁸ Twenty comments concerning information, views, acts, policies, or practices relevant to this evaluation were submitted over the two-week time frame, including by MSF.¹⁹ In December 2014, USTR announced the results of this OCR, noting 'useful comments' made by India, and urging India to 'strengthen and deepen bilateral engagement on IP issues in the coming months and beyond.'^{20,21}

DIPP defers decision on issuance of compulsory licence for cancer drug

October 2014

The new Indian government defers the decision to allow generic production of an exorbitantly-priced patented anti-cancer medicine that is unaffordable in the country—an action recommended by a Health Ministry expert committee which provided additional evidence to show that many public institutions including Indian Railways, CGHS, Army Hospitals are procuring the drug, but in small quantities partially because of its high price²².

Pressure continues in 2015...

In addition to the ongoing development of a National IPR Policy in India and the ongoing second USITC investigation in India, US President Obama is scheduled to visit India 25-27 January. During this visit, a joint statement on further IP commitments is expected, as well as the potential reinstatement of bilateral investment treaty (BIT) negotiations.²³

The US Government has a policy of negotiating and exerting pressure on governments to give its companies the right to sue governments — known as Investor-State Dispute Settlement (ISDS) —for high amounts of damages if a law or policy harms their investment. India will face the same pressure to include such provisions as it pushes to negotiate a bilateral investment treaty with the US. ISDS is controversial because it allows corporations to sue governments in international arbitration tribunals, bypassing national courts undermining the ability of the government to regulate in public interest. Several such disputes have already been filed by US corporations against governments in the area of health. For example, the US pharmaceutical company Eli Lilly used ISDS to start proceedings against Canada in a foreign tribunal, claiming \$500 million as compensation on the grounds that a Canadian court's decisions to invalidate evergreening patents on some of the company's best-selling medicines deprived it of future profits and interfered with the enjoyment of its investments.²⁴

¹ See for example: <http://timesofindia.indiatimes.com/business/india-business/India-ready-to-take-on-US-over-patents-at-World-Trade-Organization/articleshow/30967967.cms> and http://articles.economictimes.indiatimes.com/2014-03-05/news/47895347_1_anand-sharma-compulsory-licence-intellectual-property-rights

² <https://donttradeourlivesaway.wordpress.com/2014/12/02/rethinking-ip-think-tank/>

³ <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2944814/>

⁴ http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm

⁵ <http://www.supremecourt.gov/opinions/05pdf/05-130.pdf>

⁶ <http://www.gpo.gov/fdsys/pkg/FR-2013-09-05/pdf/2013-21499.pdf>

⁷ <http://www.msfaaccess.org/content/msf-oral-testimony-united-states-international-trade-commission-public-hearing-trade>

⁸ <http://www.usitc.gov/publications/332/pub4501.pdf>

⁹ <http://www.ustr.gov/sites/default/files/USTR%202014%20Special%20301%20Report%20to%20Congress%20FINAL.pdf>

¹⁰ <http://www.regulations.gov/#!documentDetail;D=USTR-2013-0040-0080>

¹¹ <http://waysandmeans.house.gov/news/documentsingle.aspx?DocumentID=394536>

¹² http://articles.economictimes.indiatimes.com/2014-09-09/news/53730889_1_ipr-policy-ipr-regime-out-of-cycle-review

¹³ In addition to drafting national IPR policy, some of the problematic terms of reference for the IP think tank include highlighting anomalies in the present IPR legislations, advising on possible solutions to the Ministry and examining the current issues raised by industry associations and those that may have appeared in media and to give suggestions to the Ministry of Commerce on such issues.

¹⁴ http://dipp.nic.in/English/Schemes/Intellectual_Property_Rights/IPR_Policy_24December2014.pdf

¹⁵ http://dipp.nic.in/English/acts_rules/Press_Release/pressRelease_IPR_Policy_30December2014.pdf

¹⁶ <http://www.whitehouse.gov/the-press-office/2014/09/30/us-india-joint-statement>

¹⁷ <http://www.ip-watch.org/2014/11/24/ustr-froman-presses-india-on-ipr-regime/>

¹⁸ <https://www.federalregister.gov/articles/2014/10/14/2014-24309/2014-special-301-out-of-cycle-review-of-india>

¹⁹ <http://www.doctorswithoutborders.org/article/msf-submission-regarding-ustr-special-301-out-cycle-review-india>

²⁰ <http://www.ustr.gov/about-us/press-office/press-releases/2014/December/Statement-by-the-Office-of-the-USTR-on-the-Out-of-Cycle-Review-of-India>

²¹ <http://indiatgether.org/commercial-versus-social-lens-for-intellectual-property-rights-ipr-policy-government>

²² http://articles.economictimes.indiatimes.com/2014-10-16/news/55106950_1_cancer-drug-dasatinib-health-ministry-compulsory-licence

²³ http://zeenews.india.com/business/news/economy/investment-treaty-intellectual-property-on-india-us-agenda_116565.html

²⁴ Eli Lilly is currently using similar investor-state-dispute-settlement provisions of NAFTA to sue the Canadian government for loss of expected profits as a result of a Canadian court decision on a patent opposition: <http://www.politico.com/story/2013/09/eli-lilly-sues-canada-over-drug-patents-96743.html?hp=r9>