



## **A TIMELINE OF U.S. ATTACKS ON INDIA'S PATENT LAW & GENERIC COMPETITION**

### **JANUARY 2015**

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Before 2005, India did not have to grant patents on pharmaceutical products, according to international trade rules. The absence of patent barriers in India meant that the country quickly became a key producer of more affordable life-saving medicines, including for HIV, which are now used across developing countries. Currently, more than 80 percent of donor-funded HIV treatments in developing countries is sourced from Indian generic manufacturers.<sup>1</sup>

India started reviewing and granting pharmaceutical patents in 2005, in line with India's obligations upon joining the World Trade Organization (WTO). When designing its patent law however, India included a number of key public health safeguards, which fully conform to international trade rules outlined in the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. India's law is strict about what does and does not deserve a patent, reserving patents for new drugs and discouraging secondary patenting on modifications of known drugs unless they show a therapeutic advantage over treatments that already exist (Section 3(d) of India's patent law). This means that some patents awarded in countries such as the U.S. do not merit patents in India.

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. Oppositions can be filed before or after a patent has been granted. These are called 'pre-grant' and 'post-grant' oppositions. India also has the right under the WTO TRIPS Agreement — as does any other signatory country — to allow a third party to produce a generic version of the drug in question by granting a compulsory license. For example, a country may do so if that drug is deemed unaffordable or unavailable by the government.<sup>2</sup>

In March 2012, India issued its first such compulsory license to allow production to proceed of a more affordable version of a cancer drug that the Indian government deemed unaffordable. This legal decision by the Indian government provoked a global outcry by multinational pharmaceutical companies, their interest groups and several representatives of the U.S. government, who continue to put forward the falsehood that compulsory licenses can only be issued in the case of public health emergencies and only for certain diseases. No such restriction applies in the TRIPS Agreement.<sup>3</sup>

Additionally, in patent infringement cases, some courts have refused to automatically hand out injunctive relief that bans the commercialization of a product. Such injunctive relief can be sought as a remedy by multinational pharmaceutical companies against generic producers. Indian courts have argued, as U.S. courts have also argued since the *eBay Inc. v. MercExchange, L.L.C.* Supreme Court decision,<sup>4</sup> that they must weigh the public interest in choosing the appropriate remedy. Indian courts have argued that the public interest includes the potential risk of denying patients access to life-saving medicines.

In April 2013, the Indian Supreme Court ruled against pharmaceutical company Novartis, ending a seven-year legal battle the company had been waging against India's patent law, following the rejection of the company's patent application for a leukaemia drug in 2006. The Indian Supreme

Court upheld the rejection of the patent application on a salt form of imatinib. The Court denied its patentability as imatinib had already been disclosed in a 1992 patent and the salt form did not fulfil the Indian law's patentability requirements. This landmark court ruling has provoked a massive multinational pharmaceutical industry outcry, as well as intensified pressure from several Members of the U.S. Congress to push the U.S. government to take action against India's legal decisions.

The U.S. has recently stepped up pressure on India in support of the U.S. pharmaceutical industry's complaints, with the U.S. International Trade Commission (USITC) two fact-finding investigations at the request of U.S. Congress on India's trade practices, including on intellectual property (IP) for pharmaceuticals. In addition, in 2014 the U.S. Trade Representative (USTR) once again placed India on the Priority Watch List in its Special 301 Report and announced an Out-of-Cycle Review (OCR) of India's IP regime, which signals the threat of sanctions against India.

At the same time, both countries have stepped up their engagement on trade and investments, including discussions on a bilateral investment treaty (BIT). The impact of the pushback by the U.S. pharmaceutical industry is expected to be reflected in the BIT negotiations that could include demands from the U.S. government to allow pharmaceutical companies to sue the Indian government — through what's known as an investor-state dispute settlement (ISDS) provision — if a national law, court decision or policy harms their investment or expected profits.<sup>5</sup>

Mr. Modi, Prime Minister of India, made his first visit to the U.S. in September 2014. In January 2015, President Obama will visit India. The issue of IP and pharmaceuticals has been one of the top issues on the discussions with between India and U.S. government and industry representatives.

Below is a timeline of events illustrating the escalation of pressure against India's generic drug policies in the wake of India issuing a compulsory license in 2012 and the Indian Supreme Court's landmark 2013 decision on Novartis' leukaemia drug. In sum, these activities and interventions are aimed at [pressuring](#) the Indian government and judiciary to change its [patentability standards](#) and practices and to limit the use of public health legal safeguards.

## **Timeline**

India issues compulsory license on sorafenib tosylate

<p><b>12 March 2012:</b> In March 2012, India's Patent Controller took the step of issuing a compulsory license to an Indian generic manufacturer. With German pharmaceutical company Bayer charging \$5,500 per person per month in India for a kidney and liver cancer medicine (sorafenib tosylate, marketed as Nexavar), the Indian government deemed this price unaffordable and granted a compulsory license to generic manufacturer Natco in exchange for a royalty to be paid to Bayer. As a result, a generic version is now available and the price is 97 percent lower.</p>
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## **27 March 2012**

US Commerce Secretary raises concerns on compulsory license

U.S. Commerce Secretary John Bryson in his New Delhi meeting with Commerce & Industry Minister Anand Sharma raised concerns about the compulsory license issued to an Indian generic company, indicating this acted as “dilution of the international patent regime.”<sup>6</sup>

## **27 June 2012**

US talks of a 'violation of the TRIPS Agreement'

Teresa Stanek Rea, the Deputy Under Secretary of Commerce for Intellectual Property and the Deputy Director of the United States Patent and Trademark Office (USPTO), stated in testimony before the U.S. House of Representatives that the compulsory license issued by India was in violation of the TRIPS Agreement. She further described the lobbying efforts by USPTO against Indian issuance of compulsory licenses through the U.S. Embassy in Delhi.<sup>7</sup> At a later day, USPTO retracted part of her testimony.<sup>8</sup>

## **January 2013**

Expert committee to identify overpriced drugs established

An expert committee was established by the Indian Ministry of Health with the mandate to identify exorbitantly-priced drugs for which compulsory licenses may be issued by the Department of Industrial Policy and Promotion (DIPP), Ministry of Commerce & Industry.

## **21 February 2013**

U.S. Chamber of Commerce ranks India lowest on IP rights strengths

The Global Intellectual Property Center (GIPC) of the U.S. Chamber of Commerce introduced their new IP Index, ranking 11 countries on the strength of their IP rights systems, with the U.S. ranked highest and India ranked lowest. In a press statement on 15 March 2013, GIPC stated that the Government of India should resist the use of compulsory licenses in all but the most extreme cases, which is contrary to international WTO rules.<sup>9</sup>

## **13 March 2013**

Pfizer attacks Indian patent law in U.S. trade hearing

Roy F. Waldron, Chief Intellectual Property Counsel for Pfizer, presented testimony before U.S. House of Representatives' Committee on Ways and Means' Subcommittee on Trade at a hearing on "U.S.-India Trade Relations: Opportunities and Challenges."<sup>10</sup> Waldron's [testimony](#) included a series of complaints against India's patent law, focusing on the revocation of patents by Indian courts, failure to obtain patents for some products, use of pre-grant oppositions, issuance of the compulsory license, absence of TRIPS-plus provisions such as patent linkage in the drug regulatory system, and the new proposal of the Health Ministry to consider compulsory licenses for patented medicines exorbitantly priced in the Indian market. He then made a misleading statement saying that India has abused compulsory licenses as they are intended to be used in national emergencies and situations of extreme urgency. Waldron expressed concern that since other developing countries look to India's generic policies as a model, India's actions reverberate far beyond its borders. He recommended that the U.S. government increase their engagement with the Indian government, and raise concerns in bilateral engagement, as well as at every available multilateral forum to send a strong signal to the Indian government and to other governments that such actions are not condoned by the U.S. government. Waldron further recommended that the U.S. government pursue a robust trade agenda that includes strong IP, including current U.S. government TRIPS-plus demands in the Trans-Pacific Partnership Agreement (TPP).

In the following months, the effects of Pfizer's testimony, no doubt combined with other lobbying efforts, were reflected in the U.S. government's engagement with India and an escalation of statements against Indian patent law.

**19 March 2013**

**US frustration with India's use of compulsory licenses grows**

During a U.S. Senate Finance Committee Hearing on the President's 2013 Trade Agenda, Senator Tom Carper (D-DE) characterized India's use of compulsory licenses as "inappropriate" and asked then-Acting United States Trade Representative (USTR) Demetrios Marantis what he intended to do about it. Marantis replied that "there are some very real frustrations regarding concerns with compulsory licensing."<sup>11</sup>

**1 April 2013:**

**Novartis loses seven year battle against Indian patent law**

The Supreme Court of India upheld the stricter patentability standard which was at the crux of Swiss company Novartis' seven year legal battle against the Indian patent law. Novartis was contesting the Indian patent office's and appellate body's decisions to reject the company's application for a secondary patent on the salt form of imatinib, a life saving drug for treating chronic myeloid leukaemia.<sup>12</sup> **The pressure intensified right after the landmark Novartis decision.**

**24 April 2013**

**India accused of moving in the wrong direction with its patent law**

In a hearing of the Senate Finance Committee on opportunities and challenges for Trans-Pacific Partnership negotiations, witness David Hirschmann of the Global Intellectual Property Center of the U.S. Chamber of Commerce specifically singled out India as a country moving in the "wrong direction" with respect to advancing innovation and IP.<sup>13</sup>

**1 May 2013**

**India included in Priority Watch List by US Trade Representative - MSF opposes**

The United States Trade Representative released the 2013 Special 301 Report listing India on the "Priority Watch List." The report cites the Novartis decision<sup>14</sup> and India's first compulsory license decision.<sup>15</sup> The report further states that the U.S. will be closely monitoring compulsory licensing "developments" in India. Médecins Sans Frontières (MSF) strongly opposes the use of the Priority Watch List to pressure India. MSF's Access Campaign said in a statement on 2 May 2013 that "by placing India on the Watch List in its annual Special 301 Report, the U.S. is disregarding the fact that India has acted within its rights under existing international trade rules and that its measures will increase access to medicines for millions."<sup>16</sup>

**4 June 2013**

**India bows under pressure and grants Pfizer relief against generic competition**

Pfizer managed to obtain prompt and effective interim relief from the Delhi High Court, the Supreme Court and the IPAB, in a shorter time than any patient or generic company has ever been able to in the Indian court system. The Intellectual Property Appellate Board stayed revocation of Pfizer's patent on sunitinib and even granted it injunctive relief against Cipla.

**6 June 2013**

**Industry writes letter to U.S. President, concerned about India's use of IP law**

The heads of 17 United States industry associations, including the U.S. Chamber of Commerce, issued a letter to President Barack Obama. The letter raised concerns about the recent policy decisions in India undermining internationally recognised IP standards, putting at risk a growing bilateral trade relationship.<sup>17</sup>

### **US Senate Committee on Finance members advocate for penalties for India**

**On the same day** at the U.S. Senate Committee on Finance hearing to consider the nomination of Michael Froman for United States Trade Representative, several members of the committee advocated for penalizing India in trade relations for recent actions, such as the Novartis ruling and other “anti-IP” practices. Senators Orrin Hatch (R-UT), Rob Portman (R-OH) and Robert Menendez (D-NJ) all specifically highlighted India in their statements and questions.<sup>18</sup>

### **13 June 2013**

#### **U.S. Senate committee writes to Secretary of State criticising India's IP policies**

The U.S. Senate Committee on Finance Chairman Senator Max Baucus (D-MT) and Ranking Member Senator Orrin Hatch (R-UT) wrote to Secretary of State John Kerry criticizing India’s IP policies. The letter specifically singled out the compulsory license issued by India and the Novartis decision by the Indian Supreme Court. The letter urged the Secretary of State to raise these concerns on his visit to India.<sup>19</sup>

### **18 June 2013**

#### **Momentum grows as 170 Members of U.S. Congress write to the President criticising India**

The campaign against India’s patent system picked up momentum when [170 Members of U.S. Congress sent a letter](#) to President Barack Obama criticizing India for its "intellectual property climate." In particular, the letter reflected concerns of Members of Congress around patent revocation policies. The Members specifically criticize the [compulsory license](#) granted by India for a cancer drug and even alleged that the new proposals by the Indian Health Ministry for compulsory licensing are being improperly driven by an interest in growing the pharmaceutical market in India. They urged the Obama administration to “send a strong signal to the Indian government that these actions are inconsistent with India’s international obligations and set a precedent.”<sup>20</sup>

#### **US business groups launch coalition against India’s trade practices**

**On the same day**, several United States business groups launched a coalition — the Alliance for Fair Trade with India (ATFI), to take aim against what they say are discriminatory trade practices in India against U.S. exports. Co-chaired by the National Association of Manufacturers (NAM) and the U.S. Chamber of Commerce’s Global Intellectual Property Center (GIPC), with Pharmaceutical Research and Manufacturers of America (PhRMA) as one of its members, AFTI is set to work with the Obama administration and Members of Congress to pursue policy options that will help create a “level playing field” for U.S. exporters operating in India.<sup>21</sup>

### **19 June 2013**

#### **India defend recent IP decisions on Embassy of India's website**

A ‘Note on India’s Intellectual Property Regime’<sup>22</sup> by Nirupama Rao, the Indian Ambassador to the United States, was hosted on the Embassy of India’s website, providing statistics on patents granted in India and providing legal context to the Novartis court decision and the compulsory license.

### **20 June 2013**

#### **India licensing practices called discriminatory by US House Committee**

A letter was sent by the U.S. House Committee on Ways and Means’ Subcommittee on Trade to President Obama arguing that India’s policies are hindering access to India’s market by U.S.

businesses “through non-transparent and often discriminatory, regulatory and licensing procedures.” Issuance of a compulsory license, revocation of patents and drug pricing policy were mentioned.<sup>23</sup>

### **On the eve of the U.S - India Strategic Dialogue, Secretary of State is urged to stop India**

**On that same day**, 40 U.S. Senators wrote a letter to Secretary of State John Kerry, on the eve of the U.S.-India Strategic Dialogue, urging the State Department to take steps to stop India’s “discriminatory trade and economic practices.” The Senators complained about the deteriorating environment for IP protection in India given the recent actions by India of revoking patents for certain lifesaving medicines.<sup>24</sup>

Pfizer’s Chief Intellectual Property Officer Roy Waldron publicly stated that they have been speaking with the Office of the U.S. Trade Representative and the administration and said, “we’re very hopeful that this issue has been raised during Secretary Kerry’s visit to India.”<sup>25</sup>

### **27 June 2013**

#### **Further criticism of India's IP laws at U.S. hearing: "A Tangle of Trade Barriers"**

U.S. House of Representatives’ Committee on Commerce & Energy’s Subcommittee on Commerce, Manufacturing and Trade held a hearing on Indian IP policy: “A Tangle of Trade Barriers: How India’s Industrial Policy is hurting U.S. Companies.” Much of the event was devoted to U.S. drug company Pfizer’s complaints about Indian policies that foster generic competition. The hearing included criticism of India’s recent actions, citing the use of compulsory licenses and denial of certain pharmaceutical patents in the past 18 months. Rohit Malpani of MSF’s Access Campaign was invited to provide testimony. MSF testimony highlighted the positive public health impact that the use of legal safeguards in Indian patent law has had and how restricting abuse of patenting practices and the issuance of compulsory licenses are legal and respect existing international trade rules.<sup>26</sup>

### **11 July 2013**

#### **U.S. Trade Representative meets with India's Commerce Minister**

U.S. Trade Representative Michael Froman, in his Washington meeting with India’s Commerce Minister Anand Sharma, raised concerns regarding the recent developments in India’s IP climate.<sup>27</sup>

#### **Indian Finance Minister defends compulsory licensing**

**On that same day**, delivering the key note address at the leadership summit of the [U.S.-India Business Council](#) (USIBC) in Washington, the Indian [Finance Minister](#) Mr. [P. Chidambaram](#) stated that because India and the U.S. were both signatories to the World Trade Organization, if the U.S. government had concerns with the Indian patent law, it should start the legal proceedings for a WTO dispute settlement resolution. The Minister confirmed that there had been only one case of compulsory drug licensing in India and that the decision had been upheld during judicial review on each of the grounds: sufficient quantities of the drug were not available in India; it was not being sold at an affordable price; and the patent was not being worked in India.<sup>28</sup>

### **14 July 2013**

#### **U.S. Vice President speaks at the Bombay Stock Exchange**

U.S. Vice President Joe Biden said in a speech at the Bombay Stock Exchange that “protection of intellectual property was a tough challenge for trade between the U.S. and India, and an obstacle in the business environment.”<sup>29</sup>

**17 July 2013**

**The American Enterprise Institute hosts event to discuss the U.S. - India IP dispute**

The American Enterprise Institute (AEI) hosted an event titled, “Pharmacy to the world: India and the global prescription drug trade,” to discuss the current IP dispute between India and the U.S. and the recent actions by India, specifically the Novartis ruling. Panelist Diane Farrell of the U.S.-India Business Council said IP rights in India are a big problem, claiming that the U.S. has never issued a compulsory license.<sup>30</sup>

**18 July 2013**

**The U.S. Chamber of Commerce issues report on India's "anti-IP" stance**

The Global Intellectual Property Center of the U.S. Chamber of Commerce issued a report, “India: International Outlier on IP” and hosted an event discussing India’s “anti-IP” stance and the need for stronger IP enforcement in India.<sup>31</sup>

**August 2013**

**Op-ed by Indian Ambassador to the United States defends India's position**

Nirupama Rao, the Indian Ambassador to the United States, published an op-ed where she presented the Indian government’s position. In her op-ed she defended the Novartis Supreme Court decision as a tool to strengthen, not weaken, patent law and argued the TRIPS compliance of the compulsory license issued to make a cancer medicine affordable for Indian patients. Ms. Rao highlighted that in more than six decades India has issued only one compulsory license on a compound pharmaceutical. From 2005 to 2011, more than 4,000 patents for pharmaceutical inventions were issued by the Indian Patent Office. Of those granted, substantial numbers — 20-30 percent — were awarded to U.S.-based companies each year, and more than 85 percent were owned by foreign companies in India.<sup>32</sup>

**2 August 2013**

**Further attacks on India: U.S. House committee writes letter to U.S. International Trade Commission**

Senator Max Baucus (D-MT), Senator Orrin Hatch (R-UT), Representative Dave Camp (R-MI) and Representative Sander Levin (D-MI), the Congressional leaders of the Senate Committee on Finance and the House of Representatives Committee on Ways and Means, wrote a letter to the U.S. International Trade Commission requesting an investigation into “India’s unfair trade practices that discriminate against U.S. exports and investments.”<sup>33</sup>

**5 September 2013**

**U.S. International Trade Commission launches investigation**

The U.S. International Trade Commission announced that it would be investigating trade policies in India at the request of the Senate Committee on Finance and the House Committee on Ways and Means.<sup>34</sup>

**24 September 2013**

**14 U.S. governors write to President ahead of Indian Prime Minister's visit**

Ahead of Indian Prime Minister Manmohan Singh’s visit to the U.S., a bipartisan group of 14 U.S. governors jointly wrote a letter to US President Barack Obama urging him to raise concerns to India regarding India’s trade and investment policies, which they claimed continue to threaten the IP rights of U.S. industry and induce barriers to trade.<sup>35</sup>

## **26 September 2013**

### **Alliance for a Fair Trade with India writes to President ahead of Indian Prime Minister's visit**

Alliance for a Fair Trade with India\* wrote to President Obama, urging him to address India's discriminatory trade barriers and weak IP protection during his meeting with India's Prime Minister Manmohan Singh, who was scheduled to visit the U.S. that week. The letter highlighted India's "harmful trade policies" including revocations of medical patents and issuing compulsory licenses.<sup>36</sup>

## **25 November 2013**

### **Commerce Minister of India stands firm**

Anand Sharma, Commerce Minister of India, stated in a press conference that the Indian government is not lax on pharmaceutical policy and is committed to protect Indian generics and also to ensure that the Indian pharmaceutical industry continues to produce new molecules, new versions, and a new generation of medicines both for HIV/AIDS and other endemic diseases like tuberculosis (TB), malaria and other life-threatening diseases. He further mentioned that the India's Patents Act does not accept evergreening or the registration of a patent when a product is going off patent if there is no new discovery.<sup>37</sup>

## **29 January 2014**

### **US Chamber of Commerce IP Index again describes India IP as weak**

The U.S. Chamber of Commerce's Global IP Center released the International Intellectual Property Index 2014, once again categorizing India as having the weakest IP environment of all countries included in the IP index. Reasons cited in the report for India's weak IP environment included the continued use of compulsory licenses, patent revocations, and weak legislative and enforcement mechanisms.<sup>38</sup>

## **12-14 February 2014**

### **MSF objects to pressure on India at the International Trade Commissions hearing**

The U.S. International Trade Commission (USITC) held a two-day hearing, "Trade, Investment and Industrial Policies in India: Effects on the U.S. Economy," as part of its investigation of Indian trade. The hearing included speakers representing pharma (BIO, PhRMA, Bayer) and civil society/public interests, including MSF. MSF expressed strong objections to "the pressure exerted on India for using legal flexibilities to protect public health." MSF reiterated the point that "India's measures are fully compliant with global trade rules and with the laws of India."<sup>39</sup> The ITC investigation result was released in a report on 22 December 2014 [see entry].<sup>40</sup>

## **24 February 2014**

### **Pharmaceutical industry calls for India to remain on the Special 301 watch list**

As part of its annual process for the Special 301 Report, the Office of the U.S. Trade Representative hosted a hearing. This year's submissions included over 100 comments, including from representatives for pharmaceutical industry recommending that India remain on the Special 301 watch

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\* Alliance for a Fair Trade with India was launched in June 2013, representing major sectors of the U.S. economy in support of increased action to resolve discriminatory trade practices, including the erosion of intellectual property (IP) rights in India. The Alliance for Fair Trade with India (AFTI) is co-chaired by the National Association of Manufacturers and the U.S. Chamber of Commerce's Global Intellectual Property Center. Since its launch, this alliance has played a critical role in mobilizing US political representatives to take a position against the trade and policy decisions being taken in India particularly in relation with Intellectual Property Rights that is affecting the US business in India.  
<http://www.aftindia.org/>



list. MSF submitted comments this year that focused on the role of India and legal use of TRIPS flexibilities and their importance for access to affordable medicines for millions worldwide.<sup>41</sup>

#### **25 February 2014**

##### **India announces WTO challenge if the U.S. issues trade sanctions**

Through an interview with a leading newspaper in India, Indian government officials made an announcement that if the US designates India with the status of “Priority Foreign Country” and puts any trade sanctions on India, then these actions will be challenged at the WTO.<sup>42</sup>

#### **4 March 2014**

##### **Indian Commerce & Industry Minister compares U.S. and India’s use of compulsory licenses**

In a press conference, Anand Sharma, Indian Commerce & Industry Minister, accused the United States of protectionist trade policies while asserting that India's trade and IP rights are compliant with the respective multilateral regimes. Defending India’s decision on issuance of a compulsory license, Sharma said that issuance of compulsory license is a flexibility available to all countries and India has used it only once after following due process, unlike the U.S. which has issued compulsory licenses several times through executive authorities. *"India has never invoked this facility through an executive authority, which India can. And in this case (of Nexavar) also it was not the executive decision,"* he said. *"The US has invoked executive decisions for compulsory licenses."*<sup>43</sup>

#### **30 April 2014**

##### **India included on USTR’s Priority Watch List for a second year**

USTR released its Special 301 Report for 2014 and listed India on Priority Watch List, the same category India was listed in the year prior.<sup>44</sup> Countries placed on the Priority Watch List are the focus of increased bilateral pressure.

In a bid to hike up the pressure on India, this year’s Special 301 Report proposed 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. The Report describes the OCR as a ‘tool’ to ‘encourage progress on IPR issues of concern.’ This tool could potentially be used as a coercive measure to pressure India to refrain from using the public health safeguards enshrined in its patent law. USTR issued a statement concluding the OCR in December [see entry].

#### **24 July 2014**

##### **U.S. Department of Commerce names IP protection and enforcement as a barrier to U.S.- India trade**

During a hearing held by the U.S. House of Representatives Committee on Foreign Affairs Subcommittee on Asia and the Pacific, Arun Kumar from the U.S. Department of Commerce made a statement regarding “U.S.-India relations under the Modi Government,” naming protection and enforcement of IP rights (IPR) among the issues that limit U.S.-India trade.<sup>45</sup>

#### **9 September 2014**

##### **Indian Government announces plans to draft National IPR Policy**

In a press briefing to mark 100 days of the newly elected Modi government, Indian Commerce & Industry Minister Nirmala Sitharaman announced the framing of a National Intellectual Property Rights (IPR) Policy to safeguard national interest and bring clarity to existing patent law. “India has well-established IPR laws, but it is important to spell it out in the form of a policy for the entire world to see,” she said in the press briefing.<sup>46</sup> A draft Policy was released in December 2014 [see entry], and comments are currently being accepted.

#### **19 September 2014**

##### **PhRMA publishes op-ed targeting Indian Prime Minister**

Rod Hunter, senior vice-president, Pharmaceutical Research and Manufacturers of America (PhRMA), published an op-ed<sup>47</sup> in the Hindustan Times of India targeting Indian Prime Minister Modi, and linking “Indian hostile IP protection” to foreign direct investment.

### **25 September 2014**

#### **U.S. Congress requests a second USITC investigation on India trade practices**

A request for a second U.S. International Trade Commission (USITC) investigation on India trade practices was made by U.S. Congress. House of Representatives Committee on Ways and Means Chairman Dave Camp and Ranking Member Sander Levin, along with Senate Committee on Finance Chairman Ron Wyden and Ranking Member Orrin Hatch, asked the USITC to deliver a report to Congress on 24 September 2015.<sup>48</sup> Another USITC investigation of India’s trade practices and policies was ongoing at the time, the result of which was released in December 2014 [see entry.]

### **30 September 2014**

#### **Both governments commit to high-level IP working group**

Following the recent visit of Prime Minister Narendra Modi to the U.S., a joint statement was released by the leaders of both governments. Embedded in the section on Economic Growth of this statement, was 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.*”<sup>49</sup>

### **3 October 2014**

#### **India clarifies position on IP rights**

The Department of Intellectual Property and Promotion, Ministry of Commerce, India issued a clarification on establishment of high level IP Working Group between U.S. and India bilaterally, highlighting the existence of trade policy forum since 2010 and that current joint statement reiterates the same.<sup>50</sup> Restating India’s position again on IPR, DIPP in its press release said, “*India has consistently pointed out that the IPR legal regime in India is fully TRIPS compliant and that any issues to be discussed have to be discussed in bilateral forums like Trade Policy Forum. India has refused to be subjected to unilateral action proposed by US under the Special 301 report, an annual report on IPR under US Trade Act.*”

### **14 October 2014**

#### **USTR launches Out-of-Cycle Review**

The U.S. Trade Representative (USTR) launched the Out-of-Cycle Review (OCR) as recommended in the Special 301 Report of 2014 to evaluate the government of India’s engagement on IPR issues of concern<sup>51</sup>. Comments were collected from public and foreign governments concerning information, views, acts, policies, or practices relevant to this evaluation. USTR issued a statement in December 2014 concluding the OCR for India [see entry].

### **24 October 2014**

#### **IP Think Tank announced, tasked with drafting National IPR Policy in India**

The Department of Intellectual Property and Promotion, Ministry of Commerce, announced<sup>52</sup> the constitution of IP (Intellectual Property) Think-Tank to draft a new National IPR Policy and to advise the department on issues related to intellectual property. The think-tank is composed of six members with former Intellectual Property Board judge as chairperson. Other members include IP lawyers, an academic and a former bureaucrat.

In addition to drafting National IPR Policy, some of the problematic terms of reference for 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.

### **13 November 2014**

#### **Public comments on National IPR Policy solicited**

Department of Industrial Policy & Promotion, Ministry of Commerce issued a notice<sup>53</sup> seeking comments from interested persons for the proposed National IPR Policy to be considered by the IPR Think Tank responsible for developing a draft Policy.

### **24 November 2014**

#### **First meeting of U.S.-India Trade Policy Forum in four years**

In November 2014 the U.S.-India Trade Policy Forum met for the first time in four years, during which U.S. Trade Representative Michael Froman “extensively highlighted” IPR concerns, specifically naming compulsory licenses among challenging issues, noting “the US is watching closely.”<sup>54</sup> Froman also said that “incentivizing life-saving innovations and promoting affordable access to quality healthcare and safe medicine will benefit all Indians and Americans,” and was therefore an area of common interest for discussion by the high-level IP working group.

### **December 2014**

#### **USTR Out-of-Cycle Review concluded**

The USTR issued a statement concluding the Special 301 Out-of-Cycle Review (OCR) for India.<sup>55,56</sup> The statement, noted ‘useful comments’ made by India, and urged India to ‘strengthen and deepen bilateral engagement on IP issues in the coming months and beyond.’

### **19 December 2014**

#### **Draft National IPR Policy for India released, comments solicited**

The Department of Industrial Policy and Promotion (DIPP) issued a press release<sup>57</sup> inviting comments from the various stakeholders by 30 Jan 2015 on the first draft of the National IPR Policy<sup>58</sup> as produced by the IPR Think Tank.

### **22 December 2014**

#### **Results of first USITC Report released**

The USITC released its report<sup>59</sup> on the investigation conducted of trade policies in India at the request of the House of Representatives Committee on Ways and Means and the Senate Committee on Finance. The report found out a wide range of restrictive Indian policies that have adversely affected U.S. companies doing business in India. Among the various key policy barriers, treatment of IP was also mentioned in the report having large negative effects on specific U.S. industries.

The Commission also highlighted in the report that if tariff and investment restrictions were fully eliminated and standards of IP protection were made comparable to U.S. and Western European levels, U.S. exports to India would rise by two thirds, and U.S. investment in India would roughly double.

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<sup>1</sup> <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2944814/>

<sup>2</sup> [http://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_faq\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm)

<sup>3</sup> [http://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_faq\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm)

<sup>4</sup> <http://www.supremecourt.gov/opinions/05pdf/05-130.pdf>

<sup>5</sup> 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>

<sup>6</sup> [http://articles.economictimes.indiatimes.com/2012-03-27/news/31245102\\_1\\_compulsory-licence-patent-owner-indian-patent-office](http://articles.economictimes.indiatimes.com/2012-03-27/news/31245102_1_compulsory-licence-patent-owner-indian-patent-office)

<sup>7</sup> This testimony was held at a hearing before U.S. House of Representatives, Judiciary Committee, Sub-committee on Intellectual Property, Competition, and the Internet, on International IP Enforcement: Protecting Patents, Trade Secrets and Market Access: [http://www.youtube.com/watch?v=k9\\_68z6De9E](http://www.youtube.com/watch?v=k9_68z6De9E)

<sup>8</sup> <http://keionline.org/node/1452>

<sup>9</sup> <http://www.uschamber.com/webcasts/tpp-and-beyond-north-american-competitiveness-and-intellectual-property-21st-century>

<sup>10</sup> [http://waysandmeans.house.gov/uploadedfiles/pfizer\\_testimony31313.pdf](http://waysandmeans.house.gov/uploadedfiles/pfizer_testimony31313.pdf)

<sup>11</sup> <http://www.finance.senate.gov/hearings/hearing/?id=bf63ffa8-5056-a032-5283-bd347de7362c>

<sup>12</sup> For more information on the Novartis case, visit: <http://www.msfacecess.org/novartis-drop-the-case>

<sup>13</sup> <http://www.finance.senate.gov/hearings/hearing/?id=03508528-5056-a032-526a-67ec511d1ced>

<sup>14</sup> <http://spicyipindia.blogspot.com/2013/04/deconstructing-judgment-of-supreme.html>

<sup>15</sup> <http://spicyipindia.blogspot.com/2013/03/ipabs-first-cl-decision-resounding.html>

<sup>16</sup> <http://www.ustr.gov/sites/default/files/05012013%202013%20Special%20301%20Report.pdf> and

<sup>17</sup> <http://www.msfacecess.org/content/us-penalises-india-promoting-access-medicines-strategies-placing-it-trade-watch-list>

<sup>18</sup> <http://www.theglobalipcenter.com/wp-content/uploads/2013/01/India-Business-Community-Ltr-6.6.13.pdf>

<sup>19</sup> <http://www.finance.senate.gov/hearings/hearing/?id=a0c1c7fe-5056-a032-52d8-95de8eef054>

<sup>20</sup> <http://www.finance.senate.gov/newsroom/chairman/release/?id=99255812-aceb-4607-851f-7b2901e1c981>

<sup>21</sup> [http://keionline.org/sites/default/files/06-18-13-House-India-Letter\\_1.pdf](http://keionline.org/sites/default/files/06-18-13-House-India-Letter_1.pdf)

<sup>22</sup> Press Release by AFTI: <http://www.nam.org/Communications/Articles/2013/06/Manufacturers-Action-Needed-to-Stop-Indias-Unfair-Trade-Practices.aspx>

<sup>23</sup> <https://www.indianembassy.org/prdetail2164/indiaandrsquo%3B-intellectual-property-regime>

<sup>24</sup> [http://waysandmeans.house.gov/uploadedfiles/us\\_india\\_business\\_dialogue\\_letter\\_to\\_the\\_president\\_june\\_20\\_2013.pdf](http://waysandmeans.house.gov/uploadedfiles/us_india_business_dialogue_letter_to_the_president_june_20_2013.pdf)

<sup>25</sup> [http://www.portman.senate.gov/public/index.cfm/files/serve?file\\_id=e4608798-8aec-41dd-8926-dc0e3f224846](http://www.portman.senate.gov/public/index.cfm/files/serve?file_id=e4608798-8aec-41dd-8926-dc0e3f224846)

<sup>26</sup> [http://www.huffingtonpost.com/2013/06/28/obama-generic-drugs\\_n\\_3513011.html](http://www.huffingtonpost.com/2013/06/28/obama-generic-drugs_n_3513011.html)

<sup>27</sup> <http://energycommerce.house.gov/hearing/tangle-trade-barriers-how-indias-industrial-policy-hurting-us-companies> and

<sup>28</sup> <http://www.doctorswithoutborders.org/news/article.cfm?id=6838&cat=field-news>

<sup>29</sup> <http://www.ustr.gov/about-us/press-office/press-releases/2013/july/readout-froman-sharma>

<sup>30</sup> <http://timesofindia.indiatimes.com/business/india-business/Dont-let-rhetoric-trump-reason-Chidambaram-tells-US/articleshow/21043653.cms>

<sup>31</sup> <http://www.whitehouse.gov/the-press-office/2013/07/24/remarks-vice-president-joe-biden-us-india-partnership-bombay-stock-exchange>

<sup>32</sup> [http://www.aei.org/events/2013/07/17/pharmacy-to-the-world-india-and-the-global-prescription-drug-trade/?utm\\_source=Paramount&utm\\_medium=Event&utm\\_campaign=pharmacy-to-the-world-india-and-the-global-prescription-drug-trade](http://www.aei.org/events/2013/07/17/pharmacy-to-the-world-india-and-the-global-prescription-drug-trade/?utm_source=Paramount&utm_medium=Event&utm_campaign=pharmacy-to-the-world-india-and-the-global-prescription-drug-trade)

<sup>33</sup> <http://about.bloomberglaw.com/law-reports/gipc-panel-and-report-considers-india-an-outlier-on-ip-protection/> and

<sup>34</sup> [http://www.theglobalipcenter.com/wp-content/uploads/2013/07/India\\_Outlier\\_FIN.pdf](http://www.theglobalipcenter.com/wp-content/uploads/2013/07/India_Outlier_FIN.pdf)

<sup>35</sup> <http://thehill.com/blogs/congress-blog/campaign/316883-india-honors--not-dishonors--patent-laws>

<sup>36</sup> <http://www.finance.senate.gov/newsroom/chairman/release/?id=21ccccd-bed4-4bd8-89f9-7b9123ed8557>

<sup>37</sup> <http://www.gpo.gov/fdsys/pkg/FR-2013-09-05/pdf/2013-21499.pdf>

<sup>38</sup> <http://aftindia.org/wp-content/uploads/2013/09/Governors-Letter-to-President.pdf>

<sup>39</sup> <http://aftindia.org/wp-content/uploads/2013/09/Business-Letter-to-Obama-Release-FINAL.pdf>

<sup>40</sup> <http://economictimes.indiatimes.com/et-now/policy/govt-not-lax-on-pharma-policy-anand-sharma/videoshow/26355228.cms>

<sup>41</sup> <http://www.theglobalipcenter.com/15339/> and [http://www.theglobalipcenter.com/wp-content/uploads/2014/01/021211\\_GIPC\\_ChartingFlyer\\_final.pdf](http://www.theglobalipcenter.com/wp-content/uploads/2014/01/021211_GIPC_ChartingFlyer_final.pdf)

<sup>42</sup> <http://www.msfacecess.org/content/msf-oral-testimony-united-states-international-trade-commission-public-hearing-trade>

<sup>43</sup> See notes on the hearing here: <http://infojustice.org/archives/32208>, <http://infojustice.org/archives/32213> and <http://infojustice.org/archives/32228>

<sup>44</sup> <http://www.regulations.gov/#!documentDetail;D=USTR-2013-0040-0080>

<sup>45</sup> <http://timesofindia.indiatimes.com/business/india-business/India-ready-to-take-on-US-over-patents-at-World-Trade-Organization/articleshow/30967967.cms>

<sup>46</sup> [http://articles.economictimes.indiatimes.com/2014-03-05/news/47895347\\_1\\_anand-sharma-compulsory-licence-intellectual-property-rights](http://articles.economictimes.indiatimes.com/2014-03-05/news/47895347_1_anand-sharma-compulsory-licence-intellectual-property-rights)

<sup>47</sup> <http://www.ustr.gov/sites/default/files/USTR%202014%20Special%20301%20Report%20to%20Congress%20FINAL.pdf>

<sup>48</sup> <http://docs.house.gov/meetings/FA/FA05/20140724/102538/HHRG-113-FA05-Wstate-KumarA-20140724.pdf>

<sup>49</sup> [http://articles.economictimes.indiatimes.com/2014-09-09/news/53730889\\_1\\_ipr-policy-ipr-regime-out-of-cycle-review](http://articles.economictimes.indiatimes.com/2014-09-09/news/53730889_1_ipr-policy-ipr-regime-out-of-cycle-review)

<sup>50</sup> <http://www.hindustantimes.com/StoryPage/Print/1265781.aspx>

<sup>51</sup> <http://waysandmeans.house.gov/news/documentsingle.aspx?DocumentID=394536>

<sup>52</sup> <http://www.whitehouse.gov/the-press-office/2014/09/30/us-india-joint-statement>

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<sup>54</sup> <https://www.federalregister.gov/articles/2014/10/14/2014-24309/2014-special-301-out-of-cycle-review-of-india>

<sup>55</sup> <http://pib.nic.in/newsite/PrintRelease.aspx?relid=110790>

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<sup>57</sup> <http://www.ip-watch.org/2014/11/24/ustr-froman-presses-india-on-ipr-regime/>

<sup>58</sup> <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>

<sup>59</sup> <http://indiatogether.org/commercial-versus-social-lens-for-intellectual-property-rights-ipr-policy-government>

<sup>60</sup> [http://dipp.nic.in/English/acts\\_rules/Press\\_Release/pressRelease\\_IPR\\_Policy\\_30December2014.pdf](http://dipp.nic.in/English/acts_rules/Press_Release/pressRelease_IPR_Policy_30December2014.pdf)

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<sup>58</sup> [http://dipp.nic.in/English/Schemes/Intellectual\\_Property\\_Rights/IPR\\_Policy\\_24December2014.pdf](http://dipp.nic.in/English/Schemes/Intellectual_Property_Rights/IPR_Policy_24December2014.pdf)

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