



# **2014 Special 301 Out-of-Cycle Review of India**

(Docket Number USTR-2014-0020)

*Written Submission*

*by*

**INDIAN PHARMACEUTICAL ALLIANCE**

Washington DC  
28 October 2014

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**IPA Submission**  
**2014 Special 301 Out-of-Cycle Review of India**

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1. My name is Dilip G Shah and I am Secretary General of the Indian Pharmaceutical Alliance (IPA). I am respectfully filing these written submissions on behalf of the IPA for the consideration of USTR in the 2014 Special 301 Out-of-Cycle Review of India.
2. The IPA's membership consists of twenty pharmaceutical companies which collectively account for close to 85% of the expenditure on pharmaceutical research and development in the private sector in India. We therefore have a vital interest in the protection of our innovations, not only for developing cost-effective and useful improvements in existing medicines, but also for discoveries of new medicines.
3. These submissions are mainly with respect to the developments since April 2014 relevant to the pharmaceutical industry, particularly the Government of India's engagement with IPR issues of concern identified in the 2014 Special 301 Report.

**I. A reinvigorated environment conducive to global economic partnerships**

4. The overwhelming electoral mandate to Prime Minister Narendra Modi in the 2014 elections in India heralds an opportunity for decisive governance that augurs well for reinvigorating economic growth in India as well as global investment and trade partnerships.
5. The renewed optimism is reflected in the rise in the Business Confidence Index for India from a record low of 45.7 in the third quarter of 2013 to 57.4 in the third quarter of 2014, the highest in recent years.<sup>1</sup>
6. The increased business confidence is consistent with increase of Foreign Direct Equity Investments into India from \$8.5 billion between April to August 2013, to \$12 billion in the same period in 2014. This is an increase of 42%.<sup>2</sup>
7. The marked optimism and confidence are reflected in big-ticket pledges of fresh investments. On September 1, 2014, Japanese Prime Minister Shinzo Abe and Prime Minister Narendra Modi issued the Tokyo Declaration establishing the India-Japan Investment Promotion Partnership and setting a target of doubling Japanese direct investment and the number of Japanese companies in India in five years. Prime Minister Abe pledged over \$30 billion of public and private investment and financing in India within this period.<sup>3</sup> Eighteen days later, China's President Xi Jinping pledged an investment of \$20 billion over five years during his visit to India.<sup>4</sup>
8. It is clear that bilateral economic relations are on the top of the Indo-US agenda. As President Obama noted in his remarks following his meeting with Prime Minister Narendra Modi on September 30, 2014, "[l]ast night, during a private dinner we spent most of our time talking about the economy." President Obama also recognised the challenge of poverty in India and Prime Minister Modi's resolve to tackle the problem.

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<sup>1</sup>The Business Confidence Index is released every quarter by the Confederation of Indian Industry, based on a survey of a sample of about 300 companies. The Index for the third quarter of 2014 was released on October 20, 2014.  
<http://www.tradingeconomics.com/india/business-confidence>

<sup>2</sup> [http://dipp.nic.in/English/Publications/FDI\\_Statistics/2014/india\\_FDI\\_August2014.pdf](http://dipp.nic.in/English/Publications/FDI_Statistics/2014/india_FDI_August2014.pdf)

<sup>3</sup>Tokyo Declaration, Full text, para 23. <http://timesofindia.indiatimes.com/india/Tokyo-Declaration-for-India-Japan-Special-Strategic-and-Global-Partnership/articleshow/41433328.cms>

<sup>4</sup> <http://www.bloomberg.com/news/2014-09-17/modi-to-host-xi-for-talks-to-bolster-india-s-china-ties.html>

He said, the “Prime Minister shared with me his vision for lifting what is still too many Indians who are locked in poverty into a situation in which their lives can improve.”<sup>5</sup>

9. The joint statement issued on September 30, 2014<sup>6</sup> noted the five-fold growth since 2001 in two-way trade to about \$100 billion and stated that President Obama and Prime Minister Modi were committed to increasing it a further five-fold. The two leaders agreed “on the need to foster innovation in a manner that promotes economic growth and job creation” and “recognized that U.S. and Indian businesses have a critical role to play in sustainable, inclusive, and job-led growth and development”. Several important Government-led initiatives were also announced, including the Indo-U.S. Investment Initiative and the Infrastructure Collaboration Platform.
10. US pharmaceutical companies are forging ahead with their investments and partnerships in India. After opening its R&D Centre in Bangalore in 2012 to deliver local science-based nutrition products, Abbott inaugurated its \$75 million greenfield plant in Gujarat on October 16, 2014. The plant will add over 400 jobs. Abbott is one of the fastest growing multinational pharmaceutical companies in India. It is also one of the largest pharmaceutical companies in the country and employs more than 14,000 people.<sup>7</sup>
11. On September 15, 2014, Gilead Sciences, Inc. announced non-exclusive licensing agreements with seven India-based generic pharmaceutical manufacturers to manufacture sofosbuvir (Sovaldi™) and the investigational single tablet regimen of ledipasvir/sofosbuvir (Harvoni™) for distribution in 91 developing countries, expanding access to affordable medication to more than 100 million people living with hepatitis C, representing 54% of the total global infected population.<sup>8</sup> The Indian licensees will be free to set prices for the products manufactured by them.
12. We urge the USTR to take note of the strong positive sentiments both domestically as well as globally, including among US pharmaceutical companies, in its out-of-cycle review and strengthen the upward momentum.

## **II. A new openness to dialogue and engagement**

13. In a meeting with the media on August 30, 2014, on the eve of his visit to Japan, Prime Minister Modi reiterated the attractiveness of India as a destination for foreign investment and declared that his Government is “open to dialogue and will strive to remove all roadblocks to invite FDI”.<sup>9</sup>
14. Two decisions announced in the joint statement of President Obama and Prime Minister Modi<sup>10</sup> are of particular importance:

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<sup>5</sup> <http://www.whitehouse.gov/the-press-office/2014/09/30/remarks-president-obama-and-prime-minister-narendra-modi-india-after-bil>

<sup>6</sup> <http://www.whitehouse.gov/the-press-office/2014/09/30/us-india-joint-statement>

<sup>7</sup> <http://www.thehindubusinessline.com/companies/abbott-all-set-to-open-nutrition-plant-in-gujarat/article6503221.ece>

<sup>8</sup> <http://www.gilead.com/news/press-releases/2014/9/gilead-announces-generic-licensing-agreements-to-increase-access-to-hepatitis-c-treatments-in-developing-countries>

<sup>9</sup> [http://www.business-standard.com/article/economy-policy/will-remove-all-roadblocks-to-attract-fdi-says-modi-114082900880\\_1.html](http://www.business-standard.com/article/economy-policy/will-remove-all-roadblocks-to-attract-fdi-says-modi-114082900880_1.html)

<sup>10</sup> <http://www.whitehouse.gov/the-press-office/2014/09/30/us-india-joint-statement>

- “The leaders discussed their concerns about the current impasse in the World Trade Organization and its effect on the multilateral trading system, and directed their officials to consult urgently along with other WTO members on the next steps.”
  - “Agreeing on the need to foster innovation in a manner that promotes economic growth and job creation, the leaders committed 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.”
15. The willingness to engage with industry and enter into dialogue is not restricted to the Prime Minister. On September 8, 2014, Nirmala Sitharaman, the Minister of State for Commerce and Industry said that the Government will announce an Intellectual Property Policy “within six months” to strengthen the country’s patent regime and encourage innovation. She also stated that a draft would be made available on the website of the Department of Industrial Policy and Promotion and public comments would be invited before its finalization.<sup>11</sup> While it has been widely reported that Minister Sitharaman reiterated that India’s patent laws were TRIPS-compliant, she is reported to have said that “[w]herever IPR is an issue, policy is going to be made in a direction that protects Intellectual Property Rights”.<sup>12</sup> A think-tank chaired by Prabha Sridevan, former Chairman of the Intellectual Property Appellate Board, has been constituted on October 24, 2014 to help draft the proposed IPR policy and advise Government on IPR issues.<sup>13</sup>
16. The office of the Controller General of Patents had put out draft guidelines for patent examination for pharmaceuticals for public comment on February 28, 2014. Comments were discussed in a meeting chaired by the Controller General of Patents in New Delhi on July 31, 2014. The draft guidelines were consequently revised and put on the website on August 12, 2014. The Controller General of Patents chaired a consultation meeting where the summary of the comments received was presented (and also posted on the website) to representatives of both domestic and international pharmaceutical companies and final written comments were invited. The comment period closed on October 16, 2014.<sup>14</sup>
17. We trust that the USTR will take note of the willingness of the Government of India to engage in meaningful dialogue at multiple levels in matters pertaining to foreign direct investment, innovation and intellectual property rights, including for pharmaceuticals.

### **III. Continued strengthening of the Patent Office**

18. The 2014 Special 301 Report commended “India on actions taken in recent years to improve the operations of its Patent Office, including digitizing records, upgrading online search and e-filing capabilities, and hiring additional patent examiners.” These efforts have continued in the last six months.

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<sup>11</sup>[http://articles.economictimes.indiatimes.com/2014-09-08/news/53691434\\_1\\_ipr-policy-ipr-laws-draft-policy](http://articles.economictimes.indiatimes.com/2014-09-08/news/53691434_1_ipr-policy-ipr-laws-draft-policy)

<sup>12</sup> <http://www.ndtv.com/article/india/government-working-on-intellectual-property-rights-policy-nirmala-sitharaman-588661>

<sup>13</sup> <http://www.thehindubusinessline.com/economy/policy/govt-sets-up-thinktank-to-finetune-ipr-policy/article6530659.ece>

<sup>14</sup> [http://www.ipindia.nic.in/iponew/stakeholdersMeet\\_09October2014.htm](http://www.ipindia.nic.in/iponew/stakeholdersMeet_09October2014.htm)

19. On September 8, 2014, a new International Searching Authority and International Preliminary Examining Authority Building at the Intellectual Property Office, was inaugurated in New Delhi.<sup>15</sup>
20. On the same day, a new payment gateway integrated with the e-filing system of the Intellectual Property Office was also inaugurated. Online filings, which account for about 75% of the total patent filings, are expected to increase with the integration of the payment gateway. Transparency in operations has been significantly enhanced with the online availability of information on the processing of applications – India will be one of the few patent offices with this level of transparency.
21. On September 30, 2014, a new version of the electronic patent register was implemented. The enhancements include online availability of the legal status of patents and the linking of parent and divisional applications. An electronic environment for the filing and processing of patents has been substantially achieved.
22. The 2014 Special 301 Report had noted the plan of the Patent Office to recruit 500 additional examiners over five years. The requirement has considerably increased with the Indian Patent Office functioning as an International Searching and Preliminary Examination Authority. On September 8, 2014, the Secretary of the Department of Industrial Policy and Promotion, has announced the further upgradation of infrastructure and the creation of 1033 positions (of which 666 positions are for patents and designs) to meet the anticipated increase in workload.<sup>16</sup>
23. The intervention of the Delhi High Court to speed up the process for examination and grant of patents has been noted in the 2014 Special 301 Report. A Committee was consequently set up by the Government and a report was submitted on March 13, 2014. The Court noted that there was some progress but was of the opinion that the measures taken by the Government would not be adequate for examination reports to be issued within the statutorily prescribed period. Further directions were issued on October 9, 2014 relating to strengthening infrastructure, additional positions, alternative methods of recruitment and training. Government was also directed to constitute a Committee to consider whether there could be a maintenance fee waiver for the period of delay beyond the statutorily prescribed period and a scheme for expedited examination.<sup>17</sup> A deadline of February 28, 2015 has been set for the Committee to submit its report.

#### **IV. Patent opposition procedures**

24. The 2014 Special 301 Report noted with concern the provisions in the Indian Patens Act that allow both pre- and post-grant oppositions on eleven grounds and the same interested person could file oppositions on the same grounds at minimal cost. The Report further states that “[a]s a result, applications can be tied up in costly challenge proceedings for years”.
25. A main objective of making provision for oppositions is to enable quick, simple and cost-effective resolution of patent challenges. The procedure ought not to be more expensive for a patent applicant than for an Opponent.

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<sup>15</sup>[http://www.ipindia.nic.in/iponew/PressReplease\\_10September2014.pdf](http://www.ipindia.nic.in/iponew/PressReplease_10September2014.pdf)

<sup>16</sup> <http://www.ndtv.com/article/india/government-working-on-intellectual-property-rights-policy-nirmala-sitharaman-588661>

<sup>17</sup> *Nitto Denko v Union of India*, Delhi High Court, Order dated October 9, 2014 in WP(C) No 3756/2013.

26. We note that the EPO has a post-grant opposition procedure. Over the last decade, over 2,000 oppositions have been filed annually. The data for 2013 evidence its effectiveness: 31% of the oppositions were dismissed and in 29% of the cases, the patents were revoked. Patents were upheld in amended form in 40% of the cases.<sup>18</sup>
27. US patent law has provided for *ex parte* reexamination since July 1, 1981 on grounds limited to 35 U.S.C. 102 and 103 with prior art limited to patents and printed documents. However, from September 16, 2012, the America Invents Act has vastly enhanced the effectiveness of *ex parte* reexamination by introducing *inter partes* review (IPR). Further, the introduction of the post-grant review (PGR) on any of the invalidity grounds under 35 U.S.C. 101 (subject matter eligibility), 102 and 103 (anticipation and obviousness, including on unpublished material), 112 (written description, enablement, indefiniteness), and 251 (claim broadening). The first-to-file provision in the America Invents Act became effective on March 16, 2013, so the first patents have very recently become eligible for PGR. At least two PGRs have been filed.
28. About a year earlier, IPR filings averaged about 60 per month. It has now increased several-fold to about 200 per month.<sup>19</sup>The effectiveness of IPR as an alternative to expensive litigation has been established. There is every likelihood that the filings of PGRs will increase exponentially. Dennis Crouch, Associate Professor at the University of Missouri School of Law notes, the “expectation is that PGR will quickly prove itself as an incredibly powerful tool for challenging patents.”<sup>20</sup>
29. As the USTR has noted, there are eleven grounds for opposition in India. Post-grant opposition under Indian law is no more onerous for a patentee, as the additional grounds of opposition in the Indian statute are mainly of a technical nature which would lead to a rejection of the application in the normal course of examination. As a matter of fact, it could be said that the America Invents Act has introduced post-grant opposition similar to European and Indian law.
30. Thus, if at all, only pre-grant oppositions can be a matter of concern. By way of background, pre-grant opposition was permitted in the Patents Act prior to its extensive amendment in 2005, to comply with the TRIPS Agreement. Post-grant opposition was introduced in the same amendment in 2005. While the burden of potentially facing two sets of oppositions has been noted by the USTR, there was considerable apprehension voiced in Parliament in the debates on the amendment about the possible burden to consumers and society should patents be wrongly granted. More so, as pharmaceutical patents were new to patent examiners. The Government reassured agitated Members that the availability of both pre- and post-grant opposition would minimize the improper grant of patents and the consequential irremediable wrong to consumers and society.
31. One of the arguments advanced for the retention of pre-grant opposition in the Patents Act is that it will aid the examination process as pertinent prior art and other relevant considerations will be brought to the notice of the examiner, which may otherwise have

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<sup>18</sup> <http://www.epo.org/about-us/annual-reports-statistics/annual-report/2013/statistics-trends/searches.html#tab=3>

<sup>19</sup> <http://www.goodwinprocter.com/~media/Files/Publications/Newsletters/IP%20Advisor/2014/Goodwin%20Procter%20IP%20Advisor%20PTAB%202nd%20Anniversary%20Edition.PDF>

<sup>20</sup> [http://patentlyo.com/patent/2014/10/grant-review-proceedings.html?utm\\_target=/feedburner&utm\\_medium=feed&utm\\_campaign=Feed%3A+PatentlyO+%28Dennis+Crouch%27s+Patently-O%29](http://patentlyo.com/patent/2014/10/grant-review-proceedings.html?utm_target=/feedburner&utm_medium=feed&utm_campaign=Feed%3A+PatentlyO+%28Dennis+Crouch%27s+Patently-O%29)

escaped attention. It is a summary procedure and is far less time consuming and expensive than regular trial. A reasoned decision at this early stage would arguably benefit the applicant if the opposition is dismissed, and increase business confidence in the enforceability of the patent when granted.

32. Similarly, an early rejection of an application would increase business confidence of other potential manufacturers, apart from avoiding the disbenefits of wrongly granted patents. For example, the patent application of Wockhardt for nadifloxacin was rejected subsequent to a pre-grant opposition filed by Cipla, in 2006.<sup>21</sup> Both Wockhardt and Cipla are Indian companies.
33. We are not aware of abusive pre- and post-grant oppositions by the same person on the same grounds for the same patent.

#### **V. Government initiated compulsory license under Section 92**

34. Section 92 of the Patents Act provides for the notification of patents for compulsory licensing for the usual conditions of emergencies or public non-commercial use.
35. The 2014 Special 301 Report urges “India to provide greater transparency about its ongoing inter-ministerial process that is considering over a dozen patented medicines as candidates for government-initiated compulsory licenses, and urges India to allow opportunities for input by rights holders, as appropriate, with respect to decisions concerning compulsory licenses.”
36. We are not aware that the Government of India is considering compulsory licenses for ‘over a dozen patented medicines’. Biotechnology Industry Organization had stated in their 2014 Special 301 submission that “[e]arly in 2013, the Indian Health Ministry began the process to compulsory license 3 cancer drugs. In September of 2013, the Ministry limited the scope of their initial request and filed a petition to compulsory license Sprycel.”<sup>22</sup>
37. The generic name of Bristol-Myer Squibb’s Sprycel<sup>TM</sup> is dasatinib. The *Economic Times* reported on October 16, 2014 that the Department of Industrial Policy and Promotion (the nodal department of the Government of India for IPR) had sought clarifications from the Ministry of Health, including the costs incurred in Government procurement of the drug and the justification for the requirement to be designated as one of extreme urgency.<sup>23</sup>

#### **VI. Compulsory license under Section 84**

38. Compulsory licenses can be granted in India under Section 84 of the Patens Act, if any one of three conditions obtain: if the reasonable requirements of the public for the patented article are not met, or if the patented article is not available at a reasonably affordable price or if the patent is not worked on a commercial scale in the territory of India. The only compulsory license granted so far is for Bayer’s Nexavar<sup>TM</sup>.

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<sup>21</sup> Rejection of patent application No.308/MUM/1175 on May 18, 2006 [*Wockhardt v Cipla* 2006 (32) PTC 261 (P.O.Mum.)]

<sup>22</sup> Biotechnology Industry Organization, 2014 Special 301 Submission, p 13

<sup>23</sup> [http://articles.economictimes.indiatimes.com/2014-10-16/news/55106950\\_1\\_cancer-drug-dasatinib-health-ministry-compulsory-licence](http://articles.economictimes.indiatimes.com/2014-10-16/news/55106950_1_cancer-drug-dasatinib-health-ministry-compulsory-licence)



39. The 2014 Special 301 Report notes that the grant of the compulsory license by the Controller-General of Patents under Section 84 “was based, in part, on the innovator’s failure to ‘work’ the patent in India because it imported its products, rather than manufacturing them in India.” The Report also noted that “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 Report pointed out that the IPAB “did not clarify the circumstances under which the ‘working’ requirement would be met without manufacturing in India.”
40. Bayer took the case to the Bombay High Court. By a judgment dated July 15, 2014, the Bombay High Court upheld the order of the IPAB on the grounds that the reasonable requirements of the public for the patented article were not met<sup>24</sup> and it was not available at a reasonably affordable price<sup>25</sup>.
41. As regards the working requirement, the Union of India contended that it meant “manufacture in India on a commercial scale”<sup>26</sup>. The Bombay High Court rejected the contention of the Union of India and held that “[i]n the circumstances, the contention of Union of India that ‘worked in India’ must in all cases mean only manufactured in India is not acceptable.”<sup>27</sup> The order of the IPAB was thus affirmed not only in this respect but also that “it would need to be decided on case-to-case basis.”
42. As regards the circumstances under which the ‘working’ requirement would be met without manufacturing in India, the Bombay High Court held that “the patent holder would nevertheless have to satisfy the authorities under the Act as to why the patented invention was not being manufactured in India keeping in view Section 83 of the Act. This could be for diverse reasons but it would be for the patent holder to establish those reasons which makes it impossible/prohibitive for it to manufacture the patented drug in India. However, where a patent holder satisfies the authorities, the reason why the patented invention could not be manufactured in India then the patented invention can be considered as having been worked in the territory in India even by import. This satisfaction of the authorities is necessary particularly when the petitioner admittedly has manufacturing facilities in India.”<sup>28</sup> (Emphasis added).

## VII. Injunctions against manufacture in infringement suits

43. The 2014 Special 301 Report notes “with concern the continuing challenges involved with enforcement of patent rights in India, including challenges that patent holders face in securing injunctions against firms that manufacture patented inventions without authorization from the patent holder.”
44. Injunctions restraining manufacture and sale have been issued by five different judges of the Delhi High Court in the last seven months when suits have been instituted by Novartis for infringement.
45. On March 5, 2014, Novartis was granted an interim injunction restraining Wockhardt from “manufacturing, importing, selling, offering for sale, export directly or indirectly

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<sup>24</sup>Writ Petition No 1323 of 2013; *Bayer Corporation vs Union of India*, para 13(c).

<sup>25</sup>*Ibid.* para 14(c)

<sup>26</sup>*Ibid.* para 7. See also. para 15(a)

<sup>27</sup>*Ibid.* para 15(b)

<sup>28</sup>*Ibid.* para 15(b)

dealing in pharmaceutical products, compound or formulation or combination containing Vildagliptin alone or Vildagliptin with Metformin Hydrochloride in combination or Vildagliptin in any other combination”.

46. Wockhardt had received permission to manufacture the products from the regulatory authorities and in September 2013, had also filed a petition for revocation of the patent before the IPAB. The injunction was granted before Wockhardt launched the product. Granting the injunction, Justice Sachdeva of the Delhi High Court held that “I am satisfied that plaintiff has made out a strong prima facie case for grant of ad-interim injunction. The balance of convenience is also in favour of plaintiff and in case, the ad-interim injunction is not granted, the plaintiff shall suffer and irreparable loss and injury.”<sup>29</sup>
47. A similar injunction was granted against Alembic Pharmaceuticals on April 16, 2014, which had received permission but had not commenced manufacture and marketing the drug.<sup>30</sup>
48. Another similar injunction was granted against Bajaj Healthcare on April 16, 2014.<sup>31</sup> The suit was disposed of on July 28, 2014 on the basis of an undertaking by Bajaj Healthcare that though they have obtained approval for manufacturing, they have not done so and do not intend to do so.<sup>32</sup>
49. According to a news report quoting Novartis, the company sought an injunction from the Delhi High Court restraining Biocon from manufacturing vildagliptin on March 27, 2014, before the product was launched. The very next day, the Court recorded an undertaking from Biocon that it “will not manufacture, sell or export Vildagliptin for commercial purposes till the next court hearing”.<sup>33</sup> The case is progressing and the undertaking remains in effect.<sup>34</sup> On being sued by Novartis, similar undertakings not to launch vildagliptin in India were given by Glenmark<sup>35</sup> and Cadila<sup>36</sup> to the Delhi High Court on April 16, 2014, which continue to bind them.
50. On September 8, 2014, The Delhi High Court restrained Ranbaxy from manufacturing vildagliptin. Ranbaxy had filed for revocation of the patent before the IPAB. The news report states that the Court noted in its order that Ranbaxy’s application for revocation of Novartis’ patent “shows that the defendant [Ranbaxy] wants to launch the compound patented”. While manufacturing authorization had been received in earlier cases where injunction was granted, Ranbaxy’s case suggests that an injunction could be triggered by the filing for a revocation of a patent, even prior to the grant of manufacturing

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<sup>29</sup> *Novartis v Wockhardt*, OS 646/2014, Delhi High Court, available at [http://delhihighcourt.nic.in/dhcqrydisp\\_o.asp?pn=48066&yr=2014](http://delhihighcourt.nic.in/dhcqrydisp_o.asp?pn=48066&yr=2014)

<sup>30</sup> *Novartis v Alembic Pharmaceuticals*, OS 1051/2014, Delhi High Court, available at [http://delhihighcourt.nic.in/dhcqrydisp\\_o.asp?pn=79147&yr=2014](http://delhihighcourt.nic.in/dhcqrydisp_o.asp?pn=79147&yr=2014)

<sup>31</sup> *Novartis v Bajaj Healthcare*, OS 1053/2014, Delhi High Court, available at [http://delhihighcourt.nic.in/dhcqrydisp\\_o.asp?pn=79148&yr=2014](http://delhihighcourt.nic.in/dhcqrydisp_o.asp?pn=79148&yr=2014)

<sup>32</sup> *Ibid.* [http://delhihighcourt.nic.in/dhcqrydisp\\_o.asp?pn=144138&yr=2014](http://delhihighcourt.nic.in/dhcqrydisp_o.asp?pn=144138&yr=2014)

<sup>33</sup> <http://businesstoday.intoday.in/story/novartis-patent-suit-biocon-denies-any-court-injunction/1/204874.html>

<sup>34</sup> *Novartis v Biocon*, OS 891/2014, Delhi High Court, available at [http://delhihighcourt.nic.in/dhcqrydisp\\_o.asp?pn=144136&yr=2014](http://delhihighcourt.nic.in/dhcqrydisp_o.asp?pn=144136&yr=2014)

<sup>35</sup> *Novartis v Glenmark*, OS 1054/2014, Delhi High Court, available at [http://delhihighcourt.nic.in/dhcqrydisp\\_o.asp?pn=79150&yr=2014](http://delhihighcourt.nic.in/dhcqrydisp_o.asp?pn=79150&yr=2014)

<sup>36</sup> *Novartis v Cadila Healthcare*, OS 1052/2014, Delhi High Court, available at [http://delhihighcourt.nic.in/dhcqrydisp\\_o.asp?pn=79149&yr=2014](http://delhihighcourt.nic.in/dhcqrydisp_o.asp?pn=79149&yr=2014)

authorization.<sup>37</sup> Ranbaxy appealed, but the Court declined to interfere with the order of injunction.<sup>38</sup>

51. The 2014 USTR Special 301 Report notes that when approving “manufacture without authorization, Indian state governmental authorities reportedly do not have a mechanism to confirm whether the item to be manufactured is under patent. Recent cases such as *Merck v. Glenmark* and *Cipla v. Roche* illustrate this problem and underscore the need for greater regulatory coordination between officials in state and central governments.” The reference to state governments is unclear to us.
52. If the implication of ‘need for greater regulatory coordination’ is to link regulatory approval of manufacture and market drugs to patent status (commonly referred to as ‘patent linkage’ in India), then the lack of a formal mechanism linking drug approval to patent status is not necessarily a problem as evidenced by the examples given above.
53. We reiterate our earlier submission during the 2014 Special 301 Review that most countries, including those in the European Union, do not have a provision for ‘patent linkage’ as found in the US. There are several good reasons for not following the US model. For example, if a patent is eventually found invalid, the delays occasioned by holding up marketing authorization during the term of the patent would cause grave injury to consumers and there is no way to compensate them. It is interesting to note that Bristol-Myers Squibb sought an injunction in 2010 to restrain Ranbaxy from manufacturing and selling Baraclude™ (the generic name is entacavir), alleging infringement of granted patent 213457 in India (equivalent to US patent 6627224) for a pharmaceutical composition of entacavir. The interim injunction was denied, in part, as a serious challenge to the validity of the patent was raised. Ranbaxy was directed to keep accounts to enable assessment of damages in the event of Bristol-Myers Squibb succeeding.<sup>39</sup> Interestingly, the basic patent covering Baraclude™, US patent 5,206,244 granted in April 1993, was successfully challenged by Teva in the US. Bristol-Myers Squibb appealed and in June 2014, the Federal Court of Appeals upheld its invalidation.<sup>40</sup> Baraclude™ was approved for marketing in the US in March 2005.<sup>41</sup> Teva launched the generic on September 4, 2014.<sup>42</sup> Consumers in the US who have been harmed by the delay in the introduction of affordable generics by a wrongful grant of patent have no remedy.
54. As regards *Merck v Glenmark* and *Roche v Cipla*, both these cases had aspects in the patents and pleadings which were peculiar to them. For example, in *Roche v Cipla*, the Court was not persuaded that Roche had made out a *prima facie* case, essential for the grant of an interim injunction, particularly because of non-disclosure of a subsequent patent application to the Court. The Court was of the view that “[t]he plaintiffs [Roche] have to make an unequivocal disclosure that the patent they hold covers the drug in question; whether there are any other pending applications seeking the grant of patent in respect of any derivatives or forms of the product for which they already hold a patent

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<sup>37</sup> [http://www.livemint.com/Industry/HiulunjR3DSHvftkPonfK/Courtgrants-Novartis-temporary-injunction-against-Ranbaxy.html?utm\\_source=copy](http://www.livemint.com/Industry/HiulunjR3DSHvftkPonfK/Courtgrants-Novartis-temporary-injunction-against-Ranbaxy.html?utm_source=copy)

<sup>38</sup> *Ranbaxy v Novartis*, Delhi High Court, Order dated October 18, 2014 in FAO(OS) 447/2014

<sup>39</sup> [http://articles.economictimes.indiatimes.com/2010-09-23/news/27574785\\_1\\_generic-version-ranbaxy-mg-tablets](http://articles.economictimes.indiatimes.com/2010-09-23/news/27574785_1_generic-version-ranbaxy-mg-tablets)

<sup>40</sup> <http://ir.tevapharm.com/phoenix.zhtml?c=73925&p=irol-newsArticle&ID=1939558>

<sup>41</sup> [http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?AppL\\_No=021797&TABLE1=OB\\_Rx](http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?AppL_No=021797&TABLE1=OB_Rx)

<sup>42</sup> <http://ir.tevapharm.com/phoenix.zhtml?c=73925&p=irol-newsArticle&ID=1963787>

and the effect of such applications on the suit patent. Short of the above details, the Court being approached for the grant of an ad interim relief will be unable to form a view on whether the plaintiff has made out a prima facie case.”<sup>43</sup>

55. Similarly, Merck was refused an injunction on April 5, 2013. However, between June 17, 2013 and October 14, 2014, the Delhi High Court has granted *ex parte* injunctions in eight cases<sup>44</sup> restraining manufacture or sale of sitagliptin (the generic name of Merck’s Januvia™) and its combination with metformin. These injunctions were granted by six different Judges (including Justice Endlaw who refused the injunction in Glenmark’s case, despite his attention being drawn to his own earlier refusal). At least five of these case have also been disposed of in favour of Merck.
56. At the request of Merck, and with the agreement of Glenmark, their case has been referred to mediation on July 4, 2014.<sup>45</sup> Earlier, on June 13, 2014, newspapers had reported that Roche and Cipla had also agreed to refer their dispute to mediation.<sup>46</sup>
57. We submit that the difficulties in obtaining injunctions as well as apprehensions about the lack of patent linkage have been overstated to the USTR. There are several other cases where injunctions have been granted to pharmaceutical patent holders before the grant of manufacturing authorization. For example, Bayer has obtained injunctions in the Delhi High Court restraining manufacture against two parties developing Rivaroxaban under a development license, which is permissible under Section 107A(a) the Patents Act, a provision similar to the Bolar exemption in the US.

### VIII. Concluding comments

58. We are aware of the vociferous complaints about India’s patent law and policy by some in the US pharmaceutical industry. It is important to note that, their views are not universally shared as is clear from the submissions made to the USTR during the 2014 Special 301 Review and elsewhere:
- Boeing<sup>47</sup>: “Indian IPR laws applicable to the range of Boeing’s business activities in India are comparable to IPR regulations in other developed countries, as India is a signatory to all major conventions and treaties on this subject. Additionally in our experience, there have not been any major patent violations in India pertaining to Boeing’s defense / aerospace products.”
  - Honeywell<sup>48</sup>: “Our experience to date has been that an acceptable intellectual property rights (IPR) legal framework exists in India and Honeywell has had positive experiences with Indian customers, partners and suppliers on respecting Honeywell’s IPR.”

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<sup>43</sup> *Roche v Cipla*, Delhi High Court, Judgment dated April 24, 2009 in FAO (OS) 188/2008, para 40

<sup>44</sup> *Merck Sharpe & Dohme v Aprica* [OS 1236/2013]; v *ShilpexPharmysis* [OS 1488/2013]; v *NMC Biopharm* [OS 1688/2013]; v *VetriVadivelan* [ (OS 2664/2013)]; v *Jayesh Mehta* [OS 1768/2014]; v *Dilip Jain* [OS 344/2014]; v *NavneetDhingra* [OS490/2014]; v *Vinod Jhadav* [OS 3132/2014]

<sup>45</sup> *Merck v Glenmark*, Delhi High Court, OS 586/2013, order available at [http://delhihighcourt.nic.in/dhcqrydisp\\_o.asp?pn=123328&yr=2014](http://delhihighcourt.nic.in/dhcqrydisp_o.asp?pn=123328&yr=2014)

<sup>46</sup> [http://articles.economictimes.indiatimes.com/2014-06-13/news/50564611\\_1\\_erlotinib-patent-expert-shamnad-basheer-patent-battle](http://articles.economictimes.indiatimes.com/2014-06-13/news/50564611_1_erlotinib-patent-expert-shamnad-basheer-patent-battle)

<sup>47</sup> The Boeing Company. Statement to the USTR, Special 301 Review 2014, March 6, 2014.

<http://www.regulations.gov/contentStreamer?objectId=0900006481613608&disposition=attachment&contentType=pdf>

<sup>48</sup> Honeywell International Inc. Statement to the USTR, Special 301 Review 2014, March 7, 2014.

<http://www.regulations.gov/contentStreamer?objectId=0900006481626712&disposition=attachment&contentType=pdf>

- Corning<sup>49</sup>: Corning while responding to media questions on the commissioning of its plant in India is reported to have said - “For Corning, patents and their protection are critically important,” said Deb Waggoner, director for the company’s global government affairs, “we don’t go into any market without that protection.”

59. It is relevant to note that allegations similar to those made against India are also made when judicial decisions, including those of the Supreme Court of the United States, go against patent owners. For example, Gene Quinn, the President and Founder of IPWatchdog Inc. made a presentation to the Association of Intellectual Property Firms’ Annual Meeting in Washington, DC, September 29, 2014. Quinn lamented some recent decisions of the Supreme Court of the US, including *Mayo v Prometheus* and *AMP v Myriad* and declared “[t]here is little doubt that the Justices of the Supreme Court are indeed public enemies, at least in so far as patent owners are concerned....The consequences of SCOTUS decisions are really severe. The U.S. is no longer a favorable jurisdiction for many biotech patents, medical devices and software. What that’s going to mean is companies are going to move.”<sup>50</sup>

60. We submit that it would be incorrect to make an overall assessment on the basis of isolated cases or aggressive advocacy. The complaints against the Indian patent regime ought to be viewed in the light of the overall record:

**Pharmaceutical patents granted and revoked in India  
January 1, 2005 – October 10, 2014**

| Details                              | Indian applicants | Foreign applicants | Total |
|--------------------------------------|-------------------|--------------------|-------|
| Patents granted                      | 1039              | 3575               | 4614  |
| Patents revoked by the Patent Office | 7                 | 15                 | 22    |
| Patents revoked by IPAB/High Court   | -                 | 2                  | 2     |

Source: Compilation from official records

61. We urge the USTR:

- To take note of the global recognition of the attractiveness of India as destination of FDI, the willingness to engage in dialogue to remove impediments to FDI, the making of IP policy and its implementation and evolving jurisprudence.
- To recognize the concerted efforts being made to improve the functioning of the Indian Patent Office.
- To give careful consideration to the categorical statements of companies like Boeing, Honeywell and Corning that they are happy with the IP law and regulation in India.
- To appreciate that the concerns of some in the pharmaceutical industry are overstated and their aggressive advocacy is misplaced.

62. We respectfully submit that pharmaceutical companies such as Abbot and Gilead have demonstrated that they see an opportunity in India with the existing IP regime that strikes a balance between innovation and public health. The assessment of the USTR in the Out-of-Cycle Review can be a powerful influence in either strengthening the positive momentum or dampening the investment climate. We trust it will be the former.

63. We are thankful for the opportunity to make this submission.

<sup>49</sup><http://www.hindustantimes.com/business-news/us-firms-come-to-india-s-rescue/article1-1201310.aspx>

<sup>50</sup><http://www.ipwatchdog.com/2014/10/02/scotus-public-enemy-number-one-for-patent-owners/id=51483/>