



USTR: 2016 SPECIAL 301 SUBMISSION

(Docket No.USTR-2015-0022)

Submitted by

INDIAN PHARMACEUTICAL ALLIANCE

(Email: dgshah@vision-india.com)

**Mumbai
5 February 2016**

Indian Pharmaceutical Alliance

USTR: 2016 Special 301 Submission

1. My name is Dilip G Shah. I am Secretary General of the Indian Pharmaceutical Alliance (IPA). I am respectfully making this submission to the USTR on behalf of the IPA for the 2016 Special 301 Review.
2. The IPA's membership consists of twenty pharmaceutical companies which collectively account for close to 85 percent of private sector investment on pharmaceutical research and development in India, 60 percent of the country's exports of pharmaceuticals and related services and about 45 percent of the domestic market. 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. This submission is confined to the issues relevant to the pharmaceutical industry. It provides information and perspectives that may aid the USTR in determining whether India denies adequate and effective protection of intellectual property rights or denies fair and equitable market access to U.S. persons who rely on intellectual property protection related to the pharmaceutical industry.
4. The facts and commentary in this submission focus on three main themes:
 - Innovation-led American pharmaceutical companies are striking deals with Indian companies to gain access not only to the Indian market but also to the developing world. As such deals are based on expectations of mutual benefit, their number has the potential to increase rapidly, making a significant difference to the revenues of American companies directly, or through their subsidiaries in India. Indian companies are investing in manufacturing facilities in the U.S. so that they can better access their most important market. This also serves to create jobs in the U.S. If these 'green shoots' of collaboration are allowed time and space to grow, they will contribute to clearing the air of past acrimony and help accelerate the momentum of engagement between the U.S. and India at the policy level.
 - Recent developments in India suggest that the procedural irritants relating to patents which have been highlighted to the USTR in the past are being seriously addressed. Specific steps have already been taken to strengthen the Patent Office. The Supreme Court of India has interpreted the Patents Act to remove apprehensions of abusive multiplicity of challenges to the validity of a patent. Important legislation is now in place to speed up the resolution of commercial disputes, including those relating to intellectual property rights. Judicial enforcement of patent rights has strengthened with a number of injunctions being granted to prevent infringement of pharmaceutical patents even before the infringement has occurred.

Indian Pharmaceutical Alliance

- Some long-standing substantive grievances of U.S. companies relating to India's intellectual property rights regime remain. These are mainly the compulsory licensing provision in Section 84 and the prohibition on grant of patents to new forms of known substances without therapeutic benefit in Section 3(d) of the Patents Act. American innovator companies are also concerned by the alleged lack of data exclusivity. India's stance is that the current patent regime is fully TRIPs compliant and strikes the appropriate balance between the grant of monopoly patent rights and public health imperatives. We have detailed our understanding of this stance in our previous submission for USTR's 2014 Special 301 Review and repeating them is superfluous. Instead, we now present further data to suggest that the gulf between the U.S. and Indian patent regimes may not be as wide as perceived in terms of outcomes for patentees. More than other approaches, data-driven dialogue may narrow the divide.

I. Collaboration

5. In August 2015, Amgen Inc. and Dr. Reddy's Laboratories Ltd. (Dr. Reddy's) entered into a strategic collaboration to market and distribute three Amgen medicines in India in the areas of oncology and cardiology. Under the terms of the collaboration, Dr. Reddy's shall perform a full range of regulatory and commercial services to seek approval and launch KyprolisTM (carfilzomib), BlincytoTM (blinatumomab) and RepathaTM (evolocumab) in India.
6. In August 2015, Gilead Sciences Inc. announced additional licensing agreements with Indian companies to manufacture generic hepatitis C medicines for 101 developing countries.¹ The total number of licensing agreements now stands at eleven, up from the seven it had announced on 15 September 2014 for the manufacture and distribution of sofosbuvir (SovaldiTM) and the investigational single tablet regimen of ledipasvir/sofosbuvir (HarvoniTM) 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.²
7. In May-June 2015, AstraZeneca (whose subsidiary is incorporated in the U.S.) has entered into co-marketing deals with Indian companies through their Indian subsidiary. Under this structure, AstraZeneca will continue marketing their products with their global brand names in India, but Indian companies will also launch their own brands of the same drugs under licence. Dr. Reddy's will market saxagliptin and its fixed dose combination with metformin for Type 2 diabetes³ and Sun Pharmaceutical Industries Ltd. (Sun Pharma) will market ticagrelor.⁴

¹<http://www.gilead.com/~media/files/pdfs/other/hcv%20generic%20agreement%20fast%20facts%2072815.pdf>

²<http://www.gilead.com/news/press-releases/2014/9/gilead-announces-generic-licensing-agreements-to-increase-access-to-hepatitis-c-treatments-in-developing-countries>

³<http://www.drreddys.com/media/press-releases/may29-2015.html>

⁴<http://www.sunpharma.com/Media/Press-Releases/Press%20Release%20-%20Sun%20AstraZeneca%20India%20Collaboration-.pdf>

Indian Pharmaceutical Alliance

A similar deal has been struck by Boehringer Ingelheim (whose subsidiary is incorporated in the U.S.) with Lupin Ltd. for linagliptin and its combination with metformin in October 2015.⁵

8. In a particularly significant development in September 2014, Merck & Co., Inc. (Merck) and Sun Pharma announced an exclusive worldwide licensing agreement for tildrakizumab, Merck's investigational therapeutic antibody candidate for the treatment of chronic plaque psoriasis, a skin ailment. Under terms of the agreement, Sun Pharma will acquire worldwide rights to tildrakizumab for use in all human indications from Merck for an upfront payment of U.S. \$80 million. Merck will continue all clinical development and regulatory activities, which will be funded by Sun Pharma.⁶The drug is currently under development.
9. The instances above evidence the multiple ways in which individual corporations are collaborating with Indian enterprises to increase their access to the Indian market, and in at least one instance, to the markets of the developing world. The licensing agreement of Sun Pharma with Merck is of particular significance as it is an instance of an Indian company acquiring worldwide rights and funding the development of a significant drug candidate.
10. The growth rate of foreign companies in India continues to be lower than Indian companies. However, it has accelerated sharply in 2015 and the gap is closing.

Sales Growth of Foreign and Domestic Pharma Companies in India

	2013		2014		2015	
	Value Rs. Billion	Growth %	Value Rs. Billion	Growth %	Value Rs. Billion	Growth %
Foreign	188	6.3%	201	6.9%	227	12.8%
Domestic	601	11.6%	681	13.4%	789	15.8%
Total	789	10.3%	882	11.8%	1016	15.1%

Source: IMS Health

Note: Figures are for year ending December. Ranbaxy is considered an Indian company for all the years for the purposes of this analysis. Domestic sales include revenues from products licensed to Indian companies or co-marketed by them under their own brand name.

11. We urge the USTR to take note of these developments that augur well for the innovation-led American pharmaceutical industry to accelerate its growth in India and the developing world.

⁵<http://www.lupinpharmaceuticals.com/14October2015.htm>

⁶<http://www.sunpharma.com/Media/Press-Releases/Press%20Release%20Licensing%20Agreement%20for%20Tildrakizumab.pdf>

Indian Pharmaceutical Alliance

II. Jobs

12. Apart from commercial and marketing jobs, the Indian pharmaceutical industry is making investments in manufacturing and research facilities in the U.S. and providing employment for skilled technical staff, as evidenced by examples from the membership of the IPA.
13. Sun Pharma has nine manufacturing facilities through its subsidiaries – three in New Jersey, two in Massachusetts and one each in Pennsylvania, Tennessee, Illinois and Michigan as well as a research center in New York.
14. Dr. Reddy's has two manufacturing sites through its subsidiaries – one in Louisiana and the other in Tennessee.
15. Wockhardt Ltd. has a manufacturing facility at Morton Grove, Illinois.
16. Lupin Ltd. opened its new Center of Excellence for Inhalation Research in Coral Springs, Florida in August 2015.⁷
17. Admittedly, these are small operations by U.S. standards, but they must be seen in the context of the estimated job gains in the U.S. if India achieves U.S. levels of IP protection. The United States International Trade Commission (USITC) has estimated the likely increase in employment in the U.S., if India provided for TRIPS-Plus IPR at par with the prevalent standard in the U.S. The simulation studies for all U.S. sectors put together indicated "employment gains of less than 10,000 jobs".⁸ The pharmaceutical industry would account for some fraction of this.
18. It is thus obvious that the net impact on employment in the pharmaceutical industry in the U.S. on account of India's IPR regime is negligible, if at all there is one. We urge the USTR to take this into consideration while assessing the adequacy of IP protection in India for pharmaceuticals.

III. Patent Office Backlog

19. The backlog of patent applications is of equal concern to Indian and foreign applicants. IPA had noted in its previous submissions to the USTR that the availability of skilled patent examiners was the major hurdle. The Government of India had announced an ambitious plan in July 2013 to recruit 500 patent and design examiners in five years to reduce application pendency from 3-5 years to one year. Action has been taken since then and the number of patents examined has increased sharply from 2013-14, though it is yet to be reflected in disposals (which is the aggregate of patent grants, rejections and abandonments).

⁷<http://www.lupinpharmaceuticals.com/7August2015.htm>

⁸USITC, Trade, Investment, and Industrial Policies in India: Effects on the U.S. Economy, December 2014
https://www.usitc.gov/publications/332/pub4501_2.pdf, p 89

Indian Pharmaceutical Alliance

Latest published data on patent applications and disposals⁹

	2012-13 (Apr-Mar)	2013-14 (Apr-Mar)	2014-15 (Apr-Dec)
Filed	43674	42950	32269
Examined	12268	18306	15525
Grants	4126	4225	4817
Disposals	9027	11672	9893

20. Examiners continue to be regularly recruited. The results of the latest round of recruitment have been declared on 22 January 2016. It is encouraging to note that 114 examiners in disciplines relevant to the pharmaceutical industry have been selected - 73 persons for Chemistry, 24 for Biotechnology and Microbiology, 15 for Biomedical Engineering and 2 for Biochemistry.¹⁰ The process for fast-track recruitment of an additional 263 examiners (in all disciplines) for patents and designs for a contractual period of one year has also commenced in October 2015.¹¹
21. India operationalized the international patent search and examination service in October 2013. As of 31 December 2014, the latest date for which published information is available, the Indian Patent Office had received 538 international applications choosing India as the International Search Authority. Eight applicants chose India as the authority for international preliminary examination.¹² International scrutiny of the work of Indian Patent Office will enable benchmarking its quality against global standards.
22. In another positive development in November 2014, the Indian Patent Office (IPO) and the European Patent Office (EPO) signed a Memorandum of Understanding (MOU) in which the “overriding objective is to support the development of the patent system in terms of service delivery and efficiency, particularly by means of technical co-operation and exchange of best practices in areas such as patent examination, administration and information. On this occasion, the EPO and the Indian IPO also signed the first biennial work plan under the MoU.”¹³

IV. Streamlining Opposition Procedures

23. Several submissions have been made in the past expressing concern about the provision of pre-and post-grant opposition under Section 25 of the Indian Patents Act. We had responded to this concern in our submission for the 2014 Special 301

⁹Annual report of the Department of Industrial Policy and Promotion, 2014-15, http://dipp.nic.in/English/Publications/Annual_Reports/AnnualReport_Eng_2014-15.pdf, p 119

¹⁰<http://npc.online-ap1.com/sectionList>

¹¹<https://npc2.online-ap1.com/NPC2-ENG-ADV.pdf>

¹²http://dipp.nic.in/English/Publications/Annual_Reports/AnnualReport_Eng_2014-15.pdf, p 114-115

¹³<http://www.epo.org/news-issues/news/2014/20141107.html>

Indian Pharmaceutical Alliance

Out-of-Cycle Review by pointing out that pre-grant opposition was a long-standing feature of the Patents Act and the compelling considerations for its retention. We had also pointed out that we were not aware of abusive pre- and post-grant oppositions by the same person on the same grounds for the same patent.

24. Another potential concern (which has not been pointed out in previous submissions to the USTR) is that there are multiple options to challenge the validity of patent under the Indian Patents Act – by way of post-grant opposition under Section 25(2), revocation proceeding before the Intellectual Property Appellate Board or as a counter-claim in a suit for infringement before a High Court under Section 64. The Supreme Court of India had occasion to consider whether the multiple options available could be pursued. By a judgement of 2 June 2014, the Supreme Court effectively ruled that a person can choose only one option to pursue from among the three to avoid multiple litigations.¹⁴
25. The judgement of the Supreme Court above does not deal with the issue of filing of both pre-and post-grant oppositions by the same party on the same patent. However, the reasoning of the Supreme Court in the case above may have a deterrent effect on such litigation if it is merely abusive.

V. Reducing Delays in Litigation

26. The delays in resolution of disputes by the Courts in India is of equal concern to Indian and foreign patentees. Our cursory analysis of the litigation referred to in this and previous submissions to the USTR suggest that there has been speedy disposal of appeals and revision applications (against interlocutory orders). It is possible that suits for infringement take a longer time to resolve. A significant piece of legislation is now in place to address this issue.
27. Parliament has enacted The Commercial Courts, Commercial Division and Commercial Appellate Division of High Courts Act, 2015 on 31 December 2015.¹⁵ The Act authorizes the setting up of Commercial Courts and Commercial Divisions of High Courts to try suits pertaining to 21 specified categories of disputes where the claim is above Rs. 10 million (nearly \$150,000 at current rates of exchange). Appeals will also be heard by a specialized Commercial Division in the High Court. Intellectual Property is one of the specified categories.
28. This is a very significant step aimed at reducing delays and improving administration of justice. It will take some time for the specialized courts to be created and become operational. However, it is likely that the setting up of these courts will considerably speed up the resolution of commercial disputes, including Intellectual Property disputes.

¹⁴ *Dr. Aloys Wobben v. Yogesh Mehra*, Civil Appeal No. 6718 Of 2013, Supreme Court of India, particularly para 26, available at <http://supremecourtindia.nic.in/outtoday/ac671813.pdf>

¹⁵ Available at <http://bombayhighcourt.nic.in/libweb/actc/yearwise/2016/2016.04.pdf>

Indian Pharmaceutical Alliance

VI. Strengthened Judicial Enforcement

29. We had noted in our 2014 Special 301 Out-of-Cycle Review submission in October 2014 that injunctions restraining manufacture and sale had been issued by five different judges of the Delhi High Court in the previous seven months when suits had been instituted by Novartis for infringement, even before the infringement had occurred. Further, between 17 June 2013 and 14 October 2014, six different Judges of the Delhi High Court granted *ex parte* injunctions in eight cases restraining manufacture or sale of sitagliptin (the generic name of Merck's JanuviaTM) and its combination with metformin.
30. More recent instances confirm that injunctions continue to be granted even before infringement has occurred, providing efficacious protection to patentees in appropriate cases. For example, Bristol- Myers Squibb has obtained continuance of injunctions against the launch of a generic version of SprycelTM (dasatinib) in June 2015.¹⁶
31. Representations had been made to the USTR in previous reviews expressing apprehension about the course of the dispute between Roche and Cipla relating to erlotinib (TarcevaTM). In the first instance, Cipla's counter-claim for revocation of the patent in the suit for infringement was rejected. However, Roche's allegation of infringement was also rejected, and as a consequence, its prayer for an injunction against the manufacture and sale of Cipla's erlotinib was not granted. In November 2015, on appeal, the Delhi High Court has affirmed the dismissal of Cipla's counter-claim of revocation of the patent and disagreed with the trial judge on the question of infringement. In effect, the Delhi High Court has upheld the validity of the patent and confirmed its infringement by Cipla. Attorney's fees were also awarded to Roche and Cipla was directed to render accounts for the determination of damages¹⁷. Cipla has reportedly appealed to the Supreme Court.
32. Another case that had figured in past submissions to the USTR was the dispute between Merck and Glenmark relating to sitagliptin (the generic name of Merck's JanuviaTM), and its combination with metformin. Merck had sued Glenmark for infringement of its patent protecting sitagliptin and Glenmark had counter-claimed that the patent was invalid. The Delhi High Court has pronounced judgement in October 2015 upholding the validity of the patent in question and has determined that Glenmark had infringed the patent. Glenmark was prohibited from continued infringement and was ordered to pay the costs incurred by Merck for the litigation. No damages were awarded as Merck did not make the claim for it.¹⁸

¹⁶*Bristol-Myers Squibb v D. Shah*, Delhi High Court, available at <http://indiankanoon.org/doc/58533709/>; *Bristol-Myers Squibb v J.D. Doshi*, Delhi High Court, available at <http://indiankanoon.org/doc/29177380/>

¹⁷*F. Hoffmann-la Roche v Cipla*, Delhi High Court, available at <http://indiankanoon.org/doc/57798471/>

¹⁸*Merck v Glenmark*, Delhi High Court, available at <http://lobis.nic.in/ddir/dhc/AKP/judgement/07-10-2015/AKP07102015S5862013.pdf>

Indian Pharmaceutical Alliance

33. Glenmark's challenge to the validity of the patent was based, in part, that it was obvious. Previous submissions to the USTR had expressed apprehension that Indian courts may incorrectly determine that patents were invalid because of obviousness based on 'hindsight' analysis. The judgement in *Merck v Glenmark* serves to allay the apprehension. The judgement rejected the contentions of Glenmark that were deemed to be based on hindsight analysis. The judgement categorically declares that "[h]indsight analysis is not permissible"¹⁹ and cites American jurisprudence in doing so.²⁰
34. Merck had not obtained an injunction on institution of the suit to prevent Glenmark from infringing its patent (though injunctions were obtained on institution of infringement suits against others) because of the peculiar circumstances of the case briefly alluded to in our 2014 Special 301 Out-of-Cycle Review submission. The Supreme Court had therefore ordered expeditious disposal of the suit. The suit was filed in 2013 and was decided in 2015, despite the time taken to arrive at a settlement through mediation.

VII. Compulsory Licensing

35. Compulsory licenses can be granted in India under Section 84 of the Patents 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 NexavarTM.
36. In June 2015, Lee Pharma sought a compulsory license for the manufacture and sale of AstraZeneca's OnglyzaTM (sitagliptin) and KombiglyzeTM, its combination with metformin used in the treatment of Type II diabetes alleging that all the three conditions prescribed in Section 84 had been met. After a detailed review of the evidence and an oral hearing, the Controller of Patents determined that Lee Pharma had not been able to substantiate its case and rejected its application on 20 January 2016.²¹
37. It has been alleged in the past India's compulsory licensing provision is directed at favoring the domestic generic industry. As the rejection of the Lee Pharma application demonstrates, and as the Intellectual Property Appellate Board declared while upholding the grant of the only compulsory license so far (for Bayer's NexavarTM), the grant of a compulsory licence is not to favor any applicant but to implement the law to meet the reasonable requirements of the public at a reasonably affordable price. Moreover, this is done in a transparent manner and is subject to judicial review through an established process.

¹⁹*ibid.*, para 93

²⁰*ibid.*, para 89

²¹Lee Pharma v AstraZeneca, Controller of Patents, available at http://www.ipindia.gov.in/iponew/compulsoryLicense_Application_20January2016.pdf

Indian Pharmaceutical Alliance

VIII. Section 3(d)

38. Section 3(d) of the Indian Patents Act is perhaps the most irksome to a section of the pharmaceutical industry in the U.S. For India, it represents a balance between the incentive to innovate and public health. Section 3(d) only prohibits the grant of patents for new forms of known substances that do not enhance efficacy. In other words, India deems it fair and equitable to reward innovation with the grant of a patent for a new and useful discovery which confers a commercially valuable monopoly to a patentee for twenty years. India also seeks to safeguard public health by prohibiting the grant of secondary patents (and extension of monopoly) for an already patented substance without evidence of therapeutic benefit. This allows the entry of affordable generics after the expiry of the primary patent and serves the cause of public health by increasing access in a country like India where most people will find the cost of patented drugs prohibitive.
39. We have made extensive submissions to the USTR in the past on this issue and have argued that is TRIPS-compliant in view of the flexibilities contained in the TRIPS Agreement and the Doha Declaration. It would be superfluous to repeat them here. Instead, we propose to show that though the paths of India's Section 3(d) and the Hatch-Waxman provisions of the U.S. are very divergent, the outcomes may not differ that much.
40. The point is perhaps best illustrated with the example of GleevecTM of Novartis, the generic name of which is imatinibmesylate. The primary patent was set to expire in the U.S. in July 2015, after reckoning the extensions it received. Novartis however filed a number of secondary patents that sought to extend patent protection till Jun 2022:

Period of Patent Protection in the U.S.

(Date of first approval: 10 May 2001)

Patent No	Patent Expiry	Patent Term Extension/ Adjustment	Pediatric Extension	Patent Claims
Primary patent				
5521184	28 May 2013	4 Jan 2015	4 Jul 2015	Imatinib and its salts
Secondary patents				
6894051	16 Jul 2018	23 May 2019	23 Nov 2019	β-crystalline form of imatinibmesylate
6958335	19 Dec 2021	-	19 Jun 2022	Treatment of gastrointestinal stromal tumors
7544799/ RE43932	16 Jan 2019	-	16 Jul 2019	Crystalline form of imatinibmesylate with non-needle shaped crystals

Source: Orange Book

Indian Pharmaceutical Alliance

41. Patent protection was therefore extended by over four years by secondary patents for polymorphic forms of imatinibmesylate (the subject of the rejection under Section 3(d) of India's Patents Act) and a further three years for the use of the product in the treatment of gastrointestinal stromal tumors. (Incidentally, there was no application for a patent for the treatment of gastrointestinal stromal tumors as TRIPS does not require grant of patents for additional new uses and India does not do so). It is easy to see why the further period of monopoly achieved through secondary patents is valuable to Novartis. It was the bestselling drug for Novartis, clocking \$ 4.7 billion in global sales in 2015²², with about half the sales coming from the U.S. alone.
42. The expectation generated by the secondary patents has, however, not been realized. Sun Pharma has introduced its generic version of GleevecTM on 1 February 2016, just seven months after the expiry of the primary patent. How did this happen?
43. Sun Pharma was the first to file an Abbreviated New Drug Application (ANDA) for imatinibmesylate with a paragraph IV certification – implying that Sun Pharma believed that the patents so certified were either invalid or non-infringed by their product. The primary patent was not challenged and they proposed to launch the generic after its expiry. While details are not publicly available, it is speculated that the paragraph IV certification was with respect to the two patents for crystalline forms of imatinibmesylate (one of which corresponds to the patent application for the β -crystalline form that was rejected in India under Section 3(d)). GleevecTM is presently approved for use in ten indications in the U.S., two of which are for the treatment of GIST.²³ Sun Pharma has 'carved out' these indications which are presumably covered by the Novartis secondary patent and one indication which may be subject to orphan drug exclusivity. Their product is approved for use in the remaining seven indications²⁴ and can be marketed for these.
44. Thus the only patent monopoly that remains for GleevecTM is for its use in three indications. The seven-month reprieve from generic competition that GleevecTM obtained was because Novartis and Sun Pharma settled the matter out of court. More generic competition is expected to follow after the 180-day period of exclusivity of Sun Pharma ends.
45. It is clear that the outcome for GleevecTM in the U.S. (which follows the Hatch Waxman Act) and in India (which has Section 3(d), subject to a transparent and established process of judicial review) is not that different.

²²<https://www.novartis.com/investors/financial-data/product-sales>

²³http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/021588s042lbl.pdf

²⁴<http://www.imatinibrx.com/>

Indian Pharmaceutical Alliance

46. It is also interesting to note that a different route was followed in China, but with a similar outcome. The primary patent for GleevecTM reportedly expired in April 2013 although patents for the crystalline form and the GIST remained in force. Two Chinese companies appear to have received approval to market the generic version of imatinibmesylate by June 2013.²⁵ One of them, Jiangsu Hansoh Pharmaceutical Co. Ltd. reportedly gained “significant market share”. It then challenged the validity of the patent of Novartis in September 2014 for the GIST indications. The Patent Reexamination Board of China held that the patent was invalid on the ground of obviousness in October 2015.²⁶
47. The question that arises is whether the GleevecTM instance can be generalized. Amy Kapczynski and her colleagues studied the patents of 432 new molecular entities (with at least one patent) approved by the U.S. Food and Drug Administration between 1985 and 2005.²⁷ Independent ‘PIPES’ patents (i.e. secondary patents for polymorphs, isomers, prodrugs, esters and salts, without any compound claims, similar to the patents prohibited by Section 3(d) in India) increased from 13% to 23%,²⁸ adding 6.3 years to the patent monopoly on an average for each product.²⁹ Though secondary patents added significantly to nominal patent life, the actual additional life was limited as they were prone to invalidation or designing-around:³⁰

“Secondary patents may be more vulnerable to attack than chemical compound patents, and if they are frequently invalidated or designed around, they will in practice have less effect on market exclusivity than their effects on nominal patent life suggest. There is reason to suspect that this is the case. Although industry groups reject the suggestion that secondary patents are weaker than chemical compound patents, in practice companies that seek such patents often appear to hold this view. Previous empirical work shows that drugs with non-active ingredient patents, particularly those that generate incremental patent life, are much more likely to attract patent challenges in the U.S. A European Commission study of the sector recently concluded that generic litigation “mainly concerns secondary patents,” and that generic companies have high success rates in cases involving secondary patents.” (Internal citations omitted)

²⁵<http://drugwonks.com/blog/china-moves-on-gleevec>

²⁶<http://www.twn.my/title2/health.info/2016/hi160101.htm>

²⁷ Kapczynski A, Park C, Sampat B (2012) Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of “Secondary” Pharmaceutical Patents. *PLoS ONE*, December 2012, Volume 7, Issue 12, p8, available at <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0049470>

²⁸ *Ibid.* p4, Col 2

²⁹ *Ibid.* Table 3, p7

³⁰ *Ibid.* p7, Col 2-p 8, Col 1

Indian Pharmaceutical Alliance

48. One of the empirical studies cited by Kapczynski and colleagues studied the new molecular entities that were subjected to generic competition between 2001 and 2010 and concluded that later expiring patents are successfully (and disproportionately) challenged, limiting the effectiveness of ‘evergreening’ of pharmaceutical patents in the United States. While there are differences in individual cases, overall, there is no significant increase in the average patent life despite the secondary patents:

“The average nominal patent term is 16 years for drugs with first generic entry between 2001 and 2010. By comparison, average effective market life for these drugs is 12 years, not much different than in the previous decade, and greater than in the decade before Hatch–Waxman. Patent challenges are the key driver of the gap between nominal patent term and effective market life.”³¹ (Internal citation omitted)

49. If secondary patents are often weak and successfully challenged, the question is why they are granted in the first instance. The study provides an answer:

“In drugs, and in other industries, resource-constrained patent examiners at the U.S. Patent and Trademark Office may lack the incentive or capacity to thoroughly assess each of the hundreds of thousands of patent applications they process annually.....In this context, generic patent challenges may reflect society’s strongest defense against non-meritorious patents that would harm payers and patients.”³²

50. The legal framework in the United States mitigates the problem of non-meritorious secondary medicinal patents by providing the incentive of exclusivity to successful generic challengers, but India does not have a comparable provision in its law. Nor is it feasible to have one as India does not have mandatory generic substitution (and the consequent rapid substitution of generics) as in the U.S. to make the incentive meaningful. Section 3(d) in India’s Patents Act provides an alternative. It is perhaps a more efficient way to avoid the grant of weak patents in the first instance and then suffer the burden of litigation to set matters right. Kapczynskiet *alsay* it best³³:

“Even if secondary patents are perceived (and perceived correctly) as more vulnerable than chemical compound patents, this does not mean that they are without meaningful effects. A patent that is ultimately invalidated could still yield substantial benefits for an originator company. Patent litigation in the pharmaceutical industry is notoriously risky and resource intensive, and becomes more so where more patents and claims are involved. This reduces

³¹Hemphill S, Sampat BN. Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals. *Journal of Health Economics*, 2012, 31(2): 327–339 p 336, Col 2

³²Kapczynskiet *al.* p 337, Col 1.

³³*Ibid.*p8

Indian Pharmaceutical Alliance

the potential pool of competitors to those with the resources to wage multi-year patent battles. Such litigation may take several years to resolve (the European Commission estimates almost three years for an average case) and in the U.S. a secondary patent may provide the basis for an automatic 30-month stay on generic approval under the Hatch-Waxman Act. This again comports with anecdotal reports from the industry, such as this one expressed by a pharmaceutical executive from an originator company: “Secondary patents will not stop generic competition indefinitely but may delay generics for a number of years, at best protecting the originator’s revenue for a period of time”. It is possible that even a weak secondary patent that is invalidated after litigation could produce years of valuable exclusivity, though this is ultimately an empirical question.

Furthermore, litigation as a means to invalidate weak secondary patents is a far less plausible policy outcome in countries without robust incentives for generics to undertake the expense of challenging these patents. Insofar as the policy response to the rise of secondary patents relies on litigation and rigorous patent examinations as a means to ensure that only truly inventive secondary patents issue, resource-limited settings are likely to be at a substantial disadvantage. This may help to explain why countries like India have sought to adopt clear statutory bars on certain types of secondary patent claims....” (Internal citations omitted)

51. The USTR noted as follows in its 2015 Special 301 Report:³⁴

The United States continues to have concerns that Section 3(d) of India’s Patents Act, as interpreted, may have the effect of limiting the patentability of potentially beneficial innovations. Such innovations could include drugs with fewer side effects, decreased toxicity, improved delivery systems, or temperature or storage stability. In practice, India has already applied this standard to deny patent protections to potentially beneficial innovations, some of which enjoy patent protection in multiple other jurisdictions.

52. As far as we are aware, there is no authoritative judicial determination as yet that fewer side effects and decreased toxicity are not attributes of efficacy; nor are we aware of a patent application being rejected on this basis. As far as improved delivery systems, or temperature or storage stability (or other advantages of this kind, such as improved manufacturability) of known substances are concerned, Section 3(d) will prohibit grant of patents to the same substances in the absence of a showing of enhancement of efficacy. This does not mean that all patents for such innovations are denied. Novel and inventive processes to manufacture substances with improved properties are patentable. This is reasonable as the innovation is not in the substance itself as in general, it is in the process to manufacture it.

³⁴ p 41

Indian Pharmaceutical Alliance

53. We have argued in earlier submissions that Section 3(d) is TRIPS-compliant. We have now shown that, in practice, the mere grant of a secondary patent of the kind that is prohibited by Section 3(d) does not necessarily translate into increased patent protection even in the U.S. Litigation, as provided for in the Hatch Waxman Act, is one path to protect against non-meritorious patents; Section 3(d) is another. We therefore respectfully urge the USTR to revisit earlier assessments of the implications and impact of Section 3(d).

IX. Concluding Comments

54. We submit that there has been considerable progress on the intellectual property front in the last year. The Patent Office continues to be strengthened to facilitate the efficient grant of patents. Judicial enforcement of patent rights have been strengthened with many injunctions restraining infringement being granted, even before it has occurred. There is reason to believe that apprehensions relating to abusive opposition procedures, incorrect application of ‘hindsight’ analysis to invalidate patents, compulsory licensing and the consequences of Section 3(d) have been significantly allayed.

55. There are only two other substantive issues of possible concern to some in the U.S. pharmaceutical industry that appear to remain: data exclusivity and ‘patent linkage’. We have previously made extensive submissions in the past detailing the basis for India’s stance against data exclusivity. Additionally, there is no estimate of the consequent harm – actual or potential - to the U.S. pharmaceutical industry that has been provided to the USTR. We have also made detailed submissions on the infeasible administrative burden that a patent-linkage system would impose in the context of the Indian system, as well as the significant welfare costs that would follow if the availability of generics is delayed by patents that are eventually found to be invalid or non-infringed.

56. At the same time, there is a noticeable increase in fair and equitable access to the Indian market for the U.S. pharmaceutical industry, as evidenced by the spurt in rate of revenue growth of foreign companies in India in 2015 and the instances of licensing and co-marketing deals that are being struck between U.S. and Indian enterprises for new and innovative medicines.

57. Both these trends – the strengthening of protection of IPR in India and accelerating the momentum of commercial engagement between the U.S. and Indian pharmaceutical industry - call for building consensus on the issues that remain. Data-driven analysis and debate, rather than other means, appears to us to be the preferable approach.

Indian Pharmaceutical Alliance

58. We are encouraged that there is now considerable engagement between the USTR and India's Minister for Commerce and Industry. Ministerial level U.S.-India Trade Forum meetings commenced in 2014 after a hiatus of four years. A High Level Intellectual Property Working Group was reportedly decided upon to function as part of the Trade Forum.³⁵ The next Ministerial meeting of the Trade Forum was held on 29 October 2015 and we are pleased that the joint communique "praised the increased engagement between technical and senior officials on intellectual property (IP) and reviewed the results of the dialogues on copyrights, trade secrets, patents, traditional knowledge and the Traditional Knowledge Digital Library (TKDL), standard essential patents, genetic resources, and IP policies that took place in 2015."³⁶ The communique also noted that "[d]iscussions in 2015 helped provide greater transparency into IPR issues, and lay the foundation for further work in 2016."
59. We are thankful for the opportunity to make this submission.

³⁵ <http://pib.nic.in/newsite/PrintRelease.aspx?relid=110288>

³⁶ <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2015/october/united-states-and-india-joint>