



Written Submissions

INDIAN PHARMACEUTICAL ALLIANCE

U.S. INTERNATIONAL TRADE COMMISSION

INVESTIGATION No. 332-543

**TRADE, INVESTMENT, AND INDUSTRIAL POLICIES IN INDIA:
EFFECTS ON THE U.S. ECONOMY**

For the Indian Pharmaceutical Alliance

/Signed/

D.G. Shah

Secretary General

Email: dgshah@vision-india.com

9 April 2014

WRITTEN SUBMISSIONS OF THE INDIAN PHARMACEUTICAL ALLIANCE

1. My name is Dilip G Shah. I am Secretary General of the Indian Pharmaceutical Alliance (IPA). I have testified before the Commission on February 12, 2014 and have also filed a post-hearing brief on February 24, 2014 to supplement my oral testimony. I am filing these written submissions on behalf of the IPA and am grateful to the Commission for the opportunity to do so.
2. As was the case with our earlier testimony and brief, these written submissions are restricted to issues relating to the pharmaceutical industry. The main purpose of these written submissions is to provide further information that may aid the investigation of the Commission. Though our earlier briefs are not repeated, the conclusions are briefly re-stated and referenced for the convenience of the Commission.

Trade, investment and overall business environment

3. The evidence suggests that the India's trade and investment policies, as well as the overall business environment has been conducive to robust growth in India-US trade and investment, particularly in the last decade.
4. Trade¹: Between 2000-2012, India-US bilateral –
 - Merchandise trade (excluding fuel and gold) grew 13.3% a year, about thrice the overall annual growth of US merchandise trade of 4.6 percent. This is higher than the growth in India's trade with EU and Japan.
 - Services trade grew 17.4 percent a year, significantly faster than overall US services trade which averaged 6.7 percent annually in the same period.

¹Subramanian, Dr. Arvind. Written testimony, USITC Investigation No 332-543.

- The rising India-US trade merchandise trade “is not a result of a large trade imbalance, which can adversely affect the U.S. economy and labor market”, but “has been roughly balanced, with deficits close to or less than \$10 billion in the last decade”. In contrast to China, India has achieved trade integration “without imposing harm on the rest of the world”.
- Overall, bilateral India-US trade in goods and services is greater than \$100 billion in 2013.²

5. Investment: Dr. Arvind Subramanian of the Petersen Institute notes that actual FDI is often higher than officially reported. The picture that emerges, based on latest estimates from transaction data is³:

- Since 2003, total FDI inflows into India have averaged about \$62 billion annually, a ten-fold increase over \$6 billion in prior years. Similarly, India’s outward FDI has averaged \$33 billion annually, compared to \$3 billion annually in the years before 2003.
- The United States has consistently been the single largest FDI investor in India for the last decade, accounting for about 22 percent of all FDI inflows, considerably greater than the UK, Japan, Germany and France. This represents a ten-fold increase compared with the early years of this millennium.
- Indian FDI to the US has also increased substantially to about US\$ 3 billion a year since 2003. Between 2004 and 2009, 90 Indian companies made 127 greenfield investments and 239 companies invested in mergers and acquisitions across a wide range of sectors, directly creating tens of thousands of jobs in the United States.

6. Overall business environment: India’s major economic policy changes in the last two decades have triggered the sharp growth in bilateral trade between India and the United States. Though the

²Summers, Ron. Pre-hearing brief and testimony, USITC Investigation No 332-543.

³Subramanian, Dr. Arvind. Written testimony, USITC Investigation No 332-543.

overall momentum has been positive, it has been choppy in recent years due to a variety of factors including the global financial crisis as well as domestic economic woes in India with the weakening rupee and debilitating inflation. While much remains that can — and should — be done, it is important to note, as Dr. Arvind Subramanian has done, that most of the issues impact both foreign and domestic businesses; for foreign businesses, residual “concerns are mostly sectoral” and should not obscure positive developments as well as positive long-term trends. These concerns are most obvious in the pharmaceutical sector as reflected in the testimony before the Commission by the PhRMA, and as the US-India Business Council noted in its testimony, it has been “aggravated by a belief by some that India is an outlier with respect to IPR”. IPA submits that these beliefs are unwarranted perceptions, which are neither universally shared, nor borne out by the facts.

7. Patent laws: India has amended its patent law in 2005, in compliance with the TRIPS agreement. (Please see paras 28-42 of IPA’s Post-hearing brief to the Commission). The adequacy of this important policy decision has been recognized by many in the United States, including in submissions made by US corporations to the USTR for the Special 301 review, 2014:

- Boeing⁴: “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.”

⁴The Boeing Company. Statement to the USTR, Special 301 Review 2014, March 6, 2014.
<http://www.regulations.gov/contentStreamer?objectId=0900006481613608&disposition=attachment&contentType=pdf>

- Honeywell⁵: “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.”
- Corning⁶: Most recently, 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.”

It is apparent that the concerns with Indian patent laws are mainly that of some in the pharmaceutical sector.

The pharmaceutical sector

8. In view of the concerns of some in the US pharmaceutical industry, it will be useful to review the growth in trade and investment by the United States in the pharmaceutical sector.
9. Trade: US exports of pharmaceutical products to India has grown 470% in 2000-2012, nearly twice as much as the growth of total US pharmaceutical exports to the world in the same period:⁷

	Total growth, 2000-2012	Average growth over prior year
US exports to India	470%	18%
US exports to world	242%	11%

10. FDI: Overall, FDI into India in the pharmaceutical sector has been significant since 2000 and has accounted for about 6% of the total FDI between April 2000 and December 2013. As a matter of

⁵Honeywell International Inc. Statement to the USTR, Special 301 Review 2014, March 7, 2014.
<http://www.regulations.gov/contentStreamer?objectId=0900006481626712&disposition=attachment&contentType=pdf>

⁶<http://www.hindustantimes.com/business-news/us-firms-come-to-india-s-rescue/article1-1201310.aspx>

⁷Palmedo, Mike, based on WTO data, at <http://infojustice.org/archives/32249>

fact, the proportion of FDI in the pharmaceutical sector has been a little higher than the long term average in the last three years.⁸

11. The investment into India in the pharmaceutical sector by US corporations is significant. Among the US corporations are Abbot, which is ranked the highest in domestic sales in India, Mylan and Bristol-Myers Squibb. Other corporations including Merck and Gilead have entered into partnerships with Indian companies. (Please see paras 5-13 of IPA’s Post-hearing brief to the Commission for details).
12. Business environment: The robust growth in trade and investment by US pharmaceutical companies belie the concerns of some in the pharmaceutical industry in the US. Ground level data show that pharmaceutical sales of foreign companies have grown faster than domestic corporations and they have gained in market share. Consistent with the overall trend, US corporations have also recorded substantial growth in their India operations between 2009 and 2013. (Please see table in para 50 of IPA’s Post-hearing brief to the Commission.)

Market share and sales growth of foreign and domestic corporations in India

Particulars	2005*		2013*		2013/2005
	Value Rs Cr	MS %	Value Rs Cr	MS %	Growth %
Foreign Companies	5,002	22%	22,092	28%	442%
Domestic Companies	18,241	78%	56,552	72%	310%
Total	23,243	100%	78,644	100%	338%

*Year ending December. MS: Market share. Source: IMS

Patent Environment

13. India’s patent environment has been assailed by some in the US pharmaceutical industry. PhRMA paints a “bleak picture of patent protection in India – a barren environment that regularly produces

⁸http://dipp.nic.in/English/Publications/FDI_Statistics/2013/india_FDI_December2013.pdf

unjustifiable patent revocations, denials, and infringement”⁹. The further allegation is that “[o]ver the past two years, at least fifteen products have had their patent rights undermined”. We submit that these sweeping indictments are incorrect and unfair.

14. Four issues of particular concern to the US pharmaceutical industry, namely, lax enforcement, data exclusivity, compulsory licensing under Section 84 and Section 3(d) of India’s Patents Act, are addressed subsequently. Other issues that are relevant across all industries, but have been pressed only by some in the pharmaceutical industry are dealt with in this section. These include Patent Office delays (oft repeated in various fora) as well as allegations in testimony before this Commission of unnecessarily burdensome patent office requirements and denials or revocations based on flawed legal reasoning. The impression that is sought to be created by such sweeping generalizations is that India flagrantly disregards patent rights. This is wholly unjustified. We invite the Commission’s attention to specific examples of pharmaceutical patents provided in this submission that paint a picture very different from that of the PhRMA.

15. Patent Office: While there is considerable scope for improvement in efficiency and reduction in delays, several steps have already been taken by the Patent Office to address the concerns of industry:

- The primary reason for the patent backlog in India is the inadequate number of patent examiners. A news item published on July 26, 2013 reports that the Controller of Patents plans to recruit 500 patent examiners over five years with the goal of reducing the examination period from the current 3-5 years to one year. About 150 examiners were recruited in 2013 and have undergone training preparatory to their joining the Patent Office.¹⁰

⁹PhRMA, Pre-hearing statement, USITC, January 390, 2014.

¹⁰<http://www.livemint.com/Politics/hgOckYuyYrRelSuRAxz4ij/To-clear-backlog-Indian-patent-office-to-hire-500-over-next.html>

- E-filing of patents has been enabled since 2007. Patent application status is also available online. Full-text search of granted patents is available from private service providers.
- The Patent Office is making efforts to improve the quality of examination of pharmaceutical patents, in consultation with the industry and other stakeholders. Very recently, Draft Guidelines for the examination of pharmaceutical patents have been published for public comment.¹¹
- The streamlining of pre-grant opposition proceedings before the Patent Office is taking place, aided by the effective oversight of the Intellectual Property Appellate Board (IPAB). In January 2014, the refusal of a patent to Abraxis Bioscience, a US corporation, consequent to a pre-grant opposition, has been set aside by the IPAB and remanded back to the Patent Office for reconsideration.¹²
- The Patents Act in India ensures that even if there are procedural delays in the grant of a patent, whether by reason of examination or opposition, there is no erosion in the effective life of the patent, which remains 20 years from the date of first filing. Further, there is no substantive damage to the patentee, as the Indian statute provides for damages from the date of publication of the patent application, in the event of infringement of a granted patent. In the United States, Infringers are liable for damages from the date of grant of the patent.

16. Burdensome patent office procedures: PhRMA provides no specifics, but it is likely that it is alluding to Section 8 of India's Patent Act, which is applicable to all patent applicants. All that this provision requires is a statement from the applicant giving particulars of applications made for the same or similar subject matter in jurisdictions outside India and updates on them till the grant or rejection of the patent in India. The intent of the provision is to ensure that Indian patent examiners have the

¹¹ http://www.ipindia.nic.in/iponew/publicNotice_PharmaGuidelines_28February2014.pdf

¹² *Abraxis Biosciences vs Union of India*; the IPAB order is available at <http://www.ipabindia.in/Pdfs/Order%20No.9-2014%20-%20OA-3-2010-PT-DEL.pdf>

benefit of being informed by the prosecution of the application elsewhere, to aid their examination. The application of this provision is not very different from the US law of inequitable conduct, and the courts in India require demonstration of both materiality and willfulness for revocation of a patent for violation of Section 8.¹³

17. Revocation of patents: Another concern relates to revocation of patents consequent to post-grant opposition proceedings. It must be recognized that patent litigation is inevitable in all jurisdictions and ought not to be demonized. The judicial system in India is transparent and fair. Several instances demonstrate that patentees' interests are not unduly compromised by the litigation. For example, in April 2013, the IPAB 'stayed' the revocation of a patent to Pfizer's Sutent™ consequent to a post-grant opposition. The patent therefore remains in force pending hearing of the appeal against the revocation.¹⁴ Most recently, the revocation by the Patent Office of another patent of Pfizer for Detrol LA™ consequent to a post-grant opposition has been stayed by the IPAB¹⁵ and the patent remains in force while the dispute is adjudicated.

18. Flawed legal reasoning: A grievance has been made of obviousness analysis underlying the revocation or denial of patents in India, though patents may have been granted in other jurisdictions. It is not uncommon for different jurisdictions arrive at different conclusions based on the same set of facts. For example, one of the grounds of revocation was obviousness in the revocation of a patent for Allergan's Combigan,™ a combination of two previously approved drugs for ophthalmic use¹⁶. The application for the same subject matter was granted in Canada, but suffered an office action for final rejection in the US Patent Office, as well as a rejection in the

¹³ *Koninklijke Philips Electronics v Sukesh Behl*, para 14; available at <http://www.indiankanoon.org/doc/21642064/>; *Fresenius Kabi Oncology v Glaxo*, IPAB, July 27, 2013, paras 34-52; available at <http://www.ipab.tn.nic.in/162-2013.htm>

¹⁴ *Sugen v Controller of Patents*; the IPAB order is available at <http://www.ipab.tn.nic.in/079-2013.htm>

¹⁵ http://www.business-standard.com/article/companies/ipab-stays-revocation-of-pfizer-s-patent-on-drug-detrol-114032600646_1.html

¹⁶ *AjanthaPharmavsAllergan*, APAB, 8 August 2013; available at <http://www.ipab.tn.nic.in/173-2013.htm>

European Patent Office, before the revocation in India. It is possible that there are genuine differences of opinion on the interpretation of law or the standard to be applied, but such differences can hardly be the basis of alleging that India disregards patent rights.

19. Thousands of patents have been granted in India for pharmaceutical products, compositions and processes to manufacture them. As in the United States, litigation is to be expected and some patents will be invalidated. An interesting analysis¹⁷ of patent cases filed in the Federal District Courts of the US shows that 283 cases challenging the validity of claims in various patents were instituted between 2007 and 2011. In 86% of these cases, the patents were held to be invalid. Interestingly, the proportion of cases where upholding the validity of the patent has decreased steadily, from 20% in 2007 to 6% in 2011. Invalidation of a few patents in India ought not to be of grave concern.
20. It is important to note that India has a well-established judicial system. The IPAB is a specialist court of appeal against the decisions of the Patent Office and for revocations, with further appeals possible to the High Court and Supreme Court. Infringement actions are heard by the regular courts with established appeal procedures. There are multiple safeguards against erroneous decisions and aggrieved patentees have access to them.
21. Finally, we may also point out that the Index of the Global Intellectual Property Center of the US Chamber of Commerce that ranked India last is flawed and ought to be disregarded. (Please see paras 21-26 of the IPA's Post-hearing brief to the Commission).
22. In summary, IPA submits that the patent environment in India, in general, is not a cause of concern to the IP-intensive industry in the United States as attested to by Boeing, Honeywell and Corning.

¹⁷Smyth, Robert: White Paper Report: United States Patent Invalidation Study, September 2012; available at <http://www.morganlewis.com/index.cfm/fuseaction/publication.detail/publicationID/484033e0-f895-463e-9fde-c913e33112ceChromeHTML.raghucidambi/Shell/Open/Command>

The pharmaceutical industry operates in the same general environment. Contrary to the allegations of some in the pharmaceutical industry, the examples cited above show that the pharmaceutical industry is not disadvantaged.

Lax patent enforcement

23. One of the concerns particular to the pharmaceutical industry is the grant of marketing approval by the drug regulatory authority to a generic applicant when a patent is in force, unlike in the US where this can be done only after 30 months, should the innovator sue for infringement within the stipulated time. This situation is held out as being tantamount to lax patent enforcement. We submit that most countries, including those in the European Union, do not have such a provision for 'patent linkage'. 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 of a generic during the term of the patent would cause grave injury to consumers and there is no way to compensate them. It must also be noted that while an injunction does not follow the institution of an infringement proceeding as a matter of law, it can nevertheless be granted by courts. For example, the Delhi High Court has granted an injunction against the marketing of vidagliptin and its combination with metformin whose patents are held by Novartis.¹⁸ Earlier, Merck had also obtained an injunction against the marketing of the generic version of Januvia™ by an Indian company.¹⁹ It is puzzling to note the sweeping allegations of lax enforcement that are being made without any reference to the effective relief that has been granted by the Indian judicial system.

Data exclusivity

¹⁸ *Novartis vs Wockhardt* available at http://delhihighcourt.nic.in/dhcqrydisp_o.asp?pn=48066&yr=2014

¹⁹ *Merck vs Aprica* http://delhihighcourt.nic.in/dhcqrydisp_o.asp?pn=120114&yr=2013

24. PhRMA complains about the lack of protection of clinical test or other data submitted for marketing approval of pharmaceutical products.

25. India makes a distinction between 'protection of undisclosed test or other data against unfair commercial use' (which is required under the TRIPS Agreement) and the grant of 'data exclusivity' that ensures that no generic version of a pharmaceutical product is approved for marketing before a specified period. India, as indeed the majority of the developing countries and other international organizations, believes that there is no obligation under the TRIPS agreement to provide for data exclusivity. India is not alone. The PhRMA has listed 27 countries, including India, which do not provide for effective data exclusivity.²⁰

Compulsory licenses

26. Compulsory licenses can be granted in India under two provisions:

- Section 84 of the Patents Act, if any one of three conditions obtain: the reasonable requirements of the public for the patented article are not met, or the patented article is not available at a reasonably affordable price or the patent is not worked on a commercial scale in the territory of India.
- Section 92 of the Patens Act, which provides for the notification of patents for compulsory licensing for the usual conditions of emergencies or public non-commercial use.

27. As far as we are aware, only two applications for compulsory licenses under Section 84 have been made since 2005. The first was for Bayer's NexavarTM, which has resulted in the grant of a compulsory license. The second was for Bristol-Myers Squibb's SprycelTM, which was rejected. Innovator pharmaceutical companies are agitated by the grant of a compulsory license under

²⁰PhRMA Special 301 Submission 2014, p10

Section 84 for Bayer's NexavarTM for reasons other than public health emergencies. The consternation is surprising as India has arguably a more restrictive provision than many countries which provide for grant of compulsory licenses in the 'public interest', a term that is universally acknowledged to have a wider ambit than public health needs or emergencies. At least eight of the twelve West European countries have provisions in their laws for grant of compulsory licenses in the public interest. So do many Asian and Latin American countries. Moreover, there is considerable testimony before the Commission attesting to the conformity of this provision in India's law to the TRIPS Agreement.

28. The decision to grant a compulsory license to Bayer's NexavarTM was made by the Patent Controller in the first instance as the reasonable requirements of the public were not met (only a few hundred patients were on the medication), at a reasonably affordable price (Bayer priced its medication at \$74000 per year) and because Bayer relied on importation. In the Patent Controller's view, importation did not satisfy the condition of the working of the patent on a commercial scale in the territory of India. The decision of the Patent Controller was appealed by Bayer before the IPAB. Though the IPAB upheld the grant of compulsory license, it held that:²¹

"Therefore, we cannot decide that.... if there is no manufacture in India, then there is no working" (para 52).

"[Bayer] had not "worked" the invention on a commercial scale even if "import" alone would satisfy the working condition" (para 46; emphasis in original).

29. Strangely, the testimony before this Commission of those who assail the grant of the compulsory license takes no notice of this decision of IPAB. They continue to reiterate that the grant of the compulsory license for NexavarTM was partly because the product was imported, rather than locally manufactured.

²¹*Bayer Corp. vs Union of India*, OA/35/2012/PT/MUM; judgement available at <http://www.ipab.tn.nic.in/045-2013.htm>

30. The grant was the result of a careful assessment of the facts and is subject to multiple rounds of judicial review. Compulsory licenses under Section 84 are not granted in India for the mere asking. And when they are granted, as the IPAB has categorically said, it is not to favor any applicant but to implement the law to meet the reasonable requirements of the public at a reasonably affordable price.

Section 3(d)

31. A major concern in some of the submissions is with Section 3(d) of India's Patents Act, which prohibits the grant of patents to new forms of known substances that do not result in enhanced efficacy. Examples of new forms include salts, esters, ethers, polymorphs, metabolites, pure forms, isomers and new particle sizes.

32. Typically, these new forms are sought to be patented as 'follow on' second or third patents on the same product and invariably prolong patent monopoly for it. These are the patents that are prohibited by Section 3(d) of the India's Patents Act. However, even such inventions, when they enhance efficacy, are granted patents. Section 3(d) is thus a safeguard against the extension of patent monopolies without any benefit of increased efficacy, a practice that has been termed by the then President, George Bush, as 'evergreening'. Measures to prohibit evergreening are permissible under the TRIPS agreement and warranted by public health concerns. (See paras 38-42 of IPA's Post-hearing brief to the Commission).

33. The clamor against Section 3(d) was triggered by the decision of India's Supreme Court upholding the denial of a patent for a new polymorphic form of imatinib mesylate (the active ingredient of Novartis' Gleevec), as Novartis could not demonstrate any enhanced efficacy over imatinib mesylate which was already known. (See paras 7-12 of IPA's Pre-hearing statement).

34. The dismay of the PhRMA with the Gleevec decision was not shared even in the United States. For

example, the *Boston Globe* editorialized²²:

“The ruling by India's supreme court to reject a patent for Gleevec, a powerful cancer drug, is a victory for patients seeking more affordable treatment. India has a woeful history of ignoring patents, but in this case, the court was rightfully skeptical of so-called "evergreening," the practice of tweaking existing drugs to prolong a firm's hold on a patent. There's good evidence this kind of widespread patenting is impeding, not promoting, the search for new, more innovative medications - and driving up costs for American consumers. It's time to reexamine the US patent system, too.....

The United States, on the other hand, has loosened its patent qualifications since the 1980s, and while the number of patents for genuinely new pharmaceutical products has dwindled, the total number approved has more than doubled. Nearly two-thirds of drug patents approved from 1989 to 2000 were for incrementally modified, or evergreened, medicines, according to the National Institutes of Health Care Management.....

Patents can often spur innovation, but granting second and third patents on the same drug may be standing in the way of future cures. For patients who need affordable treatment - inside and outside the US - the wait has been too long.”

(Note: The ‘woeful history of ignoring patents’ is a reference to the position prior to 2005, when India did not grant patents for medicinal products.)

35. PhRMA argues that the grant of secondary patents and the consequent extension of patent monopolies beyond 20 years is necessary to recover development costs. This has been contested in the context of Gleevec by 119 specialists in chronic myeloid leukemia²³ (Please see paras 10-13 of IPA’s Pre-hearing Statement to the Commission). Reporting on this protest against high prices of Gleevec and other cancer treatments, the *New York Times* on 25 April 2013 states:

“Prices for cancer drugs have been part of the debate over health care costs for several years – and recently led to a public protest from doctors at a major cancer center in New York. But the decision by so many specialists, from more than 15 countries on five continents, to join the effort is a sign that doctors, who are on the front lines of caring for patients, are now taking a more active role in resisting high prices. In this case, some of the specialists even include researchers with close ties to the pharmaceutical industry.”

²²<http://www.bostonglobe.com/editorials/2013/04/07/should-tighten-rules-for-patenting-changes-drugs/ZKRH52RSJo0hMR8LcPuwEJ/story.html>

²³Experts in chronic myeloid leukemia: The Price of Drugs for Chronic Myeloid Leukemia (CML); A Reflection of the Unsustainable Prices of Cancer Drugs: From the Perspective of a Large Group of CML Experts, *Blood*, Prepublished online April 25, 2013;doi:10.1182/blood-2013-03-490003, available at <http://bloodjournal.hematologylibrary.org/content/early/2013/04/23/blood-2013-03-490003.full.pdf>

36. The concern with the pricing of life-saving drugs during the period of patent monopoly is not unjustified. Needless to say, the impact on public health in developing economies could be disastrous and more so if patent monopolies are extended beyond 20 years, delaying the availability of affordable generics. The skepticism over the need for extensions in patent monopoly beyond 20 years to recover the costs of development – the main justification for second and third patents for medicines – cannot be brushed aside.
37. The problem is also aggravated by the quality of the second and third patents that are obtained with the objective of extending patent monopolies. Quite often, these patents are ‘weak’ and are invalidated in litigation even in the United States. Such litigation is expensive and invariably delays access to generic medication. The legal framework in the United States mitigates the problem by providing incentives to challenge of patents for medicinal products by awarding exclusivity to successful generic challengers, but other jurisdictions, including India, do not have comparable provisions in their law. Section 3(d) in India’s Patents Act provides an alternative and perhaps more efficient way to avoid the grant of weak patents in the first instance and the burden of consequent litigation to set matters right. A recent study by Amy Kapczynski *et al* says it best²⁴:

“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 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

²⁴Kapczynski 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>

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)

38. Kapczynski and 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. Independent ‘PIPES’ patents [ie 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%,²⁵ adding 6.3 years to the patent monopoly on an average for each product.²⁶ Though secondary patents add significantly to nominal patent life, the actual additional life is limited as they are prone to invalidation or designing around²⁷:

“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)

39. 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

²⁵ *Ibid.* p4, Col 2

²⁶ *Ibid.* Table 3, p7

²⁷ *Ibid.* p7, Col 2-p8, Col 1

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.”²⁸
(Internal citation omitted)

40. If secondary patents are often weak and successfully challenged, the question is why they are granted in the first instance. The authors provide 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.”²⁹

41. The United States allows secondary patenting for medicinal products which increases the nominal life of patents by about 6 years on the average. Many of these patents are weak but are nevertheless granted, possibly because US patent examiners are hard pressed. However, US law provides a mechanism to incentivize patent challenges by the grant of exclusivity to successful challengers under the Hatch Waxman Act. Such challenges effectively limit the extensions in patent monopoly, despite the increase in secondary patents and nominal life, though they do result in increased costs and delays in entry of generics. India has adopted a different approach by incorporating Section 3(d) so that patent applications are rejected at the threshold unless they increase efficacy (which is most likely a true innovation and results in a strong patent). There is no exclusivity for successful patent challenges, but the entry of generics is nevertheless timely. The

²⁸Hemphill S, Sampat BN. Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals. *Journal of Health Economics*, 2012, 31(2): 327–339 p336, Col 2.

²⁹*Ibid.* p 337, Col 1.

burden on patent examiners in India, which is currently one of the highest in the world, is also reduced.

42. In summary, Section 3(d) of India's Patents Act is TRIPS compliant and limits the chances of evergreening with secondary patents to the detriment of public health. In the final analysis, it is only an alternative way to achieve pretty much the same result as in the United States of safeguarding against weak patents of questionable value. IPA respectfully submits that Section 3(d) ought not to be identified as a policy that is restrictive or adversely impacting the pharmaceutical industry.

Economic considerations

43. Indian patent law, particularly Section 3(d), is accused of 'undermining' innovation in the pharmaceutical industry. The further argument is that it is symptomatic of 'weak' intellectual property policies that are not good for India, as they adversely impact FDI into the country and consequently, economic growth. IPA submits that this view, held by some in the pharmaceutical industry, is not shared by well-known economists in the United States, nor is the causal relationship between 'stronger' intellectual property and inflow of FDI into India clearly established. Very importantly, the social welfare costs of 'strong' intellectual property policies are completely ignored.

44. Joseph Stiglitz and Arjun Jayadev have drawn attention to the stifling of innovation in the current IP regime of the United States on the one hand and the impact on social welfare on the other, while commenting on the decision on Gleevec by the Supreme Court of India³⁰:

"But the Indian decision also means less money for the big multinational pharmaceutical companies. Not surprisingly, this has led to an overwrought response from them and their lobbyists: the ruling, they allege, destroys the incentive to innovate, and thus will deal a serious blow to public health globally.

³⁰<http://www.project-syndicate.org/commentary/the-impact-of-the-indian-supreme-court-s-patent-decision-by-joseph-e--stiglitz-and-arjun-jayadev#5Sohj3STzVXckaOW.99>

These claims are wildly overstated. In both economic and social-policy terms, the Indian court's decision makes good sense. Moreover, it is only a localized effort at rebalancing a global intellectual-property (IP) regime that is tilted heavily toward pharmaceutical interests at the expense of social welfare. Indeed, there is a growing consensus among economists that the current IP regime actually stifles innovation. (Emphasis added)

The impact of strong IP protection on social welfare has long been considered ambiguous. The promise of monopoly rights can spur innovation (though the most important discoveries, like that of DNA, typically occur within universities and government-sponsored research labs, and depend on other incentives). But there often are serious costs as well: higher prices for consumers, the dampening effect on further innovation of reducing access to knowledge, and, in the case of life-saving drugs, death for all who are unable to afford the innovation that could have saved them.....

The weight given to each of these factors depends on circumstances and priorities, and should vary by country and time. Advanced industrialized countries in earlier stages of their development benefited from faster economic growth and greater social welfare by explicitly adopting weaker IP protection than is demanded of developing countries today. Even in the United States, there is growing concern that so-called hold-up patents and me-too patents – and the sheer thicket of patents, in which any innovation is likely to become entangled in someone else's IP claims – are diverting scarce research resources away from their most productive uses.....

Indeed, the Gleevec decision is still only a small reversal for Western pharmaceuticals. Over the last two decades, lobbyists have worked to harmonize and strengthen a far stricter and globally enforceable IP regime. As a result, there are now numerous overlapping protections for pharmaceutical companies that are very difficult for most developing countries to contest, and that often pit their global obligations against their domestic obligations to protect their citizens' lives and health."

45. The reference to the advanced industrialized countries benefiting from faster economic growth and greater social welfare by adopting weaker IP protection is significant. India has had a strong patent law since 1911, except that patents on medicines and agrochemicals were prohibited from 1972 onwards. (Please see paras 28-33 of IPA's Post-hearing brief to the Commission for details). However, consequent to the TRIPS Agreement in 1995, India granted 'exclusive marketing rights' till the Patents Act was amended in 2005 for the grant of regular patents for applications lodged in a 'mail-box' from 1995 onwards. The new polymorphic form of Gleevec was granted exclusive marketing rights and enjoyed a monopoly till 2005. Thereafter, the patent application was examined and refused. The point to be noted is that monopolies were granted to medicines and agrochemicals from about 1995 onwards. Indian GDP at the time of granting monopoly protection of medicines was a fraction of the GDP of industrialized countries when they adopted patent protection for

medicines, as the table below shows, and India did not have (and still does not have) the advantage of higher GDP that industrialized countries had to cushion the welfare disbenefits when patent protection was extended to medicines.

Protection of pharmaceutical product inventions: A historical perspective³¹

OECD adopters	Year of adoption	GDP per capita at adoption	GDP per capita at adoption relative to India's at adoption	GDP per capita relative to India's in 2011
Japan	1976	14,193	9.7	8.4
Switzerland	1977	24,309	16.7	12.4
Italy	1978	15,380	10.6	8.1
Netherlands	1978	19,127	13.1	10.6
Sweden	1978	17,584	12.1	10.0
Canada	1983	21,977	15.1	9.8
Denmark	1983	19,683	13.5	9.9
Austria	1987	18,824	12.9	10.4
Spain	1992	16,881	11.6	8.0
Greece	1992	15,176	10.4	6.6
Norway	1992	24,032	16.5	14.6
Emerging Country adopters				
Brazil	1995	7,594	5.2	2.6
China	1992/93	2,297	1.6	2.2
India	1995	1,456	1.0	1.0
Argentina	1995	9,078	6.2	4.0

Source: Penn World Tables, 8.0 and Lanjouw (2002)

Notes: GDP per capita is in PPP, constant 2005 dollars; the year of adoption for emerging countries (excluding China) refers not to the enactment of their laws but to the TRIPs date for protecting pharmaceutical product inventions

46. The impact on India apart, it is by no means clear that stronger patent rights for pharmaceuticals is good from a global perspective or even for the United States. Paul Krugman, writing in the *New York Times* in the context of the Trans Pacific Partnership (TPP) says³²:

“Is this a good thing from a global point of view? Doubtful. The kind of property rights we’re talking about here can alternatively be described as legal monopolies. True, temporary monopolies are, in fact, how we reward new ideas; but arguing that we need even more monopolization is very dubious — and has nothing at all to do with classical arguments for free trade.

³¹Subramanian, A. Written submissions to the USTR for the Special 310 Review, 2014 available at <http://www.regulations.gov/#!documentDetail;D=USTR-2013-0040-0089>

³²http://www.nytimes.com/2014/02/28/opinion/krugman-no-big-deal.html?_r=0

Now, the corporations benefiting from enhanced control over intellectual property would often be American. But this doesn't mean that the T.P.P. is in our national interest. What's good for Big Pharma is by no means always good for America."

47. Dr. Robert Shapiro has argued in his testimony to the Commission that "if India adopted IP rights and enforcement comparable to the United States, U.S. FDI to India's pharmaceutical industry would increase three-fold over the next four years."Further, he says it is good for the United States as the outward foreign investment into India positively impacts growth and employment in the United States. So, are Krugman and Stiglitz to be disregarded? Not if one carefully evaluates the evidence over the last decade.

48. The IPA has drawn attention to empirical studies that do not hold out the same assurance as the studies that Dr. Shapiro relies upon. (See paras 15-27 in IPA's Post-hearing Brief to the Commission).The conclusion in a review of the literature bears repetition³³:

"In summary, this survey draws the following conclusions from the literature. Firstly, different patent-policy instruments have different effects on R&D and growth. Secondly, there is empirical evidence supporting a positive relationship between IPR protection and innovation, but the evidence is stronger for developed countries than for developing countries. Thirdly, the optimal level of IPR protection should trade off the social benefits of enhanced innovation against the social costs of multiple distortions and income inequality. Finally, in an open economy, achieving the globally optimal level of protection requires an international coordination (rather than the harmonization) of IPR protection." (Emphasis added)

49. The UK Commission on Intellectual Property Rights report, found from literature that "...strong IP rights alone provide neither the necessary nor sufficient incentives for firms to invest in particular countries... The evidence that foreign investment is positively associated with IP protection in most developing countries is lacking."³⁴

³³Chu, Angus C: Macroeconomic Effects of Intellectual Property Rights: A survey, *Academia Economic Papers*, 2009, Vol 37, pp 283-303, available at http://mpra.ub.uni-muenchen.de/17342/1/MPRA_paper_17342.pdf

³⁴UK Commission on Intellectual Property Rights, Integrating Intellectual Property Rights and Development Policy. 2002; available at http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf p23

50. An OECD study published in 2003³⁵ analyzed empirical data for 1990-2000 to determine the association of the strength of patent rights with trade and FDI flows, controlling for other factors and concluded:

- The “results do not imply that stronger patent protection (or correlated IPRs) will always raise FDI and trade. There may come a point where these types of IPRs are too strong – in the sense that they grant producers of intellectual products excessive market power – in which case IPRs may negatively influence FDI and trade. Thus, the empirical finding is conditional on intellectual property systems not reaching excessive levels of strength.”
- Overall, however, “the model only explains only about 34% to 47% of the variation in the data. The study therefore suggests that “some non-observable country factors (such as culture, environment, firm strategies, and so forth) also play an important role in shaping world FDI activity.”³⁶ This is consistent with the common sense understanding that a number of factors other than patent rights determine the flow FDI into a country.
- Patent rights insignificantly explain US outward FDI in chemicals and pharmaceuticals when controlled for all variables.³⁷ The authors say that “[t]his result is somewhat surprising in light of previous assertions that strong global patent protection is important to the chemical industry (which includes the pharmaceutical industry).”³⁸

51. The evidence that stronger patent protection leads to higher FDI is not as clear-cut as its proponents make it out to be, even in the studies that are referred to by them in testimony before this Commission. While these studies suggest that there is a positive correlation between FDI and IP protection in cross-country regressions, there is little to suggest that IP is causal, as there are a

³⁵ Park, Walter G. and Lippoldt, Douglas : The impact of trade-related intellectual property rights on trade and foreign direct investment in developing countries, OECD, 28 May 2003, available at <http://www.oecd.org/trade/tradedev/2960051.pdf>

³⁶ Park, Walter G. and Lippoldt, Douglas, *Op. Cit.* p18

³⁷ Park, Walter G. and Lippoldt, Douglas, *Op. Cit.* p19 fn25

³⁸ *Ibid.* p19

number of confounding variables (reduced cost of doing business, fewer internal regulations etc.) that are concomitant with greater IP protection but which drive FDI. For example, one of the papers cited approvingly in the briefs against India combined the indicator for the strength of patent rights with other economic parameters, as a way of testing which interactions were important for maximizing merchandise imports and FDI by income level. The authors note that “conditional on being a LDC, having a better business environment with high levels of IPR protection implied a discrete change in FDI of approximately 24%”.³⁹ However the same analysis also showed that conditional on being a LDC, having a high WEF IPR index with high levels of IPR protection implied a discrete fall in FDI of approximately -35%.⁴⁰ These contradictory results only serve to emphasize the ambiguity of the evidence.

52. Moreover, we are not concerned primarily with FDI, but rather on its impacts on growth and welfare. Here too, the results are at best ambiguous for the contention that stronger intellectual property rights have a uniformly positive impact. For example, a study of a sample of 103 countries over 1970-2009 finds that “although FDI and IPR have positive effects on growth for most of the countries, stronger IPR mitigates the growth effect of FDI for developing countries. Moreover, at the highest levels of FDI, lax IPR increase growth.”⁴¹

53. In terms of welfare, especially in terms of health and pharmaceuticals, it is an unambiguous finding that greater patent protection will be seriously detrimental to consumers in India. In perhaps the most rigorous analysis of the welfare impacts of pharmaceutical protection, published in the *American Economic Review*, the authors estimate that “in the presence price regulation the total

³⁹Cepeda, RHC, LippoldtDCandSenft, J. Policy complements to the strengthening of IPRs in developing countries, OECD Trade Policy Working Paper No. 104, 2010, p25; available at

[http://search.oecd.org/officialdocuments/displaydocumentpdf/?cote=TAD/TC/WP\(2010\)12/FINAL&doclanguage=en](http://search.oecd.org/officialdocuments/displaydocumentpdf/?cote=TAD/TC/WP(2010)12/FINAL&doclanguage=en)

⁴⁰*Ibid.* Table 23, p62

⁴¹Kascheeva M. The role of foreign direct investment in the relation between intellectual property rights and growth, *Oxford Economic Papers*, 2013, Volume 65, Issue 3, pp. 699-720

annual welfare losses to the Indian economy from the withdrawal of the four domestic product groups in the fluoroquinolone sub-segment would be on the order of U.S. \$305 million, or about 50% of the sales of the entire systemic anti-bacterials segment in 2000.....In contrast, the profit gains to foreign producers in the presence price regulation are estimated to be only around \$19.6 million per year.”⁴² (See also para 49 of IPA’s Post-hearing brief to the Commission).

54. To summarize—it is difficult to make a causally compelling case that patent protection unambiguously improves FDI, especially in low income countries. Second, the growth effects are ambiguous, and third, the welfare impacts can be seriously negative, especially in critical areas like health.

Conclusion

55. Dr. Arvind Subramanian has summarized the challenges before Indian policy makers admirably⁴³:

“ [The]Indian calculus ... balances three objectives: contributing to a “fair” share of the fixed costs of genuine global R&D generation (which is consistent with the spirit of the TRIPs agreement), promoting technological development domestically, and providing affordable access to medicines for the domestic population. This is a more difficult calculus and is at the heart of disagreements about the strength of IP protection in India and other developing countries...”

56. We trust that the Commission will be sensitive to the Indian situation while fulfilling its mandate of arriving at “a quantitative analysis of the economic effects of India’s identified restrictive measures on the U.S. economy as a whole, on U.S. trade and investment, and on selected sectors of the U.S. economy.” As we have pointed out repeatedly, policy measures such as Section 3(d) and compulsory licensing are not restrictive measures, and mainly ensure that health outcomes do not deteriorate, within the framework of the TRIPS Agreement. (Please see paras 37-44 of IPA’s Post-hearing brief to the Commission). It can never be said that the economy of the United States is adversely affected

⁴²Barwick,PJ, Chaudhuri, S and Goldberg, P. Estimating the Effects of Global Patent Protection in Pharmaceuticals: A Study of Quinolones in India *American Economic Review*, 96(5): 1477-1514, December 2006.

⁴³Subramanian, A. Written submissions to the USTR for the Special 310 Review, 2014

by India's compliance with the norms of global governance in health, trade and intellectual property. (Please see paras 52-55 of IPA's Post-hearing brief to the Commission).

57. The market for patented medicines in India at the prices of the United States is negligible and is of limited significance even at discounted prices. This is not surprising as the 'so-called middle class' in India has a *per capita* income of \$11 per day, less than the US poverty line of \$13 per person per day and there is little reimbursement of drug costs. (Please see paras 45-49 of IPA's Post-hearing brief to the Commission for details). Thus, the size of the market for patented drugs is so obviously small, that it would not make a difference to a multinational corporation's revenues and much less to the US economy, trade, investment and employment. This is the reason that prompted Congressman Waxman to urge Novartis not to pursue its challenge to Section 3(d) of the Indian Patents Act:

"In pursuing the tiny slice of the market with the money to afford its drugs, Novartis may be threatening future access to medicines to the vast majority of Indians who live in poverty – and their counterparts around the world.

Novartis and its colleagues in the pharmaceutical industry should respect countries' rights to take measures that balance the protection of innovation and promotion of public health. I urge you to reconsider your position in this case."⁴⁴

58. After the oral testimony on 12 February 2014, responding to queries from the Commissioners, the IPA had mentioned that strategic alliances between innovators and Indian generic companies had worked to their mutual advantage. These alliances were in various forms and included equity participation, co-marketing of patented products, voluntary licensing and differential pricing. The Chairman requested elaboration in the written submission of the possible reasons for other companies not pursuing this win-win strategy.

59. The IPA believes that the US pharmaceutical companies which pursue (e.g. Merck) and do not pursue (e.g. Pfizer) this strategy are the best positioned to provide an explanation. However, likely

⁴⁴Letter of Congressman Henry Waxman to Daniel Vasella, Chairman and CEO, Novartis, February 13, 2007

possibilities include apprehension of importation into the US or exports to other markets and anxiety that payors may seek lower prices in the USA. It may however be noted that US companies like Merck and Gilead as well as European companies like GSK and Roche have not experienced any adverse impact on their global businesses because of their alliances with Indian generic companies. There is merit in thinking about such alliances

60. Finally, we wish to say that India recognizes the value of innovation and the need to bear its 'fair share' of the costs of innovation. (Please see paras 52-55 of IPA's Post-hearing brief to the Commission). India indeed bears its fair share by granting patent protection for 20 years.

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

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