



2014 Special 301 Review

(Docket No.USTR-2013-0040)

Response to Hearing Testimony on India

by

INDIAN PHARMACEUTICAL ALLIANCE

**Washington D.C.
5 March 2014**

(Email: dgshah@vision-india.com)

1. My name is Dilip G Shah and I am Secretary General of the Indian Pharmaceutical Alliance (IPA). I am respectfully submitting this response on behalf of the IPA to the submissions made to the USTR for the 2014 Special 301 review.
2. The IPA's membership consists of nineteen pharmaceutical companies which collectively account for close to 80% of the expenditure on pharmaceutical research and development in the private sector in India. We therefore have a vital interest in the protection of our innovations, not only for developing cost-effective and useful improvements in existing medicines, but also for discoveries of new medicines.
3. This response is mainly with respect to the issues related to the pharmaceutical industry:
 - First, it provides brief comments on the submissions made in 2014, arising from issues identified in the Special 301 Report of 2013.
 - Second, it provides factual information and analysis in response to the submissions made on three of these issues: patentability of new forms of known substances under Section 3(d) of India's Patents Act, compulsory licensing and the overall assessment of India's intellectual property protection by the Global Intellectual Property Center.
 - Third, it responds to other issues that feature in several of the submissions.

I BRIEF COMMENTS ON SUBMISSIONS RELATING TO ISSUES IDENTIFIED IN THE SPECIAL 301 REPORT 2013

Patent application backlog and opposition procedures

4. The Special 301 Report 2013 urges "India to continue its recent efforts to address its patent application backlog and to streamline its patent opposition proceedings." In its 2014 submission, the Biotechnology Industry Organization (BIO) notes with concern "the delay in processing applications coupled with the opposition procedures" in India.¹
5. The primary reason for the patent backlog in India is the inadequate number of patent examiners. A news item published on July 26, 2013² 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.
6. The streamlining of opposition proceedings before the Patent Office is taking place, aided by the effective oversight of the Intellectual Property Appellate Board (IPAB) and the judicial system. For example, in April 2013, the IPAB 'stayed' the revocation of a patent to Pfizer's SutentTM consequent to a post-grant opposition. The patent therefore remains in force pending hearing of the appeal against the revocation.³ More recently, in January 2014, the refusal of a patent consequent to an opposition proceeding, to Abraxis

¹BIO Special 301 Submission 2014, p8.

²<http://www.livemint.com/Politics/hgOckYuyYrRelSuRAXz4ij/To-clear-backlog-Indian-patent-office-to-hire-500-over-next.html>

³*SugenvsController of Patents*; the IPAB order is available at <http://www.ipab.tn.nic.in/079-2013.htm>

Bioscience, a US corporation, has been remanded back to the Patent Office by the IPAB for reconsideration.⁴

7. BIO has called attention⁵ to the “lack of consistent adherence to patent rules and procedures between the regional patent offices” and the need for “[i]ncreased training on patentability criteria”. 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.⁶
8. BIO has also urged “more robust infrastructure for searching and procuring patents in the patent office”. E-filing of patents has been enabled about five years ago. Patent application status is also available online. Full-text search of granted patents is available from private service providers.
9. BIO states that delays in examination and opposition procedures result in “the loss of the majority of the patent term”. 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.
10. The Pharmaceutical Research and Manufacturers of America (PhRMA) has identified 11 countries “with concerning patent backlogs and marketing approval delays” in its 2014 submission⁷. India is not included in this list.

“India’s prohibition on patents for certain chemical forms”

11. In its 2013 Report, the USTR has noted that “India’s prohibition on patents for certain chemical forms absent a showing of “enhanced efficacy” may have the effect of limiting the patentability of potentially beneficial innovations”.
12. The PhRMA has alleged in its 2014 submissions that such “[r]estrictions on the scope of patent eligible subject matter undermine the patenting of important biopharmaceutical inventions, are inconsistent with international standards set forth in the TRIPS Agreement, and, perhaps more importantly, prevent U.S. businesses from realizing the potential of valuable inventions in these markets.” Several other submissions expressed similar concerns. This issue is discussed in more detail subsequently.
13. PhRMA has identified 14 countries, including India, “with behavior of concern related to scope of patentability”.

Compulsory licensing and local manufacturing

14. As rightly noted by the USTR in its 2013 Report, the Patent Controller’s decision to grant a compulsory license to Bayer’s NexavarTM was “based, in part, on the innovator’s decision to import its products, rather than manufacture them in India”. The USTR

⁴*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>

⁵ BIO Special 301 Submission 2014, pp 8-9

⁶http://www.ipindia.nic.in/iponew/publicNotice_PharmaGuidelines_28February2014.pdf

⁷PhRMA Special 301 Submission 2014, p 11

further noted that “[u]nless overturned, the decision could potentially compel innovators outside India – including those in sectors well beyond pharmaceuticals, such as green technology and information and communications technology – to manufacture in India in order to avoid being forced to license an invention to third parties.”

15. 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:⁸

- “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).

16. Strangely, none of the submissions made in 2014 take notice of this decision of IPAB. They continue to reiterate that the grant of the compulsory license for Nexavar™ was because the product was imported, rather than locally manufactured. These, and other submissions related to compulsory licensing are discussed in detail subsequently.

Data exclusivity

17. The 2013 Report “urges India to provide an effective system for protecting against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical and agricultural chemical products”.

18. India makes a distinction between ‘protection of undisclosed test or other data against unfair commercial use’ 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, also 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.⁹

Overall assessment

19. Despite the clear evidence of progress, the US Chambers of Commerce Global Intellectual Property Center (GIPC) asserts in its submission that “[n]ot only is India making no effort to correct the challenges identified repeatedly in USTR’s Special 301 report, consistent with the statutory definition of a Priority Foreign Country, they are also continuing to impose measures and take actions that rise to the level of the most onerous or egregious IP acts, policies or practices that have the greatest adverse impact on U.S. businesses.”¹⁰ The GIPC has singled out India, without any basis, as having the ‘greatest adverse impact on US businesses’ from among the many that have identified as having concerning IP policies and practices (eg., in the PhRMA submission). The specious assertions of GIPC are dealt with in more detail subsequently.

II DETAILED COMMENTS ON SUBMISSIONS RELATING TO THREE ISSUES ARISING FROM SPECIAL 301 REPORT 2013

⁸*Bayer Corp. vs Union of India*, OA/35/2012/PT/MUM; judgement available at <http://www.ipab.tn.nic.in/045-2013.htm>

⁹PhRMA Special 301 Submission 2014, p10

¹⁰GIPC Special 301 Submission p55

Section 3(d) of India's Patents Act

20. 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.
21. 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.
22. A clear understanding of the effect of this provision as evidenced by the familiar example of Gleevec, a Novartis product for cancer, provides the context for our comments on the submissions made. The generic name of the medicine is imatinib mesylate. The first patent application for imatinib and all its salts was made internationally in 1992, prior to the TRIPS Agreement. It is important to note that there was no occasion for India to grant or reject a patent for imatinib.
23. A second patent application for a new crystalline form of imatinib was made internationally in 1997. This was filed in India in 1998. But Novartis failed to demonstrate any increased efficacy of the new form over the previously known substance and the patent application was rejected. The Supreme Court of India upheld the rejection.
24. The implication for the extension in patent monopoly for the product is evident from the data for the US itself:
 - The 20-year term of the patent for imatinib and all its salts ended in 2013.
 - In the meanwhile, the USPTO granted a second patent for the new crystalline form. The 20-year term of the second patent ends in 2018, thereby extending the patent monopoly of Gleevec by five years. This does not include patent term and pediatric extensions.
25. The effect of such extensions in patent monopolies can be disastrous to public health and access to new medicines in India and elsewhere. For example, 119 experts in chronic myeloid leukemia, a condition for which Gleevec is indicated, from over fifteen countries, including the US and Western Europe published an article in *Blood*, a US medical journal, in April 2013¹¹ pointing out that:
 - The initial pricing of Gleevec in 2001 was US\$ 30,000 per patient per year. It was considered high at that time. Gleevec was expected to notch up sales of about US\$ 900 million a year, which would have recouped the cost of development within two years.

¹¹Experts 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>

- Gleevec became a blockbuster and usage exceeded expectations. The price was also increased over the years, to US\$ 92,000 per patient per year. The revenues from Gleevec were about US\$ 4.7 billion in 2012.
- This pricing ‘resulted in numerous appeals by patients and advocates to lower the price of imatinib.’

26. Section 3(d) was not enacted to further the interests of the domestic generic industry, as some submissions allege. On the contrary, as the Parliamentary debates prior to its enactment clearly show, it was in the interest of ensuring that there was no delay in assuring the availability of affordable generics after the expiry of the term of 20 years. The Gleevec example illustrates the reasoning behind the enactment of Section 3(d), which is to strike a balance between incentivizing innovation and providing access to affordable generic medicine.

27. The PhRMA, BIO and others attack Section 3(d) on two grounds:

- It is not TRIPS-compliant as it impermissibly narrows the criteria of patentability by adding an additional hurdle of enhanced efficacy to the normal criteria; and because it is applicable to only to chemical substances, it is in conflict with the non-discrimination principle of Article 27 of the TRIPS agreement with respect to field of technology.
- It undermines incentives for innovation.

These contentions are commented on below.

TRIPS compliance

28. The Government of India believes that India’s patent law is TRIPS- compliant. The IPA also believes it to be so. So do several others who have made submissions to the USTR. We do not propose to provide a detailed legal justification of this position as other submissions attest to this. We would however like to draw the USTR’s attention to the views of a few others who have not made submissions.

29. A joint publication¹² by WHO, WIPO and WTO in 2013 explored the ‘intersections between public health, intellectual property and innovation’ to “support governments and others — particularly in developing countries — who face an increasing demand to act, when governments want to increase access to effective treatments while containing costs”.¹³ We draw attention to its observations in the context of Section 3(d) of India’s Patents Act:

“Strict patentability criteria and strict patent examination supported by patenting examination guidelines contribute to prevent strategies employed to delay the entry of generic competition, such as ‘evergreening’.”¹⁴

“While the therapeutic value of a product as such is not a patentability criterion in most jurisdictions, therapeutic advantages over what exists in the prior art may be considered when determining inventive step.”¹⁵

¹² World Health Organization, World Intellectual Property Organization and World Trade Organization: Promoting Access to Medical Technologies and Innovation, Geneva, 2013, http://www.who.int/phi/promoting_access_medical_innovation/en/

¹³ http://www.who.int/mediacentre/news/releases/2013/book_summary.pdf

¹⁴ WHO, WIPO and WTO, *Op.cit.* p13

“Section 3(d) of India’s Patent Act 1970 and Section 22 of the Philippines’ Intellectual Property Code are two examples of a narrow definition of patentability criteria.”¹⁶

(Internal citations omitted)

30. The WHO, WIPO and WTO publication referred to above builds on the view of the Commission on Public Health, Innovation and Intellectual Property Rights,¹⁷ which noted that:

“As usually understood, “evergreening” occurs when, in the absence of any apparent additional therapeutic benefits, patent-holders use various strategies to extend the length of their exclusivity beyond the 20-year patent term. President Bush, in 2002, provided a working definition while announcing reforms in response to a Federal Trade Commission report on the delays of the entry of generic products onto the market.....Evergreening can occur in a number of ways but typically, as noted by President Bush, it arises when companies file and obtain patents, subsequent to the original patent, on other aspects of the same compound or reformulations of the original compound in ways that might be regarded as of no incremental therapeutic value, but which are nevertheless patentable.”¹⁸

“Countries can adopt legislation and examination guidelines requiring a level of inventiveness that would prevent evergreening patents from being granted. The TRIPS agreement gives freedom to WTO Members to determine the hurdle required for the inventive step.....The intention [of Section 3(d)] is to rule out from patentability variations on a known drug, by treating them all as the same substance, except where it can be demonstrated that a drug has superior efficacy. In that sense, the legislation is trying to make a distinction in law between evergreening (where there are no additional therapeutic benefits) and incremental innovations (where there are).”¹⁹

(Internal citations omitted)

31. Academics, including in the United States²⁰ have also published extensively, arguing that Section 3(d), as well as other provisions, in India’s patent law are TRIPS-compliant.

Incentivizing innovation

32. The second attack on Section 3(d) is that it undermines innovation by not providing patent protection for improvements which do not relate to efficacy. Examples cited include inventions relating to improved safety, or improved temperature stability.
33. IPA respectfully submits that such assertions are misleading. If new forms of known substances have advantages, they will be eligible for patents for processes to manufacture such new forms and compositions that contain them, if they satisfy the criteria for patentability, without the need to show any enhanced efficacy.

¹⁵*Ibid*, p131

¹⁶*Ibid*, p131

¹⁷World Health Organization: Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health, Geneva, April 2006 available at <http://www.who.int/intellectualproperty/documents/thereport/CIPIH23032006.pdf>

¹⁸*Ibid*, p149-150

¹⁹*Ibid*, p151-152

²⁰See for example, Kapczynski, Amy: Harmonization and its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector, *California Law Review*, Vol. 97, p. 1571, 2009; Available at SSRN:http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1557832

Compulsory licensing

34. PhRMA, BIO, the National Foreign Trade Council, the Intellectual Property Owners Association, the National Association of Manufacturers and the U.S. Chamber of Commerce's Global Intellectual Property Center assert that India has granted a compulsory license (for Bayer's NexavarTM), including on the ground that the patented product was imported and not manufactured locally. As we have said earlier in para 15, this was one of the grounds on which the Patent Controller initially granted the compulsory license, but this ground was overruled by the IPAB. We are bewildered that all the submissions noted above have ignored the decision of the IPAB.
35. BIO has also alluded to the "extensive authority" available to India to grant compulsory licenses. We would like to clarify that compulsory licenses can be granted in India under Section 84 of the Patens Act, if any one of three conditions obtain: if the reasonable requirements of the public for the patented article are not met, or 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 grant of the compulsory license was upheld by the IPAB as every one of the three conditions were met: NexavarTM was made available by Bayer at US\$ 74,000 per patient per year for a few hundred patients.
36. The authority to grant a compulsory license under Section 84 cannot to be termed 'extensive'. 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 Western European countries have provisions in their laws for grant of compulsory licenses in the public interest. So do many Asian and Latin American countries.
37. The joint publication by WHO, WIPO and WTO noted as follows:

"The Doha Declaration on the TRIPS Agreement and Public Health..... confirmed what was already implicit in the TRIPS Agreement – that WTO members have the freedom to determine the grounds upon which compulsory licenses are granted. They are thus not limited to emergencies or other urgent situations, as is sometimes mistakenly believed."²¹

"Many countries allow the granting of compulsory licenses on grounds of public interest, without further defining the term.....Public interest could also include the non-availability of the patented product, such that reasonable needs of the public are not being met....Health-specific grounds can, for example, be found in France and Morocco. Under provisions on the *licenced'officedansl'intérêt de la santé publique*, the health minister can seek the grant of a compulsory license if the product or method is made available by the right holder in insufficient quantity or unsatisfactory quality, or if the prices charged are abnormally high."²²

(Internal citations omitted)

²¹ World Health Organization, World Intellectual Property Organization and World Trade Organization *Op. Cit.* p174

²²*Ibid*, p175

38. The Commission on Public Health, Innovation and Intellectual Property Rights, noted that:

“The Doha Declaration clarifies the right of governments to use compulsory licensing as a means of resolving tensions that may arise between public health and intellectual property, and to determine the grounds for using it. Developing countries should provide in their legislation for the use of compulsory licensing provisions, consistent with the TRIPS agreement, as one means to facilitate access to cheaper medicines through import or local production.”²³

(Internal citations omitted)

39. 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. 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.

40. Section 92 of the Patens Act provides for the notification of patents for compulsory licensing for the usual conditions of emergencies or public non-commercial use. BIO states that three drugs were initially considered for compulsory licensing under this provision, but though two were dropped, one may still be under consideration now or in the future. We are not aware of the basis of BIO’s assertions and respectfully submit that such speculation ought not to receive consideration.

41. Yet another contention of BIO is that a Discussion Paper on compulsory licensing was issued by Government inviting public comment and that, among other things, the “document highlights the need for increasing access to essential medicines for the ‘common man particularly the poorer sections of the population.’”²⁴ BIO also states that it has submitted comments. We fail to see why this should be perturbing. On the contrary, it is a demonstration of the Government’s intent to engage with the pharmaceutical industry and ought to be lauded.

Overall assessment: GIPC’s specious submissions

42. “The goal of our submission” says the GIPC “is to highlight key challenges faced overseas by U.S. creative and innovative industries seeking to create high quality U.S. jobs, grow our economy and increase exports.”²⁵ The GIPC argues that strong Intellectual Property (IP) systems and enforcement abroad will benefit the US economy and it is committed “to promoting environments that foster innovation and creativity in the U.S. and abroad.”²⁶ In furtherance of its advocacy, GIPC has created an Index that “is an empirical assessment of the strengths and weaknesses of 25 economically and regionally diverse countries.”²⁷

²³World Health Organization: Public Health, Innovation and Intellectual Property Rights, *Op. Cit.* p139

²⁴BIO Special 301 Submission p13

²⁵GIPC Special 301 Submission 2014, p4

²⁶*Ibid.* p7

²⁷*Ibid.* p4

43. GIPC notes that “India has the weakest IP environment of all countries, according to both the 2014 and 2012 editions of the Chamber’s International IP Index”.²⁸ The GIPC therefore believes that India should be identified as a Priority Foreign Country for the reasons stated in para 19 above. Further, it believes that “India’s failure to develop and adhere to international best practices in the field of IP rights has hindered its economic development” and “has directly impacted India’s foreign direct investment.”

44. We will show that:

- The construction of the Index is flawed.
- A country’s ranking in the Index has no relationship with the impact on the US economy or employment.
- The ranking has little relationship, both in theory and practice, with the flow of Foreign Direct Investment (FDI) into the country, or its economic growth.

We therefore submit that the Index be disregarded by the USTR as it does not contribute meaningfully to its 2014 Review.

The construction of Index is flawed

45. Of the 25 countries ranked in the GIPC Index, the US has the highest score of 28.52, Ukraine and China are ranked 16 and 17 with scores of 11.68 and 11.62 respectively, while India is ranked last with a score of 6.95.

46. The 2014 GIPC index²⁹ claims itself to be “a rigorous statistical tool..... to map IP environments around the world in a transparent and objective way, using evidence-based resources to provide a snapshot of a nation’s IP climate.” The methodology of the index and its construction has already attracted sharp criticism.³⁰ Essentially, the GIPC index seems to be measuring the distance between US IP protection and that of other countries. In doing so, the index scores perceptions more than facts.

47. Of the 30 indicators that are used to compute the score in the GIPC index, 21 are ‘mixed indicators’, where “there are no adequate baselines and the legislative or regulatory existence of an indicator is not sufficient to determine its actual use or application”. Where “no adequate baselines are found in international law or treaties, the baselines and values used are based on what rights holders view as an appropriate environment and level of protection”.

48. The index is therefore largely constructed not just on the basis of perceptions, but the perceptions of some right holders. The basis of selection of respondents from right holders is not disclosed. It is telling that that India’s score is 2.75 out of a total of 21 in the ‘mixed indicators’, based on perceptions of some right holders, and this has largely determined its low ranking in the index.

²⁸*Ibid.* p54

²⁹<http://www.theglobalipcenter.com/GIPCindex/>

³⁰See for example, <http://spicyip.com/2014/02/gipc-ip-index-propagating-imaginary-ip-norms.html>

The Index cannot be relied upon

49. The ranking of China raises a serious question about the validity of the Index: how is it that China, despite its ranking well above India and other countries, is considered to cause the highest job and financial losses in the US because of IP ‘theft’? A recent study by the Commission on the Theft of American Intellectual Property, which claims to be “an independent and bipartisan initiative of leading Americans”³¹ asserts that annual financial losses arising from international theft of US IP is “over \$300 billion” and “millions of jobs” would be added in the US were it not for IP theft. The report adds that “China is the world’s largest source of IP theft” and accounts for between “50% and 80% of the problem”.
50. The United States International Trade Commission (USITC) has conducted its own investigation³² and estimated losses of \$48.2 billion³³ “in sales, royalties, or license fees due to IPR infringement in China” in 2009, based on responses received from US firms that operate in China. The USITC also estimated, again based on responses of firms, that “an improvement in IPR protection in China to levels comparable to those in the United States could lead to an estimated \$107.0 billion gain in U.S. exports and sales to majority-owned affiliates in China” and “would likely increase employment in their U.S. operations by 2 to 5 percent. This increase translates into approximately 923,000 new jobs for U.S. IP intensive firms”.

Ranking in the Index has limited impact on FDI

51. The relatively low ranking of China in the Index does not correspond to the stellar inflow of FDI and economic growth in China.
52. The US-India Business Council has testified to the positive momentum in Indo-US trade relationship in its pre-hearing statement to the USITC³⁴, including that:
- US investments in India have grown significantly to about \$50 billion since India opened up its economy two decades ago. Indian investments in the US have also grown to about \$ 9 billion.
 - Two-way trade in goods and services between the US and India was estimated to be more than \$100 billion in 2013 and growing at double-digit rates.
 - There is now an unprecedented level of strategic cooperation between the US and India that is deepening the trade relationship, particularly in critical sectors of telecommunication, defense, space and energy.
 - The positive spiral visible in trade and investment is mirrored in other spheres of endeavor, which are no less important merely because they cannot be measured adequately in dollars – as for example, in the number of Indians studying in the US.

³¹ The Commission on the Theft of American Intellectual Property: The IP Commission Report, May 2013, available at <http://www.ipcommission.org/Report/index.html>.

³² USITC: China: Effects of Intellectual Property Infringement and Indigenous Innovation Policies on the U.S. Economy, Investigation no. 332-519, Publication 4226, May 2011

³³This is a statistical ‘point’ estimate, with the range being \$14.2 billion–\$90.5 billion.

³⁴US-India Business Council: Pre-hearing Statement, USITC Investigation No 332-543, Trade, Investment, And Industrial Policies In India: Effects On The U.S. Economy

53. Overall, FDI in 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 fact, the proportion of FDI in the pharmaceutical sector has been a little higher than the long term average in the last three years, during which period the IP environment is said to have deteriorated.³⁵

54. The appreciation of what has been achieved and the potential for accelerating growth in trade and investment gets clouded if it is based on perceptions that are neither widely shared nor borne out by the facts. I will therefore briefly dwell on some relevant facts that serve to underscore the positive business environment for the pharmaceutical industry since 2005, when India implemented reforms in its patent legislation to comply with its obligations under the TRIPS agreement.

55. FDI into India from US companies has been significant:

- In 2010, Abbott acquired the domestic pharmaceutical formulations business of Piramal Healthcare, an Indian company, in a deal worth \$3.7 billion. Consequently, Abbot became the largest company in India by domestic sales.³⁶
- Mylan has reportedly invested \$3 billion in India in the last six years. In addition to viewing India as a global manufacturing hub, Mylan is aggressively pursuing growth in the Indian market for its products.³⁷
- Bristol-Myers Squibb (BMS) exited India in 1983, but re-entered the country in 2004-05. It is reported to have one of its biggest R&D facilities outside of the US in India. Its managing director's response to a question from the media on how he saw the first five years after the introduction of the product patent regime in India is revealing:³⁸

"It has been very satisfying. We have been able to launch our global pipeline of 10 products in India. Half of them enjoy patent-protection and, except in one case, there is no generic competition. The one we have is a case of patent infringement, where a generic firm has introduced its version of Baraclude (entecavir). We are fighting that in the court of law."

56. FDI into India from corporations headquartered outside the US, but whose American subsidiaries are PhRMA members, is also significant:

- In November 2013, GSK announced that in addition to its investment of more than \$160 million in India over the previous decade, it would invest a further \$140 million

³⁵http://dipp.nic.in/English/Publications/FDI_Statistics/2013/india_FDI_December2013.pdf

³⁶<http://timesofindia.indiatimes.com/business/india-business/Abbott-buys-Piramals-pharma-arm-for-37bn/articleshow/5960176.cms?referral=PM>

³⁷<http://timesofindia.indiatimes.com/business/india-business/Mylan-sees-India-as-a-global-hub/articleshow/26930374.cms>

http://www.business-standard.com/article/companies/mylan-bets-billions-on-india-113102801081_1.html

³⁸http://www.business-standard.com/article/companies/q-a-alok-sonig-md-bristol-myers-squibb-india-110060300084_1.html

in new manufacturing facilities in India³⁹, perhaps the first significant new manufacturing capacity of this scale for GSK, anywhere in the world in the last twenty years. Further, GSK followed it up with an announcement in December 2013, that it would invest \$ 1 billion in increasing its stake in its Indian subsidiary.⁴⁰

- In 2009, Sanofi acquired 80% of the shareholding of an Indian vaccine manufacturer for \$600 million and completed the buyout in 2012 with an additional investment of \$122 million.⁴¹

57. Companies from the US and other regions have entered into partnerships with Indian companies. In 2011, Merck and Sun Pharmaceuticals, an Indian company, have set up a joint venture to develop and commercialize novel formulations and combinations in the emerging markets.⁴² Mylan has also entered into a partnership with Biocon, an Indian company to commercialize biosimilars in international markets, as indeed Dr. Reddy's Laboratories has with Merck Serono.

58. There are also instances of companies entering into tie-ups with Indian companies for manufacturing and marketing their products in India such as Roche with Emcure for MabTheraTM and HerceptinTM.⁴³ Merck and Cipla have announced the formation of an India-specific strategic partnership within which Cipla will have a non-exclusive license to market Merck's novel HIV treatment, raltegravir under a different brand name in India.⁴⁴

59. Testimony before USITC by the US-India Business Council provides an interesting example of Gilead, an American company, providing "over 1.1 million patients in developing countries with Gilead HIV medication produced by Indian companies."⁴⁵

60. As is evident from the facts, the situation on the ground is at odds with the proposition of the GIPC that there is a correlation between the 'strength' of a country's IP polices and FDI. The only basis for this proposition disclosed by the GIPC is in a foot note:⁴⁶

"A recent study by the Organization for Economic Co-operation and Development (OECD) concludes that a 1 percent change in the strength of a national IP environment, based on a statistical index, is associated with a 2.8 percent increase in foreign direct investment inflow."

³⁹<http://www.gsk-india.com/docs/PressReleases2013/GSK%20announces%20new%20pharmaceutical%20manufacturing%20investment%20in%20India.pdf>

⁴⁰<http://www.gsk-india.com/docs/PressReleases2013/GSK%20initiates%20voluntary%20open%20offer%20to%20increase%20stake%20in%20its%20pharmaceuticals%20subsidiary%20in%20India%20%2016%2012%2013%20LSE%20Announcement.pdf>

⁴¹<http://www.vccircle.com/news/health-care/2013/11/01/sanofi-infusing-122m-complete-buy-out-shantha-biotech-and-further>

⁴²<http://www.merck.com/licensing/our-partnership/sun-partnership.html>

⁴³http://www.emcure.co.in/news/docs/ET_2_March_2012_Roche_Emcure.pdf

⁴⁴http://www.cipla.com/CiplaSite/Media/Images/2014-02-Raltegravir-COM-news-release-Feb-20-final_2.pdf?ext=.pdf

⁴⁵US-India Business Council, *Op. Cit.* p4

⁴⁶GIPC Super 301 Submission 2014, p54 fn44

61. The GIPC does not reference the study, but it is most likely that the ‘recent’ study is a 2003 publication prepared for the OECD.⁴⁷ The study analyses empirical data for 1990-2000 to determine the association of the strength of patent rights with trade and FDI flows, controlling for other factors. The findings of the study - which the GIPC does not reveal –are:

- The association of 2.8% change in FDI with a 1% change in the ‘strength’ of patent rights is for the sample of least developed nations. For developing nations (which is the sample relevant to India) a change of 1% in the patent rights index is associated with a 0.73% change in inward FDI. (All FDI for this analysis is ratio of FDI to GDP).⁴⁸
- The implication is that “[a]s nations develop and have stronger patent regimes, a given reform in patent laws has a positive but smaller impact on FDI.”⁴⁹ It must be noted that the empirical data that formed the basis of analysis was for 1990-2000, before India amended its patent laws to fully comply with the TRIPS agreement in 2005. If anything, the positive impact of ‘stronger’ patent laws would be more modest at present.
- The study concludes that 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.” GIPC’s contrary thesis appears wholly misplaced.
- 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.”⁵⁰ This is consistent with the common sense understanding that a number of factors other than patent rights determine the flow FDI into a country.

62. The UK Commission on Intellectual Property Rights report, which predated the OECD study by a year, 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.”⁵¹

⁴⁷Park, 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/traddev/2960051.pdf>

⁴⁸*Ibid.* p37

⁴⁹*Ibid.* p18

⁵⁰Park, Walter G. and Lippoldt, Douglas, *Op. Cit.* p18

⁵¹UK 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

63. Several other studies and analyses negate the thesis of GIPC. A fairly comprehensive literature review by Chu⁵² concludes as follows:

“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)

64. More importantly, perhaps, from the US perspective, the OECD study found that patent rights insignificantly explain chemical and pharmaceutical US outward FDI in chemicals and pharmaceuticals when controlled for all variables.⁵³ 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).”⁵⁴

65. The reasons are obvious. A number of factors, both external to India and internal to it, contribute to the environment for American business in India. It would be a mistake to attribute the challenges and rewards of doing business with India to largely one, or just a few, of the relevant factors.

66. Not surprisingly, the environment for the pharmaceutical industry and its investment decisions are also impacted by a number of factors, most of which affect both foreign and domestic industry in India, such as infrastructure, governance, taxes, government spending on health care and delivery of health services, as well as the size and the price sensitive nature of the market.

67. In summary, we submit that neither facts nor theoretical considerations support the perception of the GIPC that a lower standard of IP protection than in the US has been a dampener on FDI in India in general or in the pharmaceutical sector. Very importantly, the empirical evidence suggests that a ‘globally optimal level of protection’, does not call for harmonization of IP protection to US standards and strong global patent protection is not as important to the pharmaceutical industry in the US as other factors. This is consistent with the fact that 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,⁵⁵ a far cry from GIPC’s assertion that it is India’s ‘most onerous or egregious IP acts, policies or practices that have the greatest adverse impact on U.S. businesses.’

⁵² Chu, Angus C: Macroeconomic Effects of Intellectual Property Rights: A survey, *Academia Economic Papers*, 2009, Vol 37, pp 283-303, available at http://mpa.ub.uni-muenchen.de/17342/1/MPRA_paper_17342.pdf

⁵³ Park, Walter G. and Lippoldt, Douglas, *Op. Cit.* p19 fn25

⁵⁴ *Ibid.* p19

⁵⁵ Palmedo, Mike, based on WTO figures, at <http://infojustice.org/archives/32249>

68. GIPC's Index is not the 'rigorous statistical tool' that it is claimed to be. Following this 'intellectual property roadmap' appears to be inappropriate for India. At the same time, it does not seem probable that advocacy of harmonization of India's patent laws with that of the US will contribute to GIPC's stated goal of benefitting the US economy.

III COMMENTS ON SUBMISSIONS RELATING TO OTHER ISSUES

69. Several other issues have been raised in other submissions. They relate mainly to local manufacturing requirements, effectiveness of intellectual property protections and barriers to market access. These are briefly commented upon below.

Local manufacturing requirements

70. GIPC⁵⁶, the Intellectual Property Owners Association⁵⁷ and the National Foreign Trade Council⁵⁸ make an identical submission relating to a local manufacturing requirement for pharmaceuticals:

"Since 2012, India has also infringed, overridden, or revoked nearly a dozen pharmaceutical patents held by foreign firms, in part because the patented product was manufactured outside of India."

71. We are bewildered by this submission. It is wholly wrong. It is extraordinary that three independent submissions have used identical wording to make a baseless assertion. We trust that USTR will weigh the implications for the veracity of submissions made by these organizations before taking cognizance of them. GIPC and the National Foreign Trade Council have called for designating India as a Priority Foreign Country.

Intellectual Property Protections

Burdensome Patent Office Requirements

72. In yet another instance of an identical submission, GIPC⁵⁹, the Intellectual Property Owners Association⁶⁰ and the National Foreign Trade Council⁶¹ complain of the burden imposed by Form 27:

"Not only is this "Form 27" process highly burdensome from an administrative point of view, but we are concerned that the information that is provided could be eventually used to justify compulsory licenses in a variety of industries, as specifically contemplated in the Form."

73. The submission of Form27 is an annual statement required to be submitted by all patentees, whether Indian or foreign. All that it asks for is for brief information related to the working of the patent in India.

⁵⁶GIPC Special 301 Submission 2014, p60

⁵⁷Intellectual Property Owners AssociationSpecial 301 Submission 2014, p5

⁵⁸National Foreign Trade Council Special 301 Submission 2014, p4

⁵⁹GIPC Special 301 Submission 2014, p59-60

⁶⁰Intellectual Property Owners AssociationSpecial 301 Submission 2014, p5

⁶¹National Foreign Trade Council Special 301 Submission 2014, p3

74. PhRMA submits that the requirement under Section 8 of the Patents Act is a burdensome patent application procedure. This provision is applicable to all applicants, Indian and foreign. All that it 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 appears to be to ensure that Indian patent examiners have the benefit of being informed by the prosecution of the application elsewhere, to aid their examination.
75. PhRMA has cited one instance which “resulted in India revoking patents on the grounds of non-compliance with [Section 8].”⁶² Revocation of a patent for Allergan’s Combigan,TM a combination of two previously approved drugs for ophthalmic use, was sought on the grounds of obviousness and non-compliance with the requirements of Section 8, among others. The IPAB revoked the patent on both these grounds. It noted that the patentee had submitted information of grant of the patent in Canada and that the failure to disclose information on the prosecution of patents for the same subject matter in the US, which resulted in an office action of final rejection, as well as rejection in the European Patent Office, was material and wilful.⁶³
76. PhRMA is apprehensive that the failure to disclose under Section 8 can by itself lead to the invalidation of a patent, without the need for such failure to be material or intentional. PhRMA may be reassured by:
- A judgment of the Delhi High Court in November 2012. A patent was challenged on and a summary judgment was requested as the patentee admitted that the requirement of Section 8 was not met. The summary judgment was refused and the Court noted that both materiality and willfulness needed to be established in a trial.⁶⁴
 - A judgment of the IPAB in July 2013 elaborately discussed the reason for the provision and precedent. It rejected the Section 8 challenge, noting that a bald assertion of violation of the section does not make out a ground for revocation of a patent.⁶⁵

Patent enforcement and regulatory approval

77. Yet another concern of PhRMA and BIO is that it is possible in India for a generic to seek marketing approval 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. 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

⁶²PhRMA Special 301 Submission, 2014, p28

⁶³*Ajantha Pharma vs Allergan*, APAB, 8 August 2013; available at <http://www.ipab.tn.nic.in/173-2013.htm>

⁶⁴*Koninklijke Philips Electronic vs Sukesh Behl*, para 14; available at <http://www.indiankanoon.org/doc/21642064/>

⁶⁵*Fresenius Kabi Oncology v Glaxo*, IPAB, July 27, 2013, paras 34-52; available at <http://www.ipab.tn.nic.in/162-2013.htm>

occasioned by holding up marketing authorization during the term of the patent would cause grave injury to consumers and there is no way to compensate them.

Patent litigation outcomes

78. Patent litigation outcomes have been commented upon adversely by PhRMA, who believe that patents are revoked on the ground of failing to demonstrate an inventive step, using 'hindsight' analysis. BIO has specifically mentioned the revocations of patents for four drugs, including Sutent™ (the patent for which, BIO acknowledges has been 'reinstated', but is still being litigated), and Renadyl™ (the process patent of which has been revoked, but the patent for the product has been upheld as BIO acknowledges), Combigan™ and Ganfort™, which are both combinations of previously approved drugs. The Combigan™ and Sutent™ decisions referred to earlier provide relevant background.

79. BIO further states:

"Indian law recently recognized patent protection for pharmaceutical compounds. As a result, the courts in India have only recently dealt with patent enforcement issues and are still finding their way in handling complex patent issues. The standards for claim interpretation, trial, and enforcement of injunctions are still under development."⁶⁶

We submit that the Indian legal system has been able to cope with the challenges, notwithstanding the absence of a tradition of patent litigation.

80. There have also been other cases of revocation and there is ongoing litigation relating to some other pharmaceutical patents. We submit that patent litigation is to be expected and there is nothing unusual in this, when thousands of patents have been granted for pharmaceutical products, compositions and processes to manufacture them. The US is not a stranger to patent litigation or patents being invalidated. An interesting analysis⁶⁷ of patent cases filed in the Federal District Courts of the US shows that 283 cases challenging the validity of claims in a patent 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.

81. 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.

⁶⁶BIO Special 301 Submission, p11

⁶⁷Smyth, 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-c913e33112ce>

Market Access Barriers

Government Price Controls

82. PhRMA refers to the price control of 348 essential drugs. In a major departure from previous price control policy, where the pricing was determined based on the cost, the basis was changed to a market based mechanism advocated by PhRMA and the IPA, among others. Non-governmental Organizations and public health activists are critical of this change and the Supreme Court of India is scrutinizing the issue in a public interest litigation.
83. PhRMA is concerned that a provision in the Drug Price Control Order exempts the products of indigenous drug research from price control for a period of five years, as it appears to favor local companies and discriminate against foreign companies. It must be remembered that all the drugs covered by price control are old and established essential medicines. It is unlikely that this category of drugs will be of significance to foreign companies.
84. PhRMA has also pointed out with concern, a government proposal to negotiate prices based on international reference pricing for government procurement and through their health insurance schemes. No decision has been taken as yet and there is no basis to believe that it would result in an unviable pricing framework for government procurement. In any event, price controls of several kinds is in vogue in many countries around the world, as noted in the PhRMA submission itself.
85. It has been suggested in some submissions that price control is not the best way to ensure access and it is necessary to increase government spending on health and health-related infrastructure. The problem defies easy solutions, despite several major initiatives, as a review in the *Lancet* shows.⁶⁸
86. Briefly, the allocation by the central government (akin to federal funding) to health care has grown ten-fold over the last ten years and the state governments have also increased allocations. The most noticeable benefit has been in health insurance coverage by government for hospitalization, the costs of which can be catastrophic for individuals who are clawing their way out of poverty. Research for the Planning Commission of the Government of India by the Public Health Foundation of India⁶⁹ shows that insurance coverage has grown dramatically, from about 75 million in 2007 to about 300 million – about a quarter of the population - in 2010, though there are wide inter-state disparities. But it should be noted that this coverage is predominantly for hospitalization, not drug costs, which are largely met by out-of-pocket expenditure. The study notes that “evidence shows that the effect on catastrophic payments and impoverishment in India occurs due to outpatient care especially due to drugs” and as a consequence, a significant number of households slip back to poverty across every

⁶⁸Shiva Kumar, A.K. *et al*: Financing health care for all: challenges and opportunities, *Lancet*, Volume 377, issue 9766, Pages 668 - 679, 19 February 2011 available at

<http://download.thelancet.com/pdfs/journals/lancet/PIIS0140673610618843.pdf?id=caaXKORRk4IM6PJNSJr>

⁶⁹Public Health Foundation of India:A Critical Assessment of the Existing Health Insurance Models in India, 31 January 2011, http://planningcommission.nic.in/reports/sereport/ser/ser_heal1305.pdf

income-quintile of the population in both the rural and urban areas.⁷⁰ The bottom-line is there is little prospect of state funding or expanding insurance coverage for expenditure on new drugs in the near term.

Clinical Trials

87. PhRMA has alluded to the difficulties in undertaking clinical trials pursuant to orders passed by the Supreme Court of India in public interest litigation. This is an issue for the entire pharmaceutical industry, both Indian and foreign. While there has been some progress, we believe that Government of India is anxious to resolve the residual issues at the earliest.

Counterfeit Medicines

88. PhRMA alleges that “India is a major channel for the export of counterfeits to consumers worldwide.”⁷¹ We cannot comment on this as we have insufficient information. The World Health Organisation has put out a fact sheet⁷² that suggests that counterfeit drugs occurs in all countries including the US and UK. The extent of the problem is definitely higher in other countries, but as the WHO states, it is difficult to determine the extent. The problem affects both branded and generic drugs. Counterfeit drugs are a worldwide problem.

IV CONCLUSION

89. PhRMA, BIO, GIPC, the National Foreign Trade Council, the Alliance for Fair Trade with India and the National Association of Manufacturers have called for the designation of India as a Priority Foreign Country.

90. We have pointed out the extraordinary use of identical language in submissions of GIPC and the National Foreign Trade Council, as well as the Intellectual Property Owners Association (which has not called for the designation of India as a Priority Foreign Country). For this reason, we respectfully submit that the USTR ought not to take cognizance of their submissions. In addition, we have commented extensively on the GIPC’s submission and shown, among other things, that the Index is flawed and ought not be relied upon.

91. Further, the OECD study is the only one that has been relied upon by the GIPC to suggest that higher standards of intellectual property protection in India would result in higher FDI inflows. GIPC has misinterpreted the study. On the contrary, the OECD study suggests diminishing positive impacts on FDI with increasing development and intellectual property protection. Beyond a point, it appears that the impact may even be negative.

⁷⁰*Ibid.* Pages 93-95

⁷¹PhRMA Super 301 Submission 2014, p32

⁷²<http://www.who.int/mediacentre/factsheets/fs275/en/>

92. Very importantly, the OECD study relied upon by GIPC suggests that strengthening of patent protection for pharmaceuticals does not seem to significantly correlate with US outward FDI. On the other hand, there is evidence of healthy growth of US pharmaceutical exports to India and anecdotal evidence of robust FDI flows into the Indian pharmaceutical sector. The consideration of all these factors suggests that strong global patent protection is not as important to the pharmaceutical industry in the US as other factors.
93. The views of the Alliance for Fair Trade with India are largely similar to that of PhRMA. Those of the National Association of Manufacturers are a summary of the issues traversed by PhRMA and BIO as far as pharmaceuticals are concerned.
94. Thus, PhRMA and BIO are the main proponents of designating India as a Priority Foreign Country and we have the following summary comments on their submissions:
- A main grievance is with respect to Section 3(d), which India believes is TRIPS-compliant. No evidence (as opposed to assertion) has been submitted to suggest that the 'gain' from extending the patent monopoly beyond 20 years with second and third patents on the same product is significant for US companies. On the other hand, it can have serious consequences for public health by delaying access to affordable generics, as illustrated by the Gleevec example.
 - Another grievance was a perception that compulsory licenses would be granted if there was no local manufacture, despite the decision of the Intellectual Property Appellate Board to the contrary. This concern is misconceived and is plainly not an issue any more.
 - Patent revocations and denials as a consequence of oppositions were held out as matters of concern. Litigation and the consequent invalidation of patents is only to be expected. As we have shown, the number of such instances, even according to the submissions made, is not high in relation to the patents granted. The main safeguard is the established judicial system, with multiple opportunities to correct erroneous decisions, if any.
 - Some concerns, such as burdensome patent office requirements, do not appear to be justified or grievous and some such as clinical trials are expected to be resolved soon.
95. Overall, the submissions provide little reason to think India denies adequate and effective protection of intellectual property rights, or denies fair and equitable market access to companies in the United States as far as the pharmaceutical industry is concerned. There is even less reason provided in the submissions to suggest that India has the 'most onerous or egregious acts, policies, or practices'.

96. In any event, there is nothing in the submissions to suggest that India's intellectual property policies or the identified issues in market access have the 'greatest impact' on the pharmaceutical industry in the US. It is significant that the damages are not quantified (not even in order of magnitude) in any of the submissions, including that of the PhRMA.
97. We respectfully submit that there has been progress on two of the issues identified in the Special 301 Report 2013: Patent Office backlog and the overturning of the grant of compulsory license on the ground that the patented article is imported as opposed to being locally manufactured.
98. We believe that government is increasingly engaging with the pharmaceutical industry, Indian and foreign. The submission of PhRMA alludes to their advocacy of changing the basis of price control. The submission of BIO refers to their submission on the Discussion Paper on compulsory licensing. Public comment has been invited on the recently published Draft Guidelines for the examination of pharmaceutical patents. These are just three of several instances.
99. As far as we are aware, India has not refused to engage in multilateral or bilateral discussions. Our impression is that after the 2010 meeting of the US-India Trade Forum, India twice suggested holding a meeting of the Trade Forum in 2011. Again in 2013, before the visit of the Prime Minister to the US, India proposed a Trade Forum meeting.
100. Health, perhaps more than any other sector, is a fraught issue. The primary responsibility of the health of the Indian people is that of India. But, as the report of *The Lancet*—University of Oslo Commission on Global Governance for Health has argued⁷³, the reduction of the deep and unacceptable inequities in health across nations and within nations is not just a question of eradicating poverty and economic growth. It is a complex issue of many factors, both within and outside the health-care sector, including knowledge and intellectual property, finances, trade and investment.
101. The report points out that “[n]ation states are responsible for respecting, protecting, and fulfilling their populations' right to health, but with globalization many important determinants of health lie beyond any single government's control, and are now inherently global.”⁷⁴ At the end of the sometimes disturbing, but always thought-provoking analysis, the report concludes that:
- “The overarching message of the Commission on Global Governance for Health is that grave health inequity is morally unacceptable, and ensuring that transnational activity does not hinder people from attaining their full health potential is a global political responsibility.”⁷⁵

⁷³Ottersen, Ole Petter, *et al*: The political origins of health inequity: prospects for change, *Lancet*, 383: 630–67, 15 February 2014, available at

http://download.thelancet.com/pdfs/journals/lancet/PIIS0140673613624071.pdf?id=aaa3znQa_gyCQ5PkFhuru

⁷⁴*Ibid*, p632

⁷⁵*Ibid*, p661

102. The United States is the knowledge leader of the world and its pharmaceutical industry is no less. We are confident that the United States will be a leader in ensuring that its knowledge and power is used for advancing the moral imperative of global health.

103. We are thankful for the opportunity to make this submission and trust it will be considered.

RC:DGS:LF:05III14