



Post-Hearing Brief

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**

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POST-HEARING BRIEF OF THE INDIAN PHARMACEUTICAL ALLIANCE

1. My name is Dilip G Shah and I am Secretary General of the Indian Pharmaceutical Alliance (IPA). I thank the USITC for the opportunity to testify on February 12, 2014 and am filing this post-hearing brief to supplement my oral testimony.
2. This brief is a response to some of the issues that arose during the hearing. Further submissions will be provided in the written statement that will be filed subsequently.

The business environment in India

3. The US-India Business Council has testified to the positive momentum in Indo-US trade relationship in its pre-hearing brief and testimony to the USITC, including that:
 - 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.
 - 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.
 - 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.
4. These facts are ignored in some of the testimony before this Commission asserting a sweeping generalization that the business environment in India is detrimental to US business and economic interests. 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.
5. 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 in new manufacturing facilities in India¹, 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.²

¹<http://www.gsk-india.com/docs/PressReleases2013/GSK%20announces%20new%20pharmaceutical%20manufacturing%20investment%20in%20India.pdf>

²http://www.gsk-india.com/docs/PressReleases2013/GSK%20initiates%20voluntary%20open%20offer%20to%20increase%20stake%20in%20its%20pharmaceuticals%20subsidiary%20in%20India%20%2016_12_13%20LSE%20Announcement.pdf

6. In 2010, Abbott acquired the domestic pharmaceutical formulations business of Piramal Healthcare, an Indian company, in a deal worth \$3.7 billion, and became the largest company in India by domestic sales.³
7. Mylan has reportedly invested \$3 billion in India in the last six years and currently has 14 manufacturing facilities employing about 12000 people in the country. In addition to viewing India as a global manufacturing hub, Mylan is aggressively pursuing growth in the Indian market for its products.⁴
8. 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.⁵
9. 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:⁶

“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.”
10. 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.⁷ 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.
11. 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 MabThera and Herceptin.⁸ 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.⁹

³<http://timesofindia.indiatimes.com/business/india-business/Abbott-buys-Piramals-pharma-arm-for-37bn/articleshow/5960176.cms?referral=PM>

⁴<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

⁵<http://www.vccircle.com/news/health-care/2013/11/01/sanofi-infusing-122m-complete-buy-out-shantha-biotech-and-further>

⁶http://www.business-standard.com/article/companies/q-a-alok-sonig-md-bristol-myers-squibb-india-110060300084_1.html

⁷<http://www.merck.com/licensing/our-partnership/sun-partnership.html>

⁸http://www.emcure.co.in/news/docs/ET_2_March_2012_Roche_Emcure.pdf

⁹http://www.cipla.com/CiplaSite/Media/Images/2014-02-Raltegravir-COM-news-release-Feb-20-final_2.pdf?ext=.pdf

12. Testimony before this Commission 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.”
13. Overall, Foreign Direct Investment (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 investments in the pharmaceutical sector has been a little higher than the long term average in the last three years.¹⁰
14. In summary, we submit that the facts do not support the perception that India’s trade, investment and intellectual property policies have been a dampener on FDI in India in general or in the pharmaceutical sector. The obvious corollary is that these investments have been made because pharmaceutical companies and others believe that the business environment in India is positive overall.

Indices and their limitations

15. The attention of this Commission has been drawn to India’s poor ranking in several indices that purport to reflect the ‘strength’ of India’s Intellectual Property (IP) policies and its enforcement. The intended implication seems to be that these indices reinforce the perception that India’s IP policies contribute to, and are reflective of, the poor business environment in the country, which in turn limits the opportunity for American firms to invest in India and profit from its growing consumption.
16. As is evident from the facts, the situation on the ground is at odds with this proposition. 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 several factors.
17. Not surprisingly, the environment for the pharmaceutical industry is 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, delivery of health services, and the price sensitive nature of the market.
18. The task of disaggregating the impact of the many factors is not an easy one, but the difficulties involved in doing so do not justify the acceptance of over-simplification, such as the reliance on an IP index as the indicator of the business environment.
19. The argument has also been made that there is a correlation between the ‘strength’ of IP rights of a country and its economic development. A correlation may exist, but it is incorrect to suggest that there is a *causal* relationship. The available literature is indicative of the significant ambiguity as well as the uncertainty, arising from conflicting empirical evidence and the differences between the data from the North and South, even in the restricted ambit of evaluating the effects of IP protection on

¹⁰http://dipp.nic.in/English/Publications/FDI_Statistics/2013/india_FDI_December2013.pdf

innovation and FDI. This literature has been reviewed by Park, the co-author of the Ginarte-Park index.¹¹ To suggest comforting certainty in this area is not justified.

20. A fairly comprehensive literature review by Chu¹² 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)

21. The GIPC index is another index that has been cited in testimony before this Commission. The 2014 GIPC index¹³ 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.¹⁴Essentially, the GIPC index seems to be measuring the distance between US IP protection and that of other countries, and this is being used, despite Chu’s caution above, to canvass adoption of US IP protection standards in other countries. In doing so, the index scores perceptions more than facts. 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”. The index is therefore largely constructed not just on the basis of perceptions, but the perceptions of right holders. 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 right holders, which has largely determined its low ranking in the index.

22. 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. The Ginarte-Park index also ranks the US the highest with a score of 4.88, while Ukraine and China score 3.68 and 4.08 respectively, which is inconsistent with the GIPC index. India is lower at 3.76.

¹¹http://www.american.edu/cas/faculty/wgpark/upload/elsevier_ipr_Park2.pdf

¹²Chu, 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/MPPA_paper_17342.pdf

¹³<http://www.theglobalipcenter.com/GIPCindex/>

¹⁴See for example, <http://spicyip.com/2014/02/gipc-ip-index-propagating-imaginary-ip-norms.html>

23. The relatively low ranking of China does not correspond to the stellar inflow of FDI and economic growth in China, contrary to what the IP index proponents would have us believe.
24. The ranking of China also raises a serious question about the utility of these indices: how is it that China, despite its ranking above India and many 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”¹⁵ 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”.
25. The USITC has also conducted its own investigation¹⁶ and estimated losses of \$48.2 billion¹⁷ “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”.
26. Apart from the serious methodological and interpretative limitations of the IP indices and the inconsistencies in rankings between them, two factors need to be carefully considered before any reliance is placed on them for the purposes of this Commission’s investigation. As the China example shows, the ranking in the IP indices:
- Does not correlate with the losses to the US economy and employment.
 - Does not correlate with the flow of FDI and economic growth.
27. In summary, we submit that a country’s ranking in the so-called IP indices has little relationship, both in theory and practice, with the business environment, the flow of FDI into the country, or its economic growth. It has even less to do with a consequential impact on the US economy or employment. We therefore submit that IP indices be disregarded by the USITC as they do not contribute meaningfully to its investigation.

¹⁵ The Commission on the Theft of American Intellectual Property: The IP Commission Report, May 2013, available at <http://www.ipcommission.org/Report/index.html>.

¹⁶ USITC: China: Effects of Intellectual Property Infringement and Indigenous Innovation Policies on the U.S. Economy, Investigation no. 332-519, Publication 4226, May 2011

¹⁷ This is a statistical ‘point’ estimate, with the range being \$14.2 billion–\$90.5 billion.

India's patent law

28. The progress that India has made in reforming its patent laws has perhaps received inadequate attention. I am therefore providing a brief overview of the history of patent protection for medicines in India. The Patents Act has been in existence in India since 1911 and medicines were entitled to patents from then to 1972. The situation however was that there was very little domestic capability or capacity to develop or manufacture the most basic of drugs and the country was heavily dependent on imports. Prices were high and availability was limited. This was an untenable situation. The government therefore appointed several committees to make remedial recommendations.
29. These recommendations led to India's parliament amending the Patents Act in 1972 to prohibit the grant of patents for medicinal products, though processes to manufacture them continued to be eligible for patents. This regime continued till 1995.
30. On becoming a signatory to the TRIPS Agreement, India implemented the transitory provisions from 1995 onwards, and patent applications for medicinal products were lodged in a 'mail-box' for examination and grant after 2005.
31. The government was anxious to meet the deadline for the full implementation of the TRIPS Agreement with effect from January 1, 2005. A bill seeking to amend the Patents Act was introduced in parliament. There was tremendous opposition to providing patent protection for medicines, both in parliament and in the media. The battle lines were clearly drawn between honoring international obligations on the one hand and ensuring timely access to affordable generics on the other. Examples of extension of patent monopolies beyond 20 years in Western countries because of adroit patent strategies were rife. The World Health Organization as well as international public health activists weighed in on the side of timely access.
32. A deadlock, and default on the implementation of the TRIPS Agreement loomed. Finally, a late-night compromise on the eve of voting in parliament was reached among the political parties to enact the legislation as it stands today.
33. The compromise was essentially that the provisions of the TRIPS Agreement would be implemented, subject to safeguards against extension of patent monopolies beyond the mandated 20 years, as well as the use of flexibilities assured by the Doha Declaration to safeguard public health. All these safeguards, which India believes are fully compliant with TRIPS Agreement, are the ones assailed by some of the innovator pharmaceutical companies. Contrary to the allegations made by some of those testifying before this Commission, the patent amendments incorporating these safeguards were not for the benefit the Indian generic industry. The interests of the generic industry were incidental to the debate, and came up mainly in the context of ensuring access to affordable medicine.

34. For many, this was an extraordinary achievement in aligning India's patent law to standards that had been globally agreed upon and is corroborated by the briefing of the US-India Business Council to this Commission:

“In 2004, India moved legislation that many said could never be done, providing patent protection to pharmaceutical innovation. India's legislation to implement a TRIPS compliant patent system ushered in a product patent era for pharmaceutical products.” (Emphasis added)

35. The USIBC testimony draws attention to two aspects of the passage of India's patent reform legislation in 2005. First, it was an extraordinary achievement in the Indian context. We have shown that it was possible only because of the safeguards for public health provided in the new patent legislation. Legislation that went beyond the requirements of the TRIPS agreement would have been, and remains, a practical impossibility given the reality of the public health situation in India, which is briefly touched upon subsequently. Second, that it is TRIPS-compliant.

36. Yet another aspect that needs to be noticed is that the Supreme Court of India has recognized the right to health as a fundamental right under Article 21 of the Constitution of India.¹⁸ Indian law recognizes the inter-relatedness of rights and the primacy of fundamental rights. The Patents Act confers certain rights on patentees, based on the international treaty obligations of India, but these rights have to be consistent with the fundamental rights guaranteed under the Constitution. Any amendment to the statute conferring patent rights that goes beyond treaty obligations and reduces access to medicine may well be questioned on the ground of violation of the fundamental right to health. Thus, in addition to the practical difficulties in incorporating TRIPS-plus provisions in its patent laws, India will potentially be confronted with difficulties in defending its constitutional validity.

TRIPS-compliance and its implications

37. Whether India's safeguards are compliant with the TRIPS Agreement may be of particular interest to the USITC. The contentious issues are mainly:

- Section 3(d) of the Patents Act which does not permit the grant of second and subsequent patents to the same product, thereby extending patent life for a medicine beyond 20 years; and
- Section 84, which provides for compulsory licenses if the reasonable requirements of the public for the patented product are not met, or the product is not available at reasonably affordable prices, or the patent is not worked on a commercial scale in the territory of India.

For the reasons mentioned in our testimony as well as others, working of the patent in the territory of India does not necessarily mean a local manufacturing requirement as

¹⁸*PaschimBangaKhetMazdoorSamityvs State of WB* (1996) 4 SCC 37;*Surjit Singh vs State of Punjab* (1996) 2 SCC 336.

stated by the Intellectual Property Appellate Board in *Bayer*.¹⁹ We submit that the repeated assertions to the contrary in testimony to this Commission should be disregarded. We would be happy to provide further clarifications, should the Commission need them, to put this matter to rest.

38. 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 testified before this Commission. We do not propose to provide a detailed legal justification of this position as we presume that other testimonies will attest to this, but would be glad to do so, if requested. We would however like to draw the Commission's attention to the views of a few others who have not testified before it.

39. A joint publication²⁰ 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".²¹ We draw the Commission's attention to its observations in the context of Section 3(d) and Section 84 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'."²²

"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."²³

"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."²⁴

- "A wide range of policy options and flexibilities are built into the international IP regime that can be used to pursue public health objectives. These options are not self-actuating at the international level, though, and attention and action are needed at the domestic level as to how best to implement such flexibilities, so that the national IP regime responds to each country's individual needs and policy objectives. Key options include ... refining the criteria for grant of a patent, pre-grant and post-grant opposition procedures, as well as exceptions and limitations to patent rights once granted, including compulsory licences and government use."²⁵

¹⁹ *Bayer Corp. vs Union of India*, OA/35/2012/PT/MUM, para 46, "[Bayer] had not "worked" the invention on a commercial scale even if "import" alone would satisfy the working condition"; para 52 "Therefore, we cannot decide that.... if there is no manufacture in India, then there is no working"; judgement available at <http://www.ipab.tn.nic.in/045-2013.htm>

²⁰ 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/

²¹ http://www.who.int/mediacentre/news/releases/2013/book_summary.pdf

²² WHO, WIPO and WTO, *Op.cit.* p13

²³ *Ibid*, p131

²⁴ *Ibid*, p131

²⁵ *Ibid*, p13

“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 licences are granted. They are thus not limited to emergencies or other urgent situations, as is sometimes mistakenly believed.”²⁶

“Many countries allow the granting of compulsory licences 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 licence if the product or method is made available by the rightholder in insufficient quantity or unsatisfactory quality, or if the prices charged are abnormally high.”²⁷

(Internal citations omitted)

40. The WHO, WIPO and WTO publication referred to above builds on the view of the Commission on Public Health, Innovation and Intellectual Property Rights,²⁸ 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.”²⁹

“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).”³⁰

²⁶*Ibid*, p174

²⁷*Ibid*, p175

²⁸World Health Organization: Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health, Geneva, April 2006

²⁹*Ibid*, p149-150

³⁰*Ibid*, p151-152

- “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.”³¹

(Internal citations omitted)

41. Academics, including in the United States³² have also published extensively, arguing that Section 3(d) and Section 84, as well as other provisions, in India’s patent law are TRIPS-compliant.
42. It is important to note that:
 - The WTO has not determined that India’s patent laws are violative of the TRIPS agreement. No Member-country of the WTO, including the United States has even disputed it before the WTO. It must therefore be presumed that India’s patent law is TRIPS-compliant.
 - The TRIPS agreement is a ‘minimum standards’ agreement and there is no obligation on any country to go beyond these minimum standards and incorporate TRIPS-plus provisions in their domestic laws. The United States has acquiesced to this position as it is a signatory to the TRIPS agreement.
43. The IPA submits that in view of the foregoing, the effect (if any) of India’s patent law on the investments of US companies in innovation, or the US economy, or employment, should be measured against the yardstick of the TRIPS-compliant provisions in its patent law, and not the yardstick of the standards that may be prevalent in the United States.
44. In other words, the question before this Commission is not what ‘an improvement in IPR protection in India to levels comparable to those in the United States could lead to’. Apart from the reasons outlined above, such a question would be futile, given the economic realities discussed below.

Economic aspects

45. India’s economy has certainly grown in the last two decades or so and now ranks 11th in the world. At the same time, India has one of the highest income inequalities in the world, with 270 million people – nearly a quarter of the population – living below the poverty line, which was drawn in 2012 at *per capita* consumption per day of US\$0.53

³¹*Ibid*, p139

³²See 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

in the rural areas and \$0.65 in the urban areas.³³ An additional 680 million people - over half the population - are unable to “fulfill eight basic needs—food, energy, housing, drinking water, sanitation, health care, education, and social security—at a level sufficient to achieve a decent standard of living rather than bare subsistence.”³⁴

46. A large proportion of the remaining 300 million or so - about a quarter of the population - consists of the middle-class. This number appears impressive at first glance and is being cited by some in their testimony before this Commission as evidence as of the market for patented pharmaceutical products. This ‘beautiful hypothesis’ is ‘slain by ugly facts’ according to Rama Bijapurkar, India’s leading market strategist and consumer economy expert, who has marshalled the facts:³⁵

- “The topmost income quintile has increased its share of income from 48 per cent in 2004-05 to 53 per cent in 2009-10 and is estimated to increase to 53 per cent in 2014-15.”³⁶
- “Even the top 20 per cent of India, Quintile 5, the so-called middle class, despite its income growth projections is still far below international income levels - below Brazil, below Indonesia, well below ASEAN countries.”³⁷
- “Compared to the \$14,446 per capita income of China’s top 20 per cent, India’s top 20 per cent is at just under a per capita income of \$4 000.”³⁸

The ‘so-called middle class’ has a *per capita* income of \$11 per day, less than the “US poverty line of \$13 per person per day”.³⁹

47. One has to look to the top end of income groups to find a market for patented drugs, but even “the top 10 per cent of India which has 30 per cent of India’s income has a per capita income of (even taking better purchasing power parity into account) of \$13,700 (PPP).”⁴⁰ It is clear that the majority of even the top decile cannot afford the cost of most new drugs. For example, 11 out of the 12 new treatments approved by the US FDA in 2012 to treat cancer are priced at over \$100,000 per treatment per year.⁴¹ It is significant that “99 per cent” of Glivec was given away free by Novartis.⁴²

³³Government of India, Planning Commission: Poverty Estimates for 2011-2012, July 2013, http://planningcommission.nic.in/news/pre_pov2307.pdf. Conversion to US dollars at a convenience rate of Rs 51 to a dollar, based on the reference rate of the Reserve Bank of India for 30 March 2012 of Rs. 51.1565

³⁴McKinsey Global Institute: From poverty to empowerment: India’s imperative for jobs, growth, and effective basic services, February 2014, http://www.mckinsey.com/insights/asia-pacific/indias_path_from_poverty_to_empowerment

³⁵Bijapurkar, Rama: A Never-Before World: Tracking the evolution of Consumer India, New Delhi, Penguin Books India, 2013

³⁶*Ibid*, p102

³⁷*Ibid*, p103

³⁸*Ibid*, p104

³⁹*Ibid*, p 105

⁴⁰*Ibid*, p104

⁴¹Experts 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>

⁴²Novartis vs Union of India, IPAB, p 21, <http://www.ipab.tn.nic.in/Orders/100-2009.htm>

48. The argument has been advanced that the solution to the problem of access to medicines, particularly new medicines, can only be through the increase in government spending and insurance coverage. The problems are however humongous and ought not to be trivialized.⁴³
49. 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 India⁴⁴ 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 income-quintile of the population in both the rural and urban areas.⁴⁵ The bottom-line is there is little prospect of state funding or increasing insurance coverage for expenditure on new drugs in the medium-term.
50. Though the market for new patented drugs at US prices is clearly negligible, innovator pharmaceutical companies have explored promising strategies to increase revenues with differential pricing, as is illustrated by the recent examples of Roche, Merck and Gilead (see paras 11-12 above). US innovator companies are also profiting from the large generic market in India and increasing their sales and imports of finished goods:

⁴³See for example, Shiva 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=caaXKORRk4IM6PJNSJru>

⁴⁴Public 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

⁴⁵*Ibid.* Pages 93-95

WHOLESALE SALES VALUE

Rs Million

COMPANY	12 months ending Apr 09	12 months ending Apr 13	Growth 2013/2009 Per cent
Abbott Healthcare	17,247	27,100	57.1
Pfizer	8,376	17,147	104.7
Abbott India	6,946	14161	103.9
Merck	2,727	4,751	74.2
BMS India	595	949	59.4
Total	35,891	64,108	78.6

Source AWACS

IMPORTS OF FINISHED GOODS

(Illustrative Sample of Seven* Pharmaceutical Companies)

Rs Million

Year Ending 31 st March	Finished Goods Import
2005	1,871
2006	1,775
2007	2,677
2008	2,049
2009	2,443
2010	3,999
2011	6,406
2012	7,953
Total	29,173
2012/2005 Growth %	425

*Abbott, Bayer, GSK, Merck, Novartis, Pfizer and Sanofi
Source: CMIE

51. Two implications arising from the above warrant the attention of this Commission:

- The 'lost' sales claimed by innovator pharmaceutical companies in the US because of India's patent law and the impact on US employment will need to be based on estimates of revenues from the small sliver of the population which can afford to buy patented new drugs at discounted prices.
- Access to a wider population can only be through the availability of generics.

‘Free ride’ vs Fair share

52. A question that arose during the oral testimony was whether India is enjoying a free ride on the substantial expenditure incurred by the innovator pharmaceutical industry in developing new drugs. The corollary is that the free ride would reduce the returns – and therefore the incentive – on innovation.
53. The development costs of the drug should logically be spread over the markets that generate the revenues. Innovator pharmaceutical companies make decisions on investments in innovation and development of new drugs on the basis of developed country markets. In 2005, the year in which India implemented the TRIPS agreement, just three regions with 18% of the world population accounted for 89% of global pharmaceutical sales revenues:

WORLD AUDITED MARKET - 2005

Region	12 mths ending Mar 2005 ⁺		Population – 2005 [*]	
	Revenues \$billion	Share %	Millions	%
Latin America	20.3	3.8	558	9
Asia/Africa/Australia	41.0	7.7	4711	73
Japan	59.0	11.1	128	2
Europe	158.4	29.7	725	11
North America	255.1	47.8	332	5
World	533.7	100.0	6454	100

⁺Source: IMS Health: MIDAS^{*}Source: Earth Trends Data Tables

54. It must be noted that the above data include revenues from both patented and generic drugs. The sales in developing country markets are largely from generic drugs. It is easy to see why India can only contribute to a tiny sliver of the revenues to innovator pharmaceutical companies for their patented drugs.
55. We submit that India is bearing its fair share, by providing patent protection for a term of 20 years on all innovative new drugs. Only patents that extend monopoly beyond the period of 20 years without any therapeutic benefit are denied.
56. The use of compulsory licensing has been resorted to in only one case as yet and under exceptional circumstances where the price was so high that access was denied to all but a few hundred patients. There was hardly any market for the patented drug to be ‘lost’ and royalty revenues from the sale of the product under compulsory license only add to the revenue of the patentee.
57. 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

argued⁴⁶, 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.

58. The report points out that “[n]ation states are responsible for respecting, protecting, and fulfilling their populations' right to health, but with globalisation many important determinants of health lie beyond any single government's control, and are now inherently global.”⁴⁷ At the end of the sometimes searing, 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.”⁴⁸

59. In the end, all that the IPA is submitting is that both India and the United States are signatories to the TRIPS agreement under the aegis of the World Trade Organization, the main institution for the global governance of trade and intellectual property. The main institution for the global governance of health is the World Health Organization which has strongly endorsed India's patent law and its compliance with the TRIPS agreement.

60. The United States ought not to be adversely affected by India's compliance with the norms of global governance in health, trade and intellectual property.

61. We are thankful to be given the opportunity to make this submission.

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⁴⁶Ottersen, 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

⁴⁷*Ibid*, p632

⁴⁸*Ibid*, p661