



USTR: 2019 SPECIAL 301 SUBMISSION

(Docket No. USTR-2018-0037)

Submission by

INDIAN PHARMACEUTICAL ALLIANCE

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Mumbai

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1. My name is Dilip G. Shah and I am Secretary General of the Indian Pharmaceutical Alliance (IPA). I am making this submission on behalf of the IPA for the 2019 Special 301 Review.
2. IPA's membership consists of twenty-two pharmaceutical companies which collectively account for over 85 per cent of the private sector investment in pharmaceutical research and development, more than 80 per cent of India's pharmaceutical exports and over 50 per cent of the domestic pharmaceutical market. We therefore have a vital interest in the protection of our innovations, not only for developing cost-effective and useful improvements in existing medicines, but also for discoveries of new medicines.
3. India is one of the twelve countries placed on the Priority Watch List in the 2018 Special 301 Report (2018 Report). This submission is mainly on patent issues relevant to the pharmaceutical industry, particularly those which have been noted in the 2018 Report. It seeks to provide information and perspectives that may aid the USTR in determining whether India denies adequate and effective protection of Intellectual Property Rights (IPR) or denies fair and equitable market access to the U.S. pharmaceutical industry which relies on intellectual property protection.

The IPR environment

4. There have been several developments in 2018 which may offer reassurance to U.S. businesses in general, including the pharmaceutical industry. They include accession to WIPO internet treaties, continuing efforts by the Indian Patent Office to improve operational efficiencies, the judicial system delivering speedy decisions even when dealing with new laws without precedent in domestic jurisprudence, demonstration of resolve to address enforcement issues relating to cinematographic films and a continuing commitment to spread awareness of the value of IPR. These are briefly dwelt upon below.

Accession to WIPO treaties

5. India has acceded to the WIPO Copyright Treaty (WCT) and the WIPO Performers and Phonograms Treaty (WPPT), which extends coverage of copyright to the internet and the digital environment. The treaties came into force on 25 December 2018.¹

Improvements in Patent Office functioning

6. India's Patent Office took significant steps to adopt new technologies to strengthen its administration and functioning. For example, soon after video conferencing facilities were made available for patent hearings, a similar facility has been introduced for trademark hearings in October 2018.² Expressions of Interest were invited in August 2018 for the application of Artificial Intelligence/Blockchain/Internet of Things and other technologies to expedite and strengthen processes in the Patent Office to enhance efficiency, speed and quality in patent application processing.³

¹ CIPAM, IPR Initiatives (Year 2018-19)

² http://copyright.gov.in/Documents/Video_Conferencing/Public_Notice.pdf

³ http://www.ipindia.nic.in/writereaddata/Portal/Tender/175_1/1_Expression_of_Interest-AI-02-08-2018.pdf

Speeding up litigation

7. In July 2018, the Delhi High Court speedily delivered India's first post-trial Standard Essential Patent judgement, finding local manufacturers of DVDs infringed Philips' patents and awarded punitive damages to the patentee.⁴ The suit was instituted in 2016 and judgement was delivered in 2018. As there was no judicial precedent, the Court relied, in part, upon U.S. jurisprudence in arriving at its decision.
8. The passage of the 2015 Commercial Courts Act was a significant step in speeding up litigation. Its passage was noted in the 2017 Special 301 Report (2017 Report) and it was stated that two Commercial Courts had been set up. The IPA had pointed out in its 2018 Special 301 submission⁵ (2018 Submission) that a much larger number of Commercial Courts had in fact been set up. Apart from the setting up of Commercial Divisions in two High Courts (Delhi and Mumbai) which were noted in the 2017 Report, they had also been set up in Himachal Pradesh and Chennai. These are the jurisdictions where High Courts try suits above a certain value. District Courts try suits in other jurisdictions. Multiple Commercial Courts were set up in districts in at least nine other states in 2016 and 2017. Commercial Appellate Divisions had also been set up in a number of High Courts to hear appeals from trial court decisions. Effective 3 May 2018, the Commercial Courts Act has been amended to empower state governments to set up more District Courts in consultation with the High Court as well as providing for additional measures⁶ to further expedite resolution of commercial disputes, including patent and trademark disputes.

Enforcement

9. The 2017 Report and earlier Reports had noted with concern several issues relating to enforcement. IPA had therefore outlined a number of steps that had been taken by the government to administratively strengthen enforcement activity in its 2018 Submission⁷ and several of these were noticed in the 2018 Report. The 2018 Report had however noted that U.S. 'stakeholders have identified specific incidents of camcording that originate in Indian cinemas' and that 'India has yet to take the final steps to enact anti-camcording legislation'. A draft amendment to the Cinematographic Act has been published for public comment in January 2019. The amendment seeks to provide for stringent punishment for making or abetting the making of recordings of audiovisual material protected by copyright during exhibition (eg. camcording of films) with imprisonment up to three years or a fine of up to Rs. 1 million, or both.⁸
10. The National Internet Exchange of India (NIXI), a government non-profit company providing neutral Internet Exchange Point services in India and the Maharashtra Cyber

⁴ *Koninklijke Philips Electronics N.V. v Rajesh Bansal*, Delhi High Court, CS (COMM) 24/2016

⁵ IPA 2018 Submission, para 21

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<http://legalliaffairs.gov.in/sites/default/files/The%20Commercial%20Courts%2C%20Commercial%20Division%20and%20Commercial%20Appellate%20Division%20of%20High%20Courts%20%28Amendment%29%20Act%2C%202018.pdf>

⁷ IPA 2018 Submission, paras 7-9

⁸ <https://mib.gov.in/sites/default/files/Public%20Notice%20-%20Amendment%20of%20Cinematograph%20Act%20Bill.pdf>

and Digital Crime Unit (MCDCU) suspended 235 infringing websites having 186 million hits per month. An anti-piracy video campaign has been launched with prominent and popular film stars making a pitch against piracy.⁹

Awareness building

11. A number of initiatives were listed in our 2018 Submission to promote awareness of the value of innovation and creativity in schools and colleges which will have an impact in the long-term by promoting a culture of respect for Intellectual Property Rights (IPR).¹⁰ We believe that this effort is crucial for public acceptance of policy changes as well as enforcement. CIPAM continued the effort with vigor in 2018. Online modules for IP awareness reached 100,000 students in 700 colleges. Another pilot module reached over 2700 students in 46 rural schools, bringing IP awareness to the vast rural population for the first time. The National Council for Educational Research and Training (NCERT) has included content on IPR in its curriculum for the Business Studies for Commerce stream. Steps to include it in other streams are under way.¹¹
12. The private sector is also getting involved in awareness building through educational institutions. For example, the Associated Chambers of Commerce and Industry (ASSOCHAM) and Ericsson jointly launched the 'Intellectual Property Talent Search Examination 2018'. An online awareness module aimed at high school (Class 9-12) and undergraduate students was disseminated, followed by an online examination. The best performing schools and colleges as well as school students and college students at the district, state and national level will receive cash awards and have an opportunity to visit R&D centres in India and abroad.¹²

Speeding up patent and trademark examination

Patents

13. The 2018 Report noted that 'India has yet to take steps to address longstanding patent issues', among which were the 'long timelines for receiving patents' despite acknowledging that 'India continues to pursue important administrative work to reduce the time for processing patent applications'.
14. We had outlined the key administrative measures that had been initiated in our 2018 Submission. These included the quadrupling of the strength of Examiners in the Patent Office with the recruitment and training of 459 additional Patent Examiners, strengthening supervision by filling in positions of 27 Deputy Controllers and 49 positions of Assistant Controllers, process re-engineering, introduction of digital technologies and other measures.

⁹ CIPAM, IPR Initiatives (Year 2018-19)

¹⁰ IPA 2018 Submission paras 4-6

¹¹ CIPAM, IPR Initiatives (Year 2018-19)

¹² <http://iptse.com/>

15. These initiatives have yielded tangible results as is evident from the data below:

Patent Applications Processed

FY: Financial Year April - March

Details	FY 2015-16	FY 2016-17	FY 2017-18	Inc. in 2017-18 over 2016-17	Apr-Dec 2018
Applications	46904	45444	47854	5%	37706
Examined	16853	28967	60330	108%	61768
Granted	6326	9847	13035	32%	10036
Disposals	21987	30271	47695	58%	36492

Source: CIPAM

16. The government had announced an ambitious plan April 2016 to reduce the examination period from 5-7 years to 18 months by March 2018.¹³ Patent applications examined more than doubled in 2017-18 over the previous year and for the first time, the number of patents disposed of (grants, refusals, withdrawals, abandonments) kept pace with the number of applications. An official of the Department of Industrial Policy and Promotion (DIPP) is reported to have stated that 6000 first examination reports were being completed in a month as of March 2018.¹⁴
17. The most recent data indicates that the increased pace of examinations has been sustained in the current year. In April-December 2018, 61,768 patent applications were examined as against 40,790 during the corresponding period in the previous year. The pendency at the examination stage decreased from 204,177 as on 31 March 2017 to 127,881 as on 31 December 2018.¹⁵ In March 2018, an official of the DIPP was reported to have expressed the hope that the patent application backlog would be cleared in two years.¹⁶

Trademarks

18. The 2018 Report noted that India ‘has already achieved significant progress in reducing pendency for trademark applications’ and simplification of rules. We had pointed out in our 2018 Submission that the examination time for trademarks had been brought down dramatically from 13 months to 1 month even before the March 2017 deadline.¹⁷

¹³ <http://www.livemint.com/Politics/7wIzU21P5FOGvfDa4SolMP/DIPP-looks-reduce-delays-in-clearing-intellectual-property-a.html>

¹⁴ <https://timesofindia.indiatimes.com/business/india-business/dipp-likely-to-dispose-of-2-lakh-pending-patent-applications-in-2-yrs/articleshow/63274018.cms>

¹⁵ CIPAM, IPR Initiatives (Year 2018-19)

¹⁶ <https://timesofindia.indiatimes.com/business/india-business/dipp-likely-to-dispose-of-2-lakh-pending-patent-applications-in-2-yrs/articleshow/63274018.cms>

¹⁷ IPA 2018 Submission, para 16

19. The data below for 2017-18 confirms consistent speedy examination.

Trademark Applications Processed

FY: Financial Year April - March

Details	FY 2015-16	FY 2016-17	FY 2017-18	Inc. in 2017-18 over 2016-17	Apr-Dec 2018
Applications	283060	278170	272974	-2%	247615
Examined	267861	532230	306259	-42%	248919
Registered	65045	250070	300913	20%	244133
Disposals	116167	290444	555777	91%	388980

Source: CIPAM

Note: The decrease in the applications examined is due to the reduction of pendency.

20. The data for April-December indicates that examination kept pace with trademark applications in 2018. As of June 2018, 42,304 trademark applications were pending examination and a total of 454,833 trademark applications were pending disposal.¹⁸ The pendency figure suggests that trademark registrations were taking place in one year or less, even as of June 2018.
21. Despite the progress in trademark registrations in 2017-18 and the reduction in average examination time to one month in March 2017 itself, the 2018 Report states that 'U.S. brand owners continue to report significant challenges and *excessive delays in obtaining trademarks* and efficiently utilizing opposition and cancellation proceedings, as well as quality of examination issues' (italics supplied). Though we are not able to comment on the other difficulties faced, we submit that 'excessive delays' in obtaining registration of trademarks are currently unlikely.
22. We submit that the 'long standing' grievance of U.S. Industry relating to delays in grant of patents and registration of trademarks has been addressed.

International cooperation

23. The 2018 Report noted that the 'U.S. Government and right holders welcomed the steps that India took in 2017 to better integrate its patent office into the World Intellectual Property Organization (WIPO) Centralized Access to Search and Examination (CASE) system'.
24. The 2018 Submission of PhRMA pointed out that the 'IP5 Patent Prosecution Highway program may also be of interest to India. India's inclusion in this initiative will help facilitate removing anomalies in Indian patent examination process, as well as advancing India's goals of enhancing quality and consistency in Indian-issued patents.'
25. The Japan Patent Office (JPO) and the DIPP signed a wide-ranging Memorandum of Cooperation on 29 June 2015 which included the sharing of information, technical assistance for improving India's Patent Office functioning and competence building.

¹⁸ Statement in Parliament by the Minister of Commerce and Industry, 6 August 2018, <http://164.100.47.194/Loksabha/Questions/QResult15.aspx?qref=72179&lsno=16>

Pursuant to this agreement, JPO provided training for 400 new examiners recruited by India's Patent Office in 2017 and other assistance.

26. The first review meeting between JPO and DIPP was held on 1 September 2017. The Joint Statement issued after the meeting recorded '[i]n the first week of August, 2017, a team of experts from the JPO visited the Office of the [Controller General of Patents, Designs and Trademarks] to share their experience on Patent Prosecution Highway (PPH) with Indian Patent Office. The ministries agreed on establishing a working group on PPH, consisting of experts from the Offices to explore the possibility of bilateral PPH'.¹⁹
27. The Press Release of METI (the Japanese Ministry of Economy, Trade and Industry) stated that 'the JPO encouraged India to discuss implementing the Patent Prosecution Highway (PPH) program and expanding the grounds for requesting expedited examination' at the meeting.²⁰
28. In the second quarter of 2018 JPO and India's Patent Office agreed in principle to start a bilateral PPH program on a pilot basis in certain identified fields of invention, subject to completion of necessary formalities.²¹
29. One outcome of the bilateral PPH program is expedited patent examination. To this end, India has initiated the necessary legislative change. Rule 3 of the Draft Patents (Amendment) Rules published on 5 December 2018 seeks to insert a sub-clause (f) in Rule 24C (1) of the Patents Rules, 2003 enabling expedited examination of patent applications filed under a PPH agreement. The sub-clause reads:

'(f) that the applicant is eligible under an arrangement for processing an international application pursuant to an agreement between Indian Patent Office with another participating patent office.

Explanation: The patentability of patent applications filed under clause (f) above will be in accordance with the relevant provisions of the Act.²²

The other existing sub-clauses in Rule 24C set out tight time limits for various stages of expedited patent processing.

30. We trust that the USTR will take note of this development.

Pre-grant opposition

Delays

31. The 2018 Report states that U.S. companies are concerned that 'patent applicants face costly and time-consuming patent opposition hurdles'. India's Patents Act provides for both pre-grant and post-grant opposition. Post-grant oppositions or their equivalent are available in most jurisdictions and cannot be a concern. We therefore presume that the grievance is with respect to pre-grant oppositions, particularly as PhRMA has

¹⁹ <http://www.meti.go.jp/press/2017/09/20170904003/20170904003-1.pdf>

²⁰ http://www.meti.go.jp/english/press/2017/0904_003.html

²¹ CIPAM, IPR Initiatives (Year 2018-19)

²² Draft Patents (Amendment) Rules 2018, https://dipp.gov.in/sites/default/files/draft_PatentRule_10December2018.pdf

voiced its concern in its 2018 Submission that ‘pre-grant opposition procedures under Section 25 of India’s Patents Act have created significant uncertainty and delayed the introduction of new inventions by undermining patent office efficiency and delaying patent prosecution – exacerbating India’s already significant patent examination backlog of approximately 6 years.’

32. Pre-grant opposition indeed adds to patent prosecution time, but it has the advantage of a quick and summary assessment of patentability for the patent applicant. This is far less expensive and time-consuming than defending post-grant opposition proceedings. The delay, if any, in the grant of patents on account of pre-grant oppositions is mitigated by the provision in India’s Patents Act whereby (unlike in the U.S.) an alleged infringer will be liable for damages from the date of publication of the patent application. However, as in the U.S., the right to sue for infringement arises only on grant of patent. In fairness, we must point out this may operate to the disadvantage of the patentee, in the event of undue delays in patent grant, but such instances are not common.
33. The government itself has stated that patent examination times have been as long as 5-7 years in the past. These delays were attributable more to administrative and manpower limitations than pre-grant oppositions. After these limitations were addressed, the number of patent applications examined has more than doubled in 2017-18 (see paras 15-17 above). The government has an ambitious target of reducing the examination period to 18 months, and if this has been achieved, or is likely to be achieved in the near future, the time consumed by pre-grant opposition may not be of consequence.
34. Should pre-grant oppositions continue to be characterized as a concern by U.S. industry in their 2019 Submissions, we submit that the issue warrants close scrutiny. There are several reasons why delays could occur even with efficient patent processing. Delays may be attributable to the patent applicant (eg. in requesting examination or responding to office actions or oppositions) or delays due to pre-grant opposition. Further, there are individual instances where there are long delays in grant of patents due to circumstances peculiar to each of those particular cases in patent offices everywhere. For example, U.S. patent 9925174B2 assigned to Boehringer Ingelheim International GmbH was granted on 27 March 2018, more than 12 years after it was filed on 5 May 2006. U.S. patent 9309574B1 assigned to the U.S. Department of Health and Human Services was granted on 12 April 2016, nearly 21 years after it was filed on 8 February 1995. It would be wrong to generalize from these singular cases and assert that there are inordinate delays in patent processing in the U.S.

Erroneous decisions

35. The PhRMA has also made a grievance of erroneous decisions in oppositions in their 2018 Submission: ‘Patent revocations using “hindsight” analyses made during pre- and post-grant oppositions have cited a lack of inventiveness concluding that inventions were based on “old science” or failed to demonstrate an inventive step.’ This is a *verbatim* reproduction of the charge they have made in their 2015 Submission²³

²³ PhRMA 2015 Submission, p 49

without taking note of our comment in our 2016 Submission²⁴. We had pointed out that the Delhi High Court had categorically ruled that that “[h]indsight analysis is not permissible”, relying on U.S. jurisprudence in doing so,²⁵ as far back as 2015.

36. In any event, India has initiated a further safeguard against erroneous decisions in pre-grant oppositions. The Draft Patents (Amendment) Rules, 2018 has been published on 5 December 2018,²⁶ calling for public comments. Rule 5 in the Draft Patents (Amendment) Rules, provides for pre-grant oppositions being heard by a two-member bench (as against the existing practice of it being heard by a single person). If there is a difference of opinion, it will be referred to a third member. This should provide reassurance that decision making processes on pre-grant oppositions are being strengthened.
37. We respectfully urge the USTR to consider our submissions above in determining whether pre-grant oppositions continue to remain a concern.

Excessive reporting requirements

38. The 2018 Report alludes to the ‘excessive reporting requirements’ faced by patent applicants. We presume that this reflects the concern expressed by the PhRMA in their 2018 Submission relating to Section 8 of the Indian Patents Act under the heading of ‘Administrative Burdens’:

‘Section 8(1) requires patent applicants to notify the Controller and “keep the Controller informed in writing” of the “detailed particulars” of patent applications for the “same or substantially the same invention” filed outside of India. Section 8(2) requires a patent applicant in India to furnish details to the Indian Controller about the processing of those corresponding foreign patent applications if that information is requested.’

39. The requirements of Section 8 are applicable to all patentees, including Indian patentees. As mentioned by the PhRMA, several countries have a requirement to furnish information on request, similar to Section 8(2).
40. We had allayed apprehensions that Section 8 would be construed as a strict liability clause in our 2014 Submission on the basis of jurisprudence which we had cited.²⁷ We appreciate the statement of the PhRMA in their 2018 Submission that ‘current jurisprudence limits Section 8 to information that is material to patentability and to deliberate failures to disclose this information’ citing the same judgements that we done in 2014. Notwithstanding this clear understanding of the current position, PhRMA goes on to allege that ‘the failure to disclose under Section 8 can be treated as a strict liability offense that by itself can invalidate a patent (although a recent court decision indicates some flexibility for mere clerical errors). This is in contrast to a requirement that the failure to disclose be material and/or intentional as in the U.S. or Israel.’ In

²⁴ IPA 2016 Submission, para 33

²⁵ *Merck v Glenmark*, Delhi High Court, available at <http://lobis.nic.in/dhir/dhc/AKP/judgement/07-10-2015/AKP07102015S5862013.pdf>, para 89

²⁶ Draft Patents (Amendment) Rules 2018, https://dipp.gov.in/sites/default/files/draft_PatentRule_10December2018.pdf

²⁷ IPA 2014 Submission, paras 75-76

fact, the whole paragraph in the 2018 Submission is a *verbatim* reproduction of their 2015 submission.²⁸ We trust this is an oversight.

Compulsory licensing

41. The 2018 Report alludes to the concern of U.S. companies with ‘the *potential* threat of compulsory licensing and patent revocations, as well as overly broad criteria for issuing such licenses and revocations under the India Patents Act’ (italics supplied). The same concern was also reflected in the 2017 Report.
42. The first and only issue of compulsory license (for Bayer’s Nexavar™) was in March 2012. No compulsory license has been issued in the last six years. On the contrary, applications for compulsory licenses (for AstraZeneca’s Onglyza™ and Kombiglyze™) have been rejected in 2016.²⁹ No revocation in the public interest under Section 66 of the Patents Act has ever been made. As is obvious, there is no *real* or *imminent* ‘threat’ of issue of compulsory licenses or revocation in the public interest. The concern of U.S.-based pharmaceutical companies of *potential* threats is misplaced.
43. The concern with ‘overly broad criteria’ is on account Section 84(1)(a) and (b) of the Indian Patents Act which provide for the grant of compulsory licenses when the patented product is not adequately available to meet the ‘reasonable requirements of the public’ or ‘at a reasonably affordable price’. This concern has been raised in the past and we draw your attention to our response in the 2014 Submission.³⁰ Briefly, the *existence* of a statutory provision for grant of a compulsory license in India ought not to be a concern:
 - Statutes in many countries, including at least eight of twelve West European countries, have a provision to grant compulsory licenses in ‘public interest’ which is generally acknowledged to be even broader than the provision in India.
 - In France, for example, the Health Minister has the power to grant a compulsory license if the patented product is not made available in sufficient quantity or if the prices charged are abnormally high.
44. The crux of the problem is the pricing of new drugs, particularly life-saving drugs. There is no dispute that innovator companies have made remarkable contributions to reduce human suffering and extend life-spans. They have done this with the development and application of cutting edge science, taking considerable financial risks and deserve to reap the rewards. Moreover, there is no alternative to relying on innovation by private enterprise to bring new and better therapies to the market; this requires an adequate risk-adjusted return on investments. The current dispute is essentially about what constitutes fair pricing and fair return to innovator companies; of where the balance between access to medicines and innovator profits lies. This dilemma has been extensively discussed, most recently in a Technical Report of the WHO in the context of cancer medicines.³¹

²⁸ PhRMA 2015 Submission, p 51, para 1

²⁹ *Lee Pharma v AstraZeneca*, Controller of Patents, available at http://www.ipindia.gov.in/iponew/compulsoryLicense_Application_20January2016.pdf

³⁰ IPA: 2014 Submission, paras 36-39

³¹ World Health Organization. (December 2018). Technical report: pricing of cancer medicines and its impacts: a comprehensive technical report for the World Health Assembly Resolution 70.12: operative paragraph 2.9 on

45. Several approaches to arriving at this balance are being explored, including increased government spending and the implementation of Universal Health Coverage (UHC). According to the WHO, UHC is 'based on the principle that all individuals and communities should have access to quality essential health services without suffering financial hardship'.³² In the May 2018 session of the World Health Assembly, Member States asked that the WHO devise a roadmap and action plan to increase access to medicines. The draft roadmap 2019-2023³³ was considered at the meeting of the Executive Board of the WHO between 24 January and 1 February 2019 along with a special report on cancer medicines.³⁴ The Executive Board reaffirmed the TRIPS Agreement as well as the 2001 Doha Declaration 'which recognizes that intellectual property rights should be interpreted and implemented in a manner supportive of the right of Member States to protect public health and, in particular, to promote access to medicines for all'. It recommended the adoption of a resolution on UHC at the World Health Assembly in May 2019 and urged Member States to 'engage in the development of the action-oriented consensus political declaration'.³⁵
46. The UN and WHO recognize that achieving UHC will take time because of resource limitations in many countries and other factors. The goal, therefore, is to achieve UHC by 2030. In the meanwhile, compulsory licensing remains the public health safeguard.
47. The need for compulsory licensing as a safeguard cannot be wished away. Pricing is not only the problem of India or the low- and middle-income countries but also of developed economies. For example, the Health Minister of Netherlands told the Dutch Parliament in November 2017 that he would 'extensively explore' the use of compulsory licensing to tackle the problem of what he called 'absurd' pricing. In this, the Health Minister is reported to have followed the recommendations of the Netherlands Council for Public Health and Society, an official government advisory body.³⁶ Netherlands is one of the countries in the European Union whose law permits the use of compulsory licensing in the 'public interest'. Most recently, on 30 January 2019, a request has been made to the Federal Council in Switzerland to exercise its right in the public interest for a compulsory license for public non-commercial use of pertuzumab sold by Roche under the brand name PerjetaTM through a reference to the Federal Patent Court.³⁷ According to the applicant, 'monopoly power has allowed Roche to obtain and maintain an excessive price' for PerjetaTM.
48. The statutory provision for compulsory licensing in India conforms to the TRIPS agreement and the Doha Declaration to which the U.S. is signatory. WHO, WIPO and WTO have jointly endorsed the 'freedom' of WTO members under the TRIPS agreement 'to determine the grounds upon which compulsory licenses are granted'

pricing approaches and their impacts on availability and affordability of medicines for the prevention and treatment of cancer, <http://www.who.int/iris/handle/10665/277190>.

³² <https://www.uhc2030.org/our-mission/>

³³ Medicines, vaccines and health products: Access to medicines and vaccines, WHO, December 2018, http://apps.who.int/gb/ebwha/pdf_files/EB144/B144_17-en.pdf

³⁴ Medicines, vaccines and health products: Cancer medicines, WHO, November 2018, http://apps.who.int/gb/ebwha/pdf_files/EB144/B144_18-en.pdf

³⁵ http://apps.who.int/gb/ebwha/pdf_files/EB144/B144_CONF5Rev1-en.pdf

³⁶ <https://medicineslawandpolicy.org/2017/11/medicines-excitement-in-the-netherlands-new-health-minister-announces-firm-action-on-absurd-medicines-pricing-and-gets-the-european-medicines-agency/>

³⁷ https://www.publiceye.ch/fileadmin/doc/Medikamente/PublicEye_CL-Request-Perjeta_CH_2019.pdf

and this freedom is 'not limited to emergencies or other urgent situations, as is sometimes mistakenly believed'.³⁸ In September 2018, the Health Ministers of the Member States of the WHO South-East Asia Region issued the Delhi Declaration reiterating their commitment to 'full use of TRIPS flexibilities for enhanced accessibility and affordability of new medical products, including new therapies, for priority diseases in the Region including tuberculosis, hepatitis and cancer.'³⁹

49. Given the intense deliberations in multilateral fora, global alarm over high prices of patented medicines, particularly life-saving medicines, and the consideration of the use of compulsory licensing to control prices by several countries (including in Europe), we submit that it will be well-nigh impossible for India to achieve the political consensus needed to dilute existing compulsory licensing provisions until there is a clear roadmap for implementing public health approaches to improve innovation and access.
50. In the meanwhile, there is little threat that compulsory licenses will be issued in India. India has a clear understanding of the circumstances under which compulsory licensing is to be resorted to and has a fair and transparent process to adjudicate such applications. The fact that there has been no grant of a compulsory license from 2012 and not even an application for a compulsory license after 2015 despite many launches of patented products attests to the responsible application of the statutory provision.
51. In this context, we may mention the assertion of PhRMA in their 2018 Submission that:

'Indian pharmaceutical companies continue to make requests for voluntary licenses under Section 84(6)(iv) of the Patent Act as a strategy and subsequently seek a CL by using it as a commercial tool under the guise of better access to medicines, rather than a measure of last resort.'

We respectfully submit that this assertion is misleading as, to the best of our knowledge, no application for compulsory license has been made after 2015 by Indian pharmaceutical companies.

52. PhRMA is also aggrieved by the Rules promulgated under Section 146 of the Indian Patents Act which 'require all patent holders to file an annual statement summarizing the extent to which the patented invention has been worked on a commercial scale in India'. PhRMA further states that this information is commercially sensitive, and that it provides an 'impermissible basis for local companies to seek compulsory licenses'.
53. We submit that a company seeking a compulsory license has to make an application making out a case for the grant of a compulsory license. The information furnished to the Controller by the patentee as required by Section 146 is not for the purpose alleged by PhRMA. Section 87 of the Indian Patents Act requires the Controller to be 'satisfied, upon consideration of an application under section 84, or section 85, that a *prima facie* case has been made out for the making of an order' on the application. If the Controller is not satisfied that a *prima facie* case has been made out by the applicant for a compulsory license, he can summarily refuse the application at that stage. If, on the other hand, he is satisfied that a *prima facie* case has been made out, the Controller

³⁸ 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/ pp. 174-175

³⁹ <https://apps.who.int/iris/bitstream/handle/10665/274331/Delhi-Declaration.pdf?sequence=5&isAllowed=y>

can direct the applicant to serve copies of the application on the patentee and publish the application in the official journal. The patentee or any other person who desires to oppose the application can do so and will be heard before the application is disposed of. The information furnished by the patentee therefore serves the important purpose of providing information to the Controller to make the initial assessment of whether or not a *prima facie* case has been made out by an applicant of a compulsory license.

54. We may also point out that the market in India for medicines at U.S. prices is limited at best. Innovator companies have found ways to overcome this limitation with lower pricing in India or collaborating with Indian enterprises to increase their access to the market. The net result is that many new drugs have been introduced in the Indian market in adequate quantities at affordable prices, thereby negating the possibility of compulsory licensing. We have given instances of such collaboration in our 2016 Submission.⁴⁰ We have reason to believe that the positive collaborative momentum generated in 2016 has since strengthened.
55. We respectfully urge the USTR to take a pragmatic view while determining whether India's compulsory licensing provisions warrant its continuance on the Priority Watch List.

Section 3(d)

56. The 2018 Report notes that 'Section 3(d) of the India Patents Act restricts patent eligible subject matter in a way that poses a major obstacle to innovators seeking timely entry into the Indian market.' We understand this to mean that Section 3(d) prohibits the grant of patents to certain discoveries which are considered patent eligible subject matter in the U.S.
57. In its 2018 Submission, PhRMA had stated that:
- 'In 2016, two anti-cancer products and a schizophrenia product were denied patent protection, as India claimed they showed no enhanced efficacy and thus were not patentable under Section 3(d). All three products successfully obtained U.S. patent protection.' These products have not been named, so we can only comment in general terms.
 - 'Between May and December 2017, at least 149 patent applications faced rejections under Section 3(d).' It is unclear whether these applications resulted in patents in the U.S. Again, in the absence of specifics, we can only comment in general terms.

TRIPS compliance

58. As is now well-known, Section 3(d) 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. 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. Such patents are also known as 'secondary patents'. However, even such

⁴⁰ IPA 2016 Submission, paras 5-11

discoveries are granted patents in India when they enhance efficacy. They are also eligible for patents for the process of their preparation and formulation.

59. We have made extensive submissions in the past that secondary patents seek to 'evergreen' patents by extending their term and delay the entry of affordable generics. Such evergreening has been the cause of considerable concern globally, including in the U.S. and there has been extensive discussion on ways and means to contain the consequent injury to public health. The Commission on Public Health, Innovation and Intellectual Property Rights,⁴¹ 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.'⁴²

60. The Commission also endorsed India's adoption of Section 3(d):

'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).'⁴³

61. Building upon the Commission's Report, a joint publication⁴⁴ 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'.⁴⁵ 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'.⁴⁶

'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.'⁴⁷

⁴¹World 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/CIPRH23032006.pdf>

⁴²*Ibid*, p149-150

⁴³*Ibid*, p151-152

⁴⁴ 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/

⁴⁵http://www.who.int/mediacentre/news/releases/2013/book_summary.pdf

⁴⁶ *Ibid*, p13

⁴⁷*Ibid*, p131

'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.'⁴⁸ (Internal citations omitted)

62. Academics, including in the United States,⁴⁹ have also published extensively, arguing that Section 3(d), as well as other provisions in India's patent law are TRIPS-compliant.
63. The Government of India believes that India's patent law is TRIPS-compliant and represents a balance between the incentive to innovate and public health. Section 3(d) only prohibits the grant of patents for new forms of known substances that do not enhance efficacy. In other words, India deems it fair and equitable to reward innovation with the grant of a patent for a new and useful discovery, conferring a commercially valuable monopoly to a patentee for twenty years. India also seeks to safeguard public health by prohibiting the grant of secondary patents (and extension of monopoly) for a known substance without evidence of therapeutic benefit. This allows the entry of affordable generics after the expiry of the primary patent and serves the cause of public health by increasing access in a country like India where most people will find the cost of patented drugs prohibitive.
64. On the other hand, PhRMA has contended in their 2018 Submission that 'the Indian law is in conflict with the non-discrimination principles provided by TRIPS Article 27 and WTO rules' notwithstanding the contrary stand of the WTO itself implicit in their joint publication with the WHO and WIPO referred to above.
65. We urge the USTR to take cognizance of the divergence of viewpoint between a section of the U.S. pharmaceutical industry and the views of multilateral organizations (of which the U.S. is a member), academics, and many other entities and individuals who have made representations before the USTR in the past and believe that India's section 3(d) is TRIPS-compliant. Consequentially, we respectfully submit that the consideration of whether India's Section 3(d) is TRIPS-compliant or not ought to be held in abeyance till the question is settled in the appropriate forum.

Alternative to Hatch Waxman provisions

66. Quite apart from the question of TRIPS compliance, we have pointed out in the past that the *outcomes* from the application of Section 3(d) is not that different from those of the Hatch Waxman provisions. We have illustrated this in detail with respect to Novartis' GleevecTM in our 2016 Submission.⁵⁰ The primary patent of GleevecTM was set to expire in the U.S. in July 2015, after reckoning the extensions it received. Novartis however filed and obtained a number of secondary patents for polymorphic forms of the active compound (the subject of the rejection under Section 3(d) of India's Patents Act) that increased patent protection by four years and a further three years for three new indications (out of a total of ten indications that the drug is approved for). It was however of no avail as the secondary patents for polymorphic forms were challenged and Novartis opted to settle out of court, obtaining only a seven-month reprieve from generic competition after expiry of the primary patent.

⁴⁸*Ibid*, p131

⁴⁹See 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

⁵⁰ IPA 2016 Submission, paras 40-44

67. As also noted in our 2016 Submission, the illustration above can be generalized. Amy Kapczynski and her colleagues studied the patents of 432 new molecular entities (with at least one patent) approved by the U.S. Food and Drug Administration between 1985 and 2005.⁵¹ Independent ‘PIPES’ patents (i.e. secondary patents for polymorphs, isomers, prodrugs, esters and salts, without any compound claims, similar to the patents prohibited by Section 3(d) in India) increased from 13% to 23%,⁵² adding 6.3 years, on the average, to the patent monopoly for each product.⁵³ Though secondary patents added significantly to nominal patent life, the actual additional life was limited as they were prone to invalidation or designing-around.⁵⁴

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

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

‘The average nominal patent term is 16 years for drugs with first generic entry between 2001 and 2010. By comparison, average effective market life for these drugs is 12 years, not much different than in the previous decade, and greater than in the decade before Hatch–Waxman. Patent challenges are the key driver of the gap between nominal patent term and effective market life.’⁵⁵ (Internal citation omitted)

69. India does not have the equivalent of Hatch Waxman provisions, nor is it feasible to do so as there is no system of mandatory substitution of generics. India therefore needs to have an alternative appropriate to its legal framework and market. India’s alternative is Section 3(d). As Kapczynski *et al* noted:

‘Furthermore, litigation as a means to invalidate weak secondary patents is a far less plausible policy outcome in countries without robust incentives for generics to undertake the expense of challenging these patents. Insofar as the policy response to the rise of secondary patents relies on litigation and rigorous patent examinations as a means to ensure that only truly inventive secondary patents issue, resource-limited settings are likely to be at a substantial disadvantage. This may help to

⁵¹Kapczynski A, Park C, Sampat B (2012) Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of “Secondary” Pharmaceutical Patents. *PLoS ONE*, December 2012, Volume 7, Issue 12, p 8, available at <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0049470>

⁵²*Ibid.* p 4, Col 2

⁵³*Ibid.* Table 3, p7

⁵⁴*Ibid.* p7, Col 2-p 8, Col 1

⁵⁵Hemphill S, Sampat BN. Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals. *Journal of Health Economics*, 2012, 31(2): 327–339 p 336, Col 2

explain why countries like India have sought to adopt clear statutory bars on certain types of secondary patent claims....⁵⁶ (Internal citations omitted)

70. We urge the USTR to consider Section 3(d) as a reasonable alternative to the Hatch Waxman provisions.

Data exclusivity

71. The 2017 and 2018 Reports note that ‘India continues to lack an effective system for protecting against the unfair commercial use, as well as the unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for such products’. This is commonly referred to as data exclusivity.
72. We have in the past elaborated India’s stand that the prohibition on unfair commercial use mandated by the TRIPS Agreement does not extend to a regulator in India relying in part on the approval of a new drug by a foreign regulatory agency such as the U.S. FDA or the European Medicines Agency for regulatory approval of a generic version.
73. In our 2017 Submission, we dwelt pragmatically on whether the lack of data exclusivity makes a material difference to U.S.-based pharmaceutical companies and suggested that it would be reasonable to require a realistic, data-driven estimate of the extent of actual and potential injury occasioned by the lack of data exclusivity, before concluding that U.S. companies are denied adequate and effective intellectual property protection in India.⁵⁷
74. We urge consideration of our submission.

Patent enforcement and regulatory approval

75. The 2018 Report notes ‘India still lacks an effective system for notifying interested parties of marketing approvals for follow-on pharmaceuticals in a manner that would allow for the early resolution of potential patent disputes.’
76. This observation possibly stems from PhRMA’s grievance that ‘Indian law permits state drug regulatory authorities to grant manufacturing approval for a generic version of a medicine four years after the original product was first approved’ and that ‘[s]tate regulatory authorities are not required to verify or consider the remaining term of the patent protection on the original product’. This, the PhRMA states, forces the patent holder ‘to seek redress in India’s court system, which often results in irreparable harm to the patent holder’.
77. PhRMA therefore requires India to ‘ensure innovators have timely notice of marketing approval applications and are able to seek injunctive relief before potentially infringing products enter the market.’
78. India does not have an equivalent of the Orange Book and the Hatch Waxman provisions whereby an applicant seeking marketing approval for a generic drug is statutorily required to give notice to the innovator and the drug can be approved only after 30 months, should the innovator sue for infringement within the stipulated time.

⁵⁶ Kapczynski et al, *op. cit.*, p 8

⁵⁷ IPA: 2017 Submission, paras 35-39

79. We submit that most countries, including Japan and countries in the European Union, do not have a provision for ‘patent linkage’. There are several good reasons for not following the U.S. model. If a patent is eventually found invalid or non-infringed, the delays occasioned by holding up marketing authorization of generics during the term of the patent would cause grave injury to consumers and there is no way to compensate them. For example, the primary patent covering Bristol-Myers Squibb’s Baraclude™, U.S. patent 5,206,244, was granted in April 1993. The patent was successfully challenged by Teva. Bristol-Myers Squibb appealed and in June 2014 and the Federal Court of Appeals upheld its invalidation.⁵⁸ Baraclude™ was approved for marketing in the U.S. in March 2005.⁵⁹ Teva launched the generic on 4 September 2014.⁶⁰ Consumers in the U.S. who had been harmed by the delay in the introduction of affordable generics occasioned by wrongful grant of the patent had no remedy.
80. The key issue, therefore, is to focus on whether ‘irreparable harm’ is being caused to the patent holder without a formal system of notification as apprehended by PhRMA. The lack of a formal system is of little consequence as pharmaceutical manufacturers in India are aware of potential launches of generic drugs through routine commercial intelligence. The system in India is that patent holders sue a generic manufacturer intending to market an allegedly infringing drug. The suit for infringement is usually accompanied by an application for injunctive relief, restraining the generic manufacturer from producing or marketing the drug. The court weighs the *prima facie* case of the patent holder against the challenge to the validity of the patent or the *prima facie* defense of non-infringement by the allegedly infringing generic manufacturer in arriving at its decision to grant or refuse and injunction.
81. Judicial scrutiny thus provides a safeguard against affordable generics being delayed and consumers suffering irreparable harm because of a wrongly granted patent. On the other hand, even if the injunction is not granted, the harm to patent holders is mitigated by damages in the event of their eventually succeeding in the suit for infringement.
82. Our 2014 Special 301 Out-of-Cycle Submission listed the instances where injunctions had been granted before the commercial launch of competing generics in 2013-14. These were briefly alluded to in our 2016 Submission and the continued issuance of such injunctions in 2015 were listed.⁶¹ We are not aware of any denial of such injunctions in 2016, 2017 and 2018.
83. As patent holders have obtained injunctions before the launch of an allegedly infringing generic in appropriate cases, there is no question of ‘irreparable harm’.
84. We submit that the history of grant of injunctions to a patent holder before the launch of an allegedly infringing generic in the last four years ought allay any fears that may linger of ‘irreparable harm’ to the patent holder.

⁵⁸ <http://ir.tevapharm.com/phoenix.zhtml?c=73925&p=irol-newsArticle&ID=1939558>

⁵⁹ http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=021797&TABLE1=OB_Rx

⁶⁰ <http://ir.tevapharm.com/phoenix.zhtml?c=73925&p=irol-newsArticle&ID=1963787>

⁶¹ IPA: 2016 Submission, paras 29-30

Concluding comments

85. We respectfully submit that there is a case for reviewing the continuance of India on the Priority Watch List. In summary –

Progress made

- IPR Environment: India acceded to the WIPO internet treaties. The Indian Patent Office continued its efforts in 2018 to improve operational efficiencies. The judicial system delivered speedy decisions even when dealing with new IPR laws without precedent in domestic jurisprudence. India demonstrated resolve to address enforcement issues relating to camcording of cinematographic films and infringing websites. There is a visible, substantial, and continuing commitment to spread awareness of the value of IPR. (paras 5-12)
- Speeding up patent examination: India has significantly increased the pace of patent examination. Patent applications examined more than doubled in 2017-18 over the previous year and for the first time, the number of patents disposed of (grants, refusals, withdrawals, abandonments) kept pace with the number of applications. The pendency at the examination stage was reduced from 204,177 as on 31 March 2017 to 127, 881 as on 31 December 2018. Patent examination times have been substantially reduced. The effort is on to eliminate patent application backlog at the examination stage in two years. (paras 13-17)
- Speeding up trademark examination: The goal of examining trademark applications in one month was achieved in 2017. As of June 2018, 42,304 trademark applications were pending examination and a total of 454,833 trademark applications were pending disposal. The pendency figure suggests that trademark registrations were taking place in a year or less, as of June 2018. (paras 18-22)
- International cooperation: JPO and India's Patent Office agreed in principle in the second quarter of 2018 to start a bilateral PPH program on a pilot basis in certain identified fields of invention. The process of legislative change needed to realise the potential benefit of expedited examination of PPH patent applications has been initiated in December 2018 with the publication of the draft Patents (Amendment) Rules. (paras 28-30)

Concerns allayed

- Pre-grant opposition: Pre-grant opposition indeed adds to the time for examination, but it has the advantage of a quick and summary assessment of patentability for the patent applicant. With the reduction in examination time for patent applications, the time consumed by pre-grant opposition is unlikely to be of much consequence. India has published the Draft Patents (Amendment) Rules, 2018 on 5 December 2018 to provide for pre-grant oppositions being heard by a two-member bench (as against the existing practice of it being heard by a single person). If there is a difference of opinion, it will be referred to a third member. This will significantly strengthen adjudication of pre-grant oppositions and reduce concerns of erroneous decisions. (paras 32-37)

- Excessive reporting requirements: The concern that Section 8 (which requires information on the working of patents to be submitted) will be construed as a strict liability clause is misplaced. Indian courts have ruled that intention and materiality are essential if patents had to be revoked for failure to adhere to Section 8 requirements. We had allayed this apprehension five years ago in our 2014 Submission. (para 40)

Pragmatic consideration is warranted

- Compulsory licensing: No compulsory license has been granted after 2012 and not even an application for a compulsory license was made after 2015 despite many launches of patented products. No patent has ever been revoked under Section 66. There is no discernable threat that compulsory licenses will be issued in India. Given the intense deliberations in multilateral fora, global alarm over high prices of patented medicines, particularly life-saving medicines, and the consideration of the use of compulsory licensing to control prices by several countries (including in Europe), it will be well-nigh impossible for India to achieve the political consensus needed to dilute existing compulsory licensing provisions until there is a clear roadmap for implementing public health approaches to improve innovation and access. (paras 41-55)
- Section 3(d): Section 3(d) of the Indian Patents Act effectively prohibits only *secondary* patents aimed at increasing the patent monopoly for a drug – the so-called ‘evergreening’ of patents. We have shown on the basis of empirical data that the benefits of extended monopoly from secondary patents are often limited by successful patent challenge in the U.S. Section 3(d) is an effective way in the Indian context to achieve outcomes similar to that of the Hatch Waxman provisions in the U.S. (paras 56-70)
- Data exclusivity: We have explained India’s stand that granting approval for new generic drugs, based in part upon their approval in other jurisdictions, is TRIPS-compliant. We have also dwelt pragmatically on whether the lack of data exclusivity makes a material difference to U.S.-based pharmaceutical companies and suggested that it would be reasonable to require a realistic, data-driven estimate of the extent of actual and potential injury occasioned by the lack of data exclusivity, before concluding that U.S. companies are denied adequate and effective intellectual property protection in India. (paras 71-73)
- Patent enforcement and regulatory approval: The key issue is to focus on whether ‘irreparable harm’ is being caused to the patent holder without a formal system of notification enabling them to seek injunctive relief. The history of grant of injunctions to a patent holder *before* the launch of an allegedly infringing generic in the last four years in India ought to allay any fears that may linger of ‘irreparable harm’ to the patent holder. (paras 78-84)

86. The apprehensions and concerns of the U.S. pharmaceutical industry have figured prominently in the Special 301 Reports of past years and have likely been a major reason for the placement of India on the Priority Watch List. It is now clear that substantial and consistent progress has been made by India and overall, Indian patent law and its application does not deny adequate and effective protection of IPR; nor

does it deny fair and equitable market access to the U.S. pharmaceutical industry which relies on intellectual property protection.

87. We urge the USTR to consider the removal of India from the Priority Watch List. It would be encouraging recognition of the strides that India has made in promoting, protecting and enforcing IPR and sustain its forward momentum.
88. We thank you for the opportunity to make this submission.