



USTR: 2018 SPECIAL 301 SUBMISSION

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Submission by

INDIAN PHARMACEUTICAL ALLIANCE

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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 2018 Special 301 Review.
2. IPA's membership consists of twenty pharmaceutical companies which collectively account for about 85 percent of private sector investment on pharmaceutical research and development in India, 60 percent of the country's exports of pharmaceuticals and related services and 46 percent of the domestic market. We therefore have a vital interest in the protection of our innovations, not only for developing cost-effective and useful improvements in existing medicines, but also for discoveries of new medicines.
3. India is one among eleven countries that has been placed on the Priority Watch List in the 2017 Special 301 Report (2017 Report). This submission is limited to patent issues relevant to the pharmaceutical industry, particularly those which have been noted in the 2017 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. Public awareness of the value of IPR and respect for them are essential to creating a healthy climate for innovation and a supportive environment for enforcement. The 2017 Report noted that the 'United States was encouraged by the creation of the Cell for IPR Promotion and Management (CIPAM) under DIPP [Department of Industrial Policy and Promotion] to move forward implementation of the policy and hopes that CIPAM can harness enthusiasm for more robust IP protection into meaningful policy reforms.' CIPAM is now fully operational (<http://cipam.gov.in/>) and has undertaken a far-reaching program of creating awareness of IPR in schools and universities. Other programs of CIPAM address the needs of Industry, Police and the Judiciary to promote effective enforcement.¹
5. CIPAM has tied up with Agastya International Foundation to conduct awareness programs in schools. The training of the first batch of Trainers, who in turn will conduct programs in schools, has been completed. The National Council of Educational Research and Training has included IPR in the curriculum of Class XII in schools. This initiative 'catches them young' and demonstrates the government's commitment to fostering awareness and a culture of respecting IPR in the country.
6. A campaign is also underway to build similar awareness in universities and colleges. For example programs have been conducted at King George's Medical University, Lucknow, Amity University and Sharda University.

¹ See CIPAM: *Intellectual Property Rights Regime In India- Initiatives by the Government*, 24 January 2018 accessible at <https://spicyip.com/wp-content/uploads/2018/01/IPR-Regime-In-India-Government-Initiatives.pdf>

7. The 2017 Report took note of India's efforts at improving enforcement with the development of an 'IPR Enforcement Toolkit for Police' aimed at improving policing of IP crimes, particularly trademark counterfeiting and copyright piracy. A similar toolkit is now being developed for customs authorities.
8. An advisory has been issued by the Ministry of Home Affairs to all State Police Academies to incorporate IPR in their training curriculum for in-service police officers and fresh recruits. Twenty-six programs for training of police officials in IP Enforcement have already been organized in the states of Andhra Pradesh, Uttar Pradesh, West Bengal, Madhya Pradesh, Telangana, Haryana and Jharkhand as also two programs in the North-East Police Academy (which included participants from 9 states) and three programs at Sardar Vallabhbhai National Police Academy, Hyderabad. Such extensive training programs (which will continue in the future) are unprecedented.
9. In addition, CIPAM and the DIPP organized a three-day 'National Workshop on Enforcement of Intellectual Property Rights' in August 2017. For the first time, state police officials, public prosecutors, industry and academia were brought together on a single platform to strengthen enforcement.
10. Efforts aimed at sensitizing all levels of the judiciary with appropriate programs have been intensified. Two colloquia on commercial laws for High Court Judges were held at National Judicial Academy (NJA) of Bhopal. DIPP officials sensitized participating judges on government policies relating to IPR. In November 2017, DIPP in collaboration with WIPO and NJA organized a three-day conference on IPR for High Court Justices. Training programs in collaboration with NJA are now being planned at various State Judicial Academies.
11. Programs inculcating awareness of IPR and its value in schools and colleges will have an impact in the long-term by promoting a culture of respect for IPR. This is crucial for public acceptance of policy changes as well as enforcement. Training programs for the judiciary and the police will have an impact in the shorter-term by enhancing enforcement capabilities.

Speeding up patent issue and reducing backlog

12. The 2017 Report took note of several positives, particularly 'the initiative taken by the Indian Patent Office (IPO) to hire new examiners' and 'important administrative work to reduce the time for processing patent and trademark applications'. These initiatives have yielded tangible results.
13. The recruitment and training of 459 new Patent Examiners has been completed, quadrupling the strength of Examiners in the Patent Office. Supervisory control has also been strengthened and 27 positions of Deputy Controllers and 49 positions of Assistant Controllers in the Patent Office have been filled through promotion'.²

² CIPAM, *Ibid*, p. 8

14. The recruitment was part of an ambitious plan announced in April 2016 to reduce the examination period from 5-7 years to 18 months by March 2018.³ The plan included process reengineering, introduction of digital technologies and other measures. There were more than 237,000 patent applications pending as of November 2016. Current figures are not publicly available, but there are encouraging indications that the backlog will be reduced in the near term.
15. For example, a novel process for preparation of a pharmaceutical product was granted a patent on 12 July 2017 (Patent No. IN2885091) within four months of the request for expedited examination. The full examination procedure was followed. Excluding the time taken by the applicant to submit responses, the Patent Office took only 19 days in all to examine the application and grant the patent.⁴
16. Though the number of patent filings increased by 6% in 2016-17, CIPAM asserts that ‘for the 1st time in the past few years, the actual number of patent applications examined exceeded the number filed in any one month.’ It is noteworthy that the examination time for trademarks has already been brought down dramatically from 13 months to 1 month even before the March 2017 deadline.⁵
17. The Economic Survey 2017-18 tabled in Parliament on 29 January 2018 (Economic Survey) recognizes that patents are an incentive for innovation and underscores the importance of clearing the backlog as ‘the inordinate delays in processing patents penalizes innovation and innovators within the country’.⁶
18. Given the attention that is paid to clearing the backlog at the highest levels of government, we are optimistic that the government will meet its goal of bringing down the examination time from the current 5-7 years to 18 months and reduce the backlog as expeditiously as possible.

Enforcement

19. The 2017 Report voices concern over ‘enforcement action and policies that are insufficient’ and the lack of ‘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’. The main apprehension of the U.S.-based pharmaceutical industry was the potential difficulty in obtaining injunctions *before* the launch of an allegedly infringing generic as provided for by the Hatch-Waxman provisions in the U.S.

³ <http://www.livemint.com/Politics/7wlzU21P5FOGvfDa4SolMP/DIPP-looks-reduce-delays-in-clearing-intellectual-property-a.html>

⁴ <https://patentsrewind.wordpress.com/2017/07/27/expedited-examination-patent-in-9-months/>

⁵ *Ibid*, p. 5

⁶ Economic Survey 2017-18, Government of India, Vol 1, paras 8.20 -8.22 accessible at <http://www.thehindu.com/business/budget/article22550002.ece/BINARY/Chapter8>

20. We had pointed out in our 2017 Special 301 Submission (2017 Submission) that the lack of notification does not materially disadvantage patent holders.⁷ 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 continuation of such injunctions in 2015 was listed.⁸ We are not aware of any denial of such injunctions in 2016 and 2017. This history of grant of injunctions before the launch of an allegedly infringing generic in the last four years should allay any fears that may linger on this count.

Litigation delays

21. The 2017 Report acknowledged the passage of legislation in 2015 to set up Commercial Courts and their potential to reduce delays in litigation. However it noted that ‘to date, India has established only two courts’. We do not have comprehensive information of the current status but apart from the two Commercial Divisions of High Courts (i.e. in jurisdictions where High Courts try suits) set up in Delhi and Mumbai, two more have been set up in Himachal Pradesh⁹ and Chennai¹⁰ in 2017. The government is planning to set up more Commercial Courts in these jurisdictions at the district level.¹¹ Commercial Appellate Divisions have also been set up in a number of High Courts to hear appeals from trial court decisions. In jurisdictions where High Courts do not try suits, multiple Commercial Courts have been set up in a number of States including Andhra Pradesh,¹² Telangana,¹³ Gujarat,¹⁴ Odisha,¹⁵ Madhya Pradesh,¹⁶ Rajasthan,¹⁷ Uttar Pradesh,¹⁸ Chhattisgarh¹⁹ and Bihar²⁰ in 2016 and 2017.

22. The government is fully seized of the problem of pendency and delays in adjudicating commercial disputes. In an unprecedented step, a full chapter on the problem finds place in the Economic Survey titled ‘“Ease of Doing Business” Next Frontier: Timely Justice’.²¹ It declares in no uncertain terms that the ‘next frontier on the ease of doing business is addressing pendency, delays and backlogs in the appellate and judicial arenas. These are hampering dispute resolution and contract enforcement, discouraging investment, stalling projects, hampering tax collections but also stressing tax payers, and escalating legal costs’. The Economic Survey says that the ‘importance of an effective, efficient and

⁷ IPA: 2017 Submission, paras 42-44

⁸ IPA: 2016 Submission, paras 29-30

⁹ <http://hphighcourt.nic.in/pdf/commercialdivision02062017.pdf>

¹⁰ http://www.stationeryprinting.tn.gov.in/extraordinary/2017/381_Ex_VI_1.pdf

¹¹ <http://www.thehindu.com/news/national/centre-plans-to-set-up-more-commercial-courts/article19988214.ece>

¹² <https://www.apindustries.gov.in/APIndus/Data/OtherGOs/G.O.Ms.%20No.%2074%20for%20Constitution%20of%20Commercial%20Courts.PDF>

¹³ <http://law.telangana.gov.in/commCourts1.do>

¹⁴ <http://indianexpress.com/article/cities/ahmedabad/three-commercial-courts-start-functioning-in-gujarat-2829640/>

¹⁵ <http://www.uniindia.com/odisha-to-establish-three-commercial-courts/other/news/1029475.html>

¹⁶ <https://timesofindia.indiatimes.com/city/bhopal/Seven-commercial-courts-functional-across-state/articleshow/53071221.cms>

¹⁷ <http://commercialcourtraj.nic.in/>

¹⁸ <http://indianexpress.com/article/india/commercial-courts-to-be-set-up-in-uttar-pradesh-4917048/>

¹⁹ <http://businessworld.in/article/Chhattisgarh-Becomes-First-State-To-Have-Commercial-Dispute-Resolution-Centre-And-Commercial-Court/04-07-2016-99973/>

²⁰ <http://law.bih.nic.in/ORDER/COURT%20CREATION-17-1150.pdf>

²¹ <http://www.thehindu.com/business/budget/article22550003.ece/BINARY/Chapter9>

expeditious contract enforcement regime to economic growth and development cannot be overstated. A clear and certain legislative and executive regime backed by an efficient judiciary that fairly and punctually protects property rights, preserves sanctity of contracts, and enforces the rights and liabilities of parties is a prerequisite for business and commerce.’

23. The Economic Survey does not restrict itself to a statement of intent. It presents an analysis of the pendency and concludes with rare candor that ‘[p]endency, delays and injunctions are overburdening courts and severely impacting the progress of cases, especially economic cases, through the different tiers of the appellate and judicial arenas.’ Specific attention has been drawn to 1,555 IPR cases (including patents, copyrights and trademarks) pending in the Delhi High Court which is the preferred venue for such litigation in the country. Though the negotiation and implementation of suitable mechanisms to reduce pendency and litigation delays will necessarily take time, it is clear that government is focused on initiating major changes to remedy the unhappy delays in litigation.

Compulsory licensing

24. The 2017 Report has noted that ‘[i]nnovative companies remain concerned about the *potential* threat posed to their IP through the *possible* use of compulsory licensing and patent revocation, as well as overly broad criteria for issuing such licenses and revocations under the India Patents Act’ (italics supplied).
25. The first and only issue of compulsory license (for Bayer’s NexavarTM) was in March 2012. No compulsory license has been issued in the last five years. On the contrary, applications for compulsory licenses (for AstraZeneca’s OnglyzaTM and KombiglyzeTM) have been rejected in 2016.²² 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* and *possible* threats is misplaced.
26. 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.²³ 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.

²² Lee Pharma v AstraZeneca, Controller of Patents, available at http://www.ipindia.gov.in/iponew/compulsoryLicense_Application_20January2016.pdf

²³ IPA: 2014 Submission, paras 36-39

- 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.
 - 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’ and this freedom is ‘not limited to emergencies or other urgent situations, as is sometimes mistakenly believed’.²⁴
27. If it is not the *existence* but the apprehended *use* of the provision that is a matter of concern, it ought to be evaluated on the basis of its application. The application for compulsory license for Bayer’s NexavarTM and those for AstraZeneca’s OnglyzaTM and KombiglyzeTM were all considered in a transparent process. The former was granted (and subjected to multiple rounds of judicial review) while the latter were rejected with reasoned opinions. In actual fact, there is no threat whatsoever of the grant of a compulsory license for a patented product made adequately available to meet reasonable requirements at a reasonably affordable price. The fact that there has not even been an application for a compulsory license after 2015, despite many launches of products where patents are held by U.S.-based companies, attests to the clear understanding of the statutory provision and its application in India.
28. The statutory provision for compulsory licensing in India conforms to the TRIPS agreement and the Doha Declaration to which the U.S. is signatory. We respectfully urge the USTR to balance the apprehension of U.S.-based pharmaceutical companies of potential or possible adverse impact of compulsory licensing in India against the demonstrably legitimate and fair use of the provision while determining whether India’s compulsory licensing provision results in the denial of adequate and effective protection of IPR to the U.S. pharmaceutical industry.

Other concerns

29. The 2017 Report draws attention to other long-standing concerns of U.S. pharmaceutical industry related to IPR. We have sought to address them in our previous submissions. We draw your attention to our most recent submission in 2017:
- Section 3(d): We have argued that Section 3(d) of the Indian Patents Act effectively prohibits only *secondary* patents aimed at increasing the patent monopoly for a novel 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. and that Section 3(d) is an effective way to achieve similar outcomes in the Indian context.²⁵

²⁴ 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

²⁵ IPA: 2017 Submission, paras 17-30

- Patent opposition procedures: The 2017 Report notes that patent opposition procedures are ‘time consuming’. We have pointed out in our 2017 Submission that unlike in the U.S. where damages for infringement run from the date of grant of the patent, the damages in India run from the date of publication of the application. Patentees are therefore at no material disadvantage on account of delays in patent grant. We have also allayed apprehensions of possible abuse of the process by multiple oppositions (pre- and post-grant) being filed by the same person.²⁶
- Data exclusivity: The 2017 Report notes 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. 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. 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.²⁷ We urge consideration of our submission.
- Excessive reporting requirement: This presumably refers to a grievance that has repeatedly been aired in the past relating to the requirement of furnishing information under Section 8 and in Form 27 of the Indian Patents Act and Rules. We have explained the circumstances of these requirements and that they are equally applicable to all patentees, Indian or foreign.²⁸

Concluding comments

30. In our 2016 Submission we had given instances of the multiple ways in which individual U.S.-based pharmaceutical companies had collaborated with Indian enterprises to increase their access to the Indian market and to the markets of the developing world. We have reason to believe that the positive momentum has strengthened since. Foreign Direct Investment (FDI) into India has also increased over previous years in the pharmaceutical sector in 2017 which is indicative of the satisfaction of foreign investors with the patent system. In the six-month period April-September 2017 alone (the latest period of for which data is available), global FDI into India in the pharmaceutical sector was USD 863 million, exceeding the total FDI for the financial year (April-March) 2016-17 (USD 857 million) and 2015-2016 (USD 754 million)²⁹.

²⁶ IPA: 2017 Submission, paras 31-34

²⁷ IPA: 2017 Submission, paras 35-39

²⁸ IPA: 2017 Submission, paras 45-49

²⁹ http://dipp.nic.in/sites/default/files/FDI_FactSheet_Updated_September2017.pdf

31. We therefore respectfully submit that there is a case for reviewing the continuance of India on the Priority Watch List. In summary:
- The administrative improvements in patent issue and enforcement demonstrated in 2015 and 2016 have been sustained and accelerated in 2017. Adequate examiners are now in place and the pace of examination of patents has noticeably improved. Trademark examination time has been drastically reduced to one month.
 - We are not aware of abusive patent opposition proceedings or material disadvantage to U.S. companies because of patent oppositions.
 - We are not aware of denial of timely injunctions in 2016 and 2017 before the launch of a follow-on generic when a patent for the product is in force and the patented product is in the market.
 - There been no grant of compulsory license in the last five years nor any revocation of patents under Section 66.
 - We have shown that Section 3(d) of the Patents Act only limits secondary patents that do not enhance efficacy and typically result in ‘evergreening’. We have also shown that Section 3(d) and Hatch-Waxman provisions are not dissimilar in terms of outcomes. Therefore, Section 3(d) ought not to be of concern.
 - We continue to be unclear about the extent of adverse impact of the lack of data exclusivity for U.S. companies. Though general assertions have been made, no specifics have been provided in past submissions by U.S. companies. We do not expect that the impact, if any, will be significant as products without patent protection that outlasts data exclusivity are unlikely to be launched in India for commercial reasons. We submit that in the absence of such data, no cognizance should be taken of apprehensions and speculation about possible or potential adverse impacts.
 - The administrative burden cast on U.S. companies by reporting requirements prescribed under the Patents Act is not significant enough to warrant notice by the USTR.
32. 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 the 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 laws relating to patents and their application do not deny adequate and effective protection of IPR; nor do they deny fair and equitable market access to the U.S. pharmaceutical industry which relies on intellectual property protection.
33. 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.
34. We thank you for the opportunity to make this submission.