INNOVATION. QUALITY. GLOBAL REACH.

USTR: 2021 Special 301 Submission
(Docket No. USTR-2020-0041)

Submission by

INDIAN PHARMACEUTICAL ALLIANCE

Mumbai
28 January 2021

I. Introduction

1. This submission is on behalf of the Indian Pharmaceutical Alliance (IPA). IPA's membership consists of twenty-four large pharmaceutical companies. We collectively account for more than 80 percent of India's exports of pharmaceuticals and related services, over 57 percent of the domestic market, and about 85 percent of the private sector investment in pharmaceutical research and development in the country. IPA, therefore, has a vital interest in the protection of innovations, not only for developing cost-effective and useful improvements in existing medicines, but also for discoveries of new medicines.

2. The IPA companies are committed to providing safe and effective drugs to all consumers in the U.S. and across the globe. Our member companies manufacture drugs both in the United States and in India. During the COVID 19 pandemic in 2020, Indian pharmaceutical companies have shown commitment to uninterrupted supply of quality medicines. Generics have been playing a critical role in the U.S. healthcare. In 2019, generics accounted for 90 per cent of prescriptions filled in the U.S. yet only 20 per cent of prescription drug spending. In the last decade, generics contributed significant US$ 2.2 Tn to America's patients.

3. The trade in pharmaceuticals between India and the U.S. has attained greater importance over the years, with the Indian pharmaceutical industry contributing nearly 40 per cent of generic drugs to the U.S. Indian companies have played a significant role in developing the generic drugs that have led to wider access to affordable medicines for the American consumers and the U.S. healthcare system saving approximately USD 2.2 trillion over the last decade (USD 313 billion in 2019).[1]

4. The leading Indian pharmaceutical companies have set up manufacturing facilities with investments of over USD 4.5 billion in the last four years in approximately twenty states across the U.S. IPA member companies employ more than 5500 employees in the U.S. in 2019-20, besides investing within India to cater to the needs of needy patients in the U.S. In the year 2019, Indian pharmaceutical companies have secured around 336 ANDA approvals out of total 837 approvals i.e., 40 percent of total approved applications at the USFDA to bring new generic drugs to the U.S. market.

5. This submission addresses the patent issues, particularly relevant to the pharmaceutical industry, which have been noted in the 2020 Special 301 Report prepared by the USTR (2020 Report). India is one of the 10 countries placed on the Priority Watch List in the 2020 Report. This submission summarizes a range of key developments undertaken by the Government of India, the Indian judicial system, and other stakeholders to strengthen and modernize India's intellectual property (IP) ecosystem.

   It seeks to submit information and perspectives that articulate that India provides adequate and effective protection of Intellectual Property Rights (IPR) as also fair and equitable market access to the U.S. pharmaceutical industry. Hence, IPA submits that India should no longer be placed on the Priority Watch List of the Special 301 review process.

[1] 2020 Generic Drug & Biosimilars Access & Savings in the U.S. Report

II. The IPR environment

6. India has a well-established legislative, administrative, and judicial framework for safeguarding IP Rights. Importantly, India has been consistent in its efforts and has made significant progress in the last few years towards attaining an effective IPR ecosystem.

7. India's IPR system is ever-growing. The Department for Promotion of Industry and Internal Trade (DPIIT), Government of India, has continued to take action through the Indian Patents Office (IPO) to enhance the operational efficiency and disseminate awareness about the value of IPR. This has been done through organizing IPR awareness programs across the country, focused training programs for enforcement agencies (police and customs) and sensitization of the judiciary about intellectual property rights. Our 2020 submission made a point of all the steps taken toward IP protection, enforcement, and awareness building[2]. Adding to those measures, some other developments are briefly discussed below.

a. Global Innovation Index

8. As revealed by the Global Innovation Index 2020, India has entered the league of top 50 economies by improving by four positions and achieving the 48th rank from a total of 131 economies of the world. This indicates India's consistency in the research and development ecosystem. Further, the government of India is working to simplify the regulatory system and in further strengthening the industry-academia linkages.

b. IPR Awareness Programs

9. Numerous IPR awareness programs have been conducted in various schools and colleges/ universities pan India. Adapting to the COVID-19 pandemic, the Cell for IPR Promotion and Management (CIPAM) of DPIIT organised 200+ webinars for different stakeholders. Many of these programs were conducted online to ensure wider coverage. Through 290 programs, approximately 3000 academic institutions have been covered till date. 296 programs were held for industry including MSMEs and Start-ups and 100 programs for enforcement agencies and the judiciary.

10. CIPAM conducted over 20 online IPR awareness webinars in May 2020. While all the sectors, businesses and processes were adversely affected by the COVID-19 pandemic, CIPAM utilised online platforms to continue creating awareness for IPR across the country.

    For this purpose, CIPAM collaborated with organisations such as Ministry of Micro, Small and Medium Enterprises(MSME), The International Chamber of Commerce Business Action to Stop Counterfeiting and Piracy(ICC BASCAP), Karnataka State Council of Science and Technology (KSCST), FICCI (Federation of Indian Chambers of Commerce & Industry), All India Council for Technical Education (AICTE) and Atal Innovation Mission (AIM) of NITI Aayog.

[2] IPA Submission-Paras 4-9

11. Eight online sessions and webinars were conducted by CIPAM in collaboration with various organisations that reached out to more than 51,000 participants from schools, colleges, and industries. Collaborating partners for these sessions included AICTE, AIM and KSCST.

12. On the industry front, around three cluster awareness workshops were conducted online in collaboration with the Ministry of MSME. Awareness programmes were organised in MSME clusters. 190 such awareness programmes have been conducted till date. About eighty IPR webinars have been conducted so far in the current financial year (2020-21), for participants from the industry, start-ups, young entrepreneurs, and innovators.

13. In May 2020, CIPAM conducted a webinar on 'Brand Protection for MSMEs during COVID-19' in collaboration with the Ministry of MSME and ICC BASCAP. These seminars saw the participation of more than 600 people. Early in 2020, CIPAM and AIM joined hands to conduct six online sessions every Tuesday for students of Atal Tinkering Labs until the end of June 2020. In July 2020, an 'Online Certificate Course on Intellectual Property Rights' was launched in collaboration with i-Hub Gujarat. More than 5000 faculties registered for the course.

14. CIPAM collaborated with the Danish Embassy and Danish Patent & Trademark Office (DKPTO) to strengthen the IP relations between the countries by launching 'India-Denmark IP Webinar Series'. Experts from DKPTO delivered sessions in the six-part webinar series that was held in November 2020.

c. Patent Amendment Rules

15. A significant development in India's IPR regime came through with the enforcement of Patent (Amendment) Rules, 2020, which came into force on 20 October 2020. The amendment primarily streamlined the rules to promote ease of doing business. The amendment is regarding the submission of Priority documents and Form-27 related to the Statement of Working for a granted patent. According to the amended rules, the Priority Documents are no longer required to be submitted if they are available with WIPO. Further, English translation of Priority Documents is only needed in certain cases.

16. Rules for Form-27 have been simplified allowing a patent holder to submit a consolidated statement of working of multiple patents. If a patent has been granted to two or more persons, they may now file a joint Form-27. The form can be submitted by authorised agents on behalf of the patentee(s). Further, the Statement of Working for a granted patent will have to be filed for each financial year i.e., beginning April 1, instead of the calendar year as stipulated previously. Applicants will get six months to file Form-27 instead of the current three months and will not be required to file the form in respect of a part or fraction of the financial year.

17. Further, as per the new Form-27, the patentee/ licensee is required to submit the approximate revenue/ value accrued in India through manufacturing in India/import into India of the patented invention, in contrast to the earlier requirement of "quantum and value (in rupees) of the patented product manufactured/ imported in India". Previously, patentees have faced difficulties in determining the exact "quantum" and "value" of the patented product manufactured/imported in India as for some types of inventions these figures are not easily discernible and also raise concerns over confidentiality. Another cause for concern from a confidentiality perspective in the earlier Form-27 was the requirement to provide details of licensees and sub-licensees. This requirement has now been removed in the amended rules.

18. The amendment benefits small entities by providing them a fee reduction in all proceedings under the Patents Act, 1970. With regard to applicable official fee, small entities are now at par with natural person(s)/start-up(s). Most importantly, the amendment has also done away with the requirement under Form-27 concerning declaration by the patentee or licensee to disclose whether the public requirement has been met. Therefore, the process for patent applications has been streamlined and simplified.

d. Patents filed by Start-ups under SIPP scheme

19. We would like to draw attention to over 3,400 patents filed by start-ups under the Start-ups Intellectual Property Protection (SIPP) scheme till date. The SIPP scheme was launched in 2016 with a vision to protect and promote IPR of start-ups for encouraging innovation and creativity.

20. As of May 2020, 3,459 start-ups had filed applications for patents. For the benefit of start-ups, the office of Controller General of Patents, Designs & Trademarks (CGPDTM) has empanelled 510 facilitators for patents and designs and 392 facilitators for trademarks. As of 31 May 2020, 942 start-ups had requested expedited examination of patent applications, out of which 821 applications have already been examined, and 324 patents already granted. This indicates India's consistent efforts towards improving the patent ecosystem and encouraging start-ups by enhancing the patent application process.

e. MoUs for Intellectual Property Cooperation

21. In December 2020, the DPIIT also signed a MoU with the United States Patent and Trademark Office (USPTO), Department of Commerce of the United States of America in the field of Intellectual Property Cooperation. It aims at increasing IP cooperation between the two countries by way of:

    - facilitating exchange and dissemination of best practices, experiences, and knowledge on IP among the public, and between and among the industry, universities, research, and development organizations, and MSMEs through participation in programs and events organized singly or jointly by the participants.

    - collaboration in training programs, exchange of experts, technical exchanges, and outreach activities.

    - exchange of information and best practices on processes for registration and examination of applications for patents, trademarks, copyrights, geographical indications, and industrial designs, as well as the protection, enforcement and use of IP rights.

    - exchange of information on the development and implementation of automation and modernization projects, new documentation and information systems in IP and procedures for management of IP office services;

- cooperation to understand various issues related to traditional knowledge, and the exchange of best practices, including those related to traditional knowledge databases and awareness raising on the use of existing IP systems for the protection of traditional knowledge; and other cooperation activities as may be mutually decided by the Participants.

As USTR is aware, the two sides will draw up a Biennial Work Plan to implement the MoU which will include detailed planning for carrying out the cooperation activities including the scope of action.

22. In September 2020, the Union Cabinet approved signing a MoU with Denmark in the field of IP Cooperation. The MoU, signed between DPIIT and the Danish Patent and Trademark Office, aims at increasing IP cooperation between the two countries by way of exchange of best practices, experiences, and knowledge on IP awareness among public, government authorities, businesses and research and educational institutions of both countries. Further, the two nations will also collaborate in training programmes, exchange of experts, technical exchanges, and outreach activities. The MoU will allow an exchange of information and best practices on processes for disposal of applications for patents, trademarks, industrial designs, and geographical indications, as well as the protection, enforcement and use of IP rights. It aims to facilitate cooperation in the development of automation and implementation of modernization projects, new documentation and information systems in IP and procedures for management of IP. It will be a landmark step forward in India's journey towards becoming a major player in global innovation and further the objectives of National IPR Policy, 2016.

f. Technology and Innovation Support Centre (TISC)

23. DPIIT and WIPO have signed an agreement to establish TISC further to India's accession to three WIPO treaties last year. CIPAM is designated as the national focal point for the TISC national network. CIPAM will identify potential host institutions, assess their capacities, and support them in joining the TISC project. CIPAM will also act as the main intermediary between WIPO and TISC host institutions and coordinate all the activities of the national TISC network. Till date, six TISCs have been established in India at PIC Chandigarh; Anna University, Chennai; NRDC-IPFC Visakhapatnam; PIC Kerala; GUJCOST, Gujarat and RAJCOST, Rajasthan.

24. In association with WIPO, CIPAM conducted six workshops. The workshops were a part of the TISC Program of WIPO. The workshop aimed to acquaint the participants about the usefulness of patent information and patent search strategies/tools and to provide them hands-on training for conducting patent and freedom to operate searches by using various online databases.

25. The IPR Division of partner association of IPA, FICCI is intensively involved with issues pertaining to protection and enforcement of IPR. It has taken decisive steps in raising the levels of awareness about IPR amongst the citizens of India. FICCI IPR Division has established an Intellectual Property Education Centre (IPEC) with the objective to impart specialized education in the IP field as well as to develop a pool of professionals in the area of IPR, whose knowledge and services will benefit the industry at large.

g. Social Media Campaigns

26. Multiple successful campaigns have been executed online for spreading awareness about different Intellectual Property Rights.

    a) Quiz Time with CIPAM – was executed for disseminating bite-sized information on IPR and encouraging a response from the audience through comments on posts. The campaign was run to spread basic awareness of IPR with the vision to stand committed to practices that protect IPR.

    b) Defeat Counterfeit – was run to raise awareness against the practices of counterfeiting presenting the socio-economic disadvantages associated with counterfeiting. This campaign was run in the month of June 2020, which is officially anti-counterfeiting awareness-raising month with the aim of prevention of IP crimes by increasing the public's IP knowledge.

III. Speeding up of Patent and Trademark Applications

27. The 2020 Report had reiterated its concerns over India's patent regime. It was stated in the report that "patent applicants continue to confront costly and time-consuming pre- and post-grant oppositions, long waiting periods to receive patent approval, and excessive reporting requirements".
    In this regard, we would like to state that India has been consistently taking significant steps to reduce the time for processing patent and trademark applications. The progress made so far was also outlined in our previous 2020 submission as well[3].

28. The augmentation in the technical manpower has resulted in favourable outcomes, declining the pendency of IP applications. The additional hiring of examiners and enhancement in the online filing system of the IPO has helped to address the existing patent application backlog.

29. **The period of examination of new trademark applications has reduced from 13 months to less than 30 days** and trademark is being registered in about six months, if there is no objection or opposition filed, as compared to three to five years required earlier. The reform in IP filing and digitization of the whole process has led to more than 90 percent e-filing of applications in patents, trademarks, and copyrights.

30. All the steps undertaken have offered substantial results. Cumulative statistics along with year wise comparison (FY 2015-16 – FY 2019-20) is given below.

31. IP filing data for patents has seen a fourfold increase in the past five years. The Intellectual Property Appellate Board (IPAB) is now conducting online hearings.

[3] IPA 2020 Submission-Paras 12-14

Patent Application Process

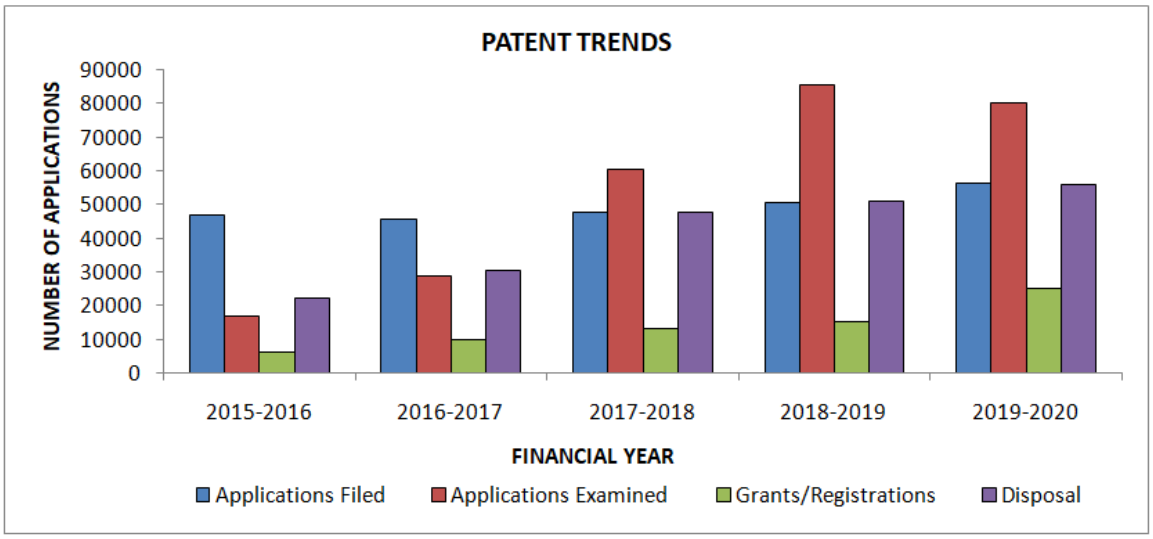
Patent Trends	Financial Year (FY)					% change FY 2019-2020 vs. 2015-2016
	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020	
Applications Filed	46,904	45,444	47,854	50,659	56,284	20
Applications Examined	16,853	28,967	60,330	85,426	80,088	375
Grants/Registrations	6,326	9,847	13,045	15,283	24,936	294
Disposal	21,987	30,271	47,695	50,884	55,945	154

Source: CIPAM

32. FY 2019-20 saw efficient processing of IP applications, especially in terms of their examination and disposal. Compared to figures from the past five years, the current numbers reflected an overall increase in application filings across all IPs. **Examination of patent applications saw an increase to more than four times in FY 2019-20 as compared to FY 2015-16, and a three-fold increase in grants and near two-fold increase in disposal of applications was observed.**
The number of grants provided for the patent applications saw a rise from 15,283 in FY 2018-19 to 24,936 in FY 2019-20. There was also an increased disposal of applications (grants, refusals, withdrawals, abandonments) in FY 2019-20 i.e., 55,945 from 50,884 in FY 2018-19.

33. **For FY 2020-21, 43,028 patent applications were filed, 50,381 were examined and 19,533 grants were provided till 31 December.**

34. The trend of patent applications from 2015 to 2020 can be seen in the graphical representation given below.



Source: CIPAM

35. **Trademark applications too saw a four-fold increase in registrations; disposal went up by more than three times.** A comparative analysis of trademark trends across FY 2015-16 to FY 2019-20 as given in the figures, illustrate a significant progress.

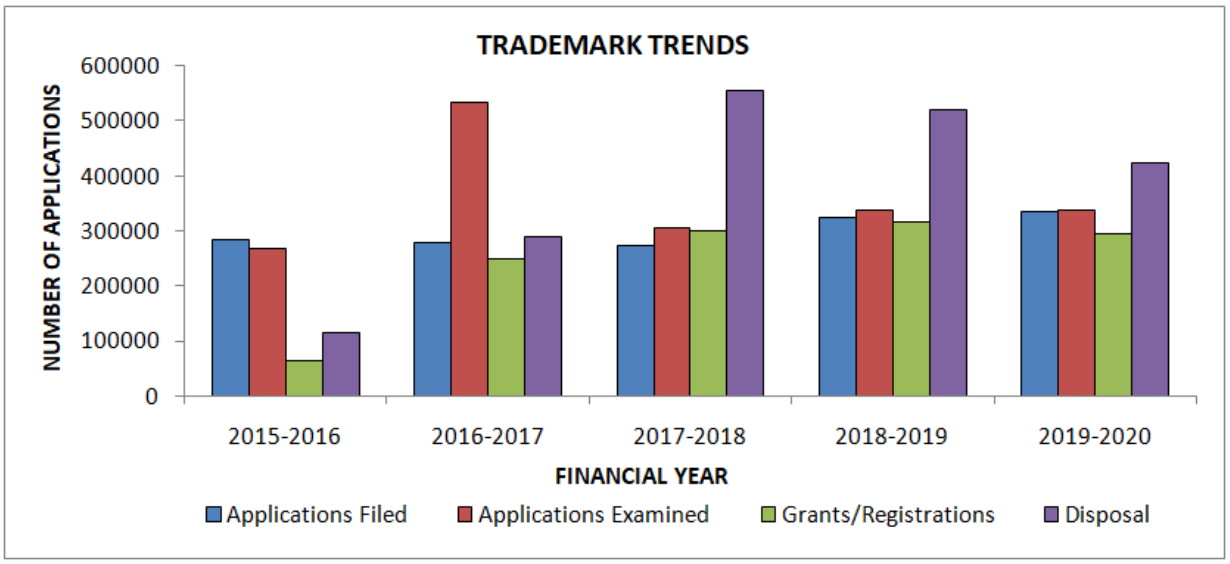
Trademarks

Trademark Trends	Financial Year (FY)					% change FY 2019-2020 vs. 2015-2016
	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020	
Applications Filed	283,060	278,170	272,974	323,798	334,815	18
Applications Examined	267,861	532,230	306,259	337,541	338,551	26
Grants/Registrations	65,045	250,070	300,913	316,798	294,172	352
Disposal	116,167	290,444	555,777	519,185	422,566	264

Source: CIPAM

36. It can be observed from the data that the IPO kept pace with the number of applications filed and examined nearly all applications filed in FY 2019-20. The trend in trademark applications from 2015 to 2020 can be seen in the graphical representation given below.

37. **For FY 2020-21, 318,985 trademark applications were filed, 347,100 were examined and 146,996 trademark applications were provided grants till 31 December**.



Source: CIPAM

IV. Regulatory Approval

a. Regulatory Data Protection

38. USTR has continuously mentioned in their Special 301 reports 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'. It is respectfully submitted that during the approval process, at no point/stage, the innovator company's confidential data is accessed for obtaining marketing approval for their product. The protection against unfair commercial use does not make a materialistic difference to U.S. based pharmaceutical companies and we request for an authentic data driven estimate of extent of actual and potential injury incurred by lack of such a system.

39. Introduction of an exclusivity provision causes unnecessary delays in patient access to life saving drugs at affordable prices thereby impacting the patient's treatment. This has been experienced in Mexico, where introduction of a five-year data exclusivity term for small molecule medicines was implemented in the year 2012 as part of the North American Free Trade Agreement (NAFTA), which resulted in total loss of USD 320 million in cost savings. As per a study by the International Generic and Biosimilar Medicines Association (IGBA) and IQVIA, without this five-year data exclusivity term, over 150,000 patients could have been treated. Thus, the introduction of such a provision adversely affects patient health.[4]

40. Article 39.3 of the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement requires member states of the World Trade Organisation (WTO) to protect undisclosed data required to be submitted for approval of pharmaceutical and agricultural chemical products against unfair commercial use, when such products are new chemical entities. It also mentions that "Members shall protect such data against disclosure, except where necessary to protect the public". India, in this context, is fully consistent with the requirements of the TRIPS Agreement by protecting undisclosed tests or other data which does not require an exclusivity period.

41. India is fully compliant with the TRIPS obligations in protecting undisclosed data which does not require an exclusivity period. In addition to this, we reiterate that providing an exclusivity period is a TRIPS-plus provision. We urge USTR to kindly consider our submission on this topic.

[4] https://www.igbamedicines.org/doc/IQVIA-IGBA_Impact%20of%20FTAs%20on%20generic%20and%20biosimilar%20markets_Final%20Deck%20-%20October%202020.pdf

b. Marketing approvals for follow-on pharmaceuticals

42. USTR report 2020 voiced concern over alleged 'lacking 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. We would like to mention that in India, the information about new drug approvals is provided by the Drugs Controller General of India (DCGI) at multiple levels prior to actual approval. For e.g.,

    a) The information on conduct of clinical trials for obtaining marketing approval is published online;

    b) Minutes of meetings of various committees responsible for granting marketing approval e.g., Subject Expert Committee (SEC) are published online;

    c) DCGI provides information through Right to Information (RTI) queries.

43. The information about the potential launch of a generic drug can thus be availed by all the interested parties. Therefore, it would be inappropriate to say that innovators do not get information on parties who are seeking approval of follow-on pharmaceuticals. On the contrary, there are instances wherein the innovators have been routinely using these routes to try and stifle the legitimate business of the generic players by filing frivolous suits.

44. The Indian patent regime provides sufficient protection to the patent holder. The patentee has rights to file a suit in respect of patent infringement committed after the issuance of the licence as per the section 109 of the Indian Patent Act, 1970[5]. Thus, the patent holder is provided all rights under the system to sue a generic manufacturer intending to manufacture a potentially patent-infringing commodity. Further, as per section 108 of the Act, the patent holder is provided an injunction prohibiting a generic manufacturer from producing or marketing the drug till any challenge to the validity of the patent is finally decided[6]. 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. For example:

    - Lundbeck filed cases against Unichem Laboratories, Hetero Drugs and Alembic Pharmaceuticals for infringement of Patent No. 227963 for their compound 'Vortioxetine' which has validity till 2 October 2022.
      The case against Unichem Laboratories was disposed off on the basis of the undertaking by Unichem Laboratories that they will not manufacture 'Vortioxetine' until the expiry of the patent and/or inform Lundbeck three months prior to such a launch before the expiry of the patent. Further, Hetero Drugs was injuncted and Alembic Pharmaceuticals was only allowed to conduct activities that are permitted under Bolar Provision.

[5] http://ipindia.nic.in/writereaddata/Portal/ev/sections/ps109.html

[6] http://ipindia.nic.in/writereaddata/Portal/ev/sections/ps108.html

- Eli Lilly filed a case against Natco Pharma for infringement of Patent No. 297760 for their compound 'ABEMACICLIB' which has validity till 15 December 2029. The defendants offered to provide an undertaking stating that whenever they will launch the 'Abemaciclib' drug, a prior notice will be made to the plaintiffs so that they can approach the court for appropriate relief. Despite the defendant offering to provide such an undertaking, the Delhi High Court granted an *ad-interim* injunction in favour of the plaintiffs, thus restraining Natco Pharma from manufacturing and selling the 'Abemaciclib' drug.

- Pharmacyclics LLC filed a case against Indian pharmaceutical company Shilpa Medicare. The case was filed for infringement of the suit patent with Patent No. 262968 for their compound 'IBRUTINIB' which has validity till 28 December 2026. The plaintiff got information about the potential launch of the product compound 'ibrutinib' on 14 October 2020. On the same day, the Delhi High Court granted an *ad-interim* injunction.

  There is a pending suit against other generic infringers, namely Alkem, BDR, Natco and Lucius Pharmaceuticals for infringement of the same patent.

45. Thus, the rights of the patent holder are adequately protected in India. Further, we would like to reiterate that India does not have analogous provisions like the 'Orange Book and the Hatch Waxman' whereby it is mandatory to give notice to the innovator for getting market approval of a generic drug and the drug can only be approved after 30 months.

46. Additionally, many countries, such as European Union member states, do not have a provision for 'patent linkage'.[7] Further, the patent linkage is a TRIPS plus provision. As India is a signatory to the TRIPS requirements, it would not be obligatory to adopt the concept of patent linkage.[8]

47. India is a signatory of TRIPS Agreement and the patent law is compliant of the TRIPS agreement. In case a patent is eventually found to be non-infringed, the delays due to holding up marketing authorization of generics for the patent term would ultimately cause injury to patients which cannot be compensated. Thus, it is apparent that the Indian judicial system continues to enforce the IP Rights of the Patent holders and is considering various options to safeguard the interests of the patent holders.

V. Pre-grant Opposition

48. The 2020 Report voices concern that 'patent applicants continue to confront costly and time-consuming pre- and post-grant oppositions, long waiting periods to receive patent approval, and excessive reporting requirements. This issue has been addressed in all our submissions including that in 2020.[9] We would like to reiterate that India's Patents Act has been amended several times over the years in order to be WTO TRIPS compliant. The Supreme Court of India has upheld the Act as being compliant with the provisions of TRIPS.[10]

[7] IPA submission 2020 para 42

[8] https://www.lexorbis.com/wp-content/uploads/2015/10/Patent-Lawyer-as-published.pdf

[9] IPA Submission-2020 Paras 46-49

[10] Novartis Ag vs Union Of India &Ors on 1 April 2013

49. During FY 2018-19, a total of 46,345 patent applications were published under section 11A and 426 pre-grant oppositions were filed under section 25(1) of the Patents Act, 1970, which is about 0.9 percent of the total published applications. Under Section 25(1), **out of the 426 pre-grant oppositions received, 399 pre-grant oppositions were disposed of during the year.** The details of the applications published, and pre-grant oppositions filed in the past few years are given below:

Publication and pre-grant opposition		
FY	**Publication**	**Pre-grant Opposition**
2014-2015	26,934	247
2015-2016	41,752	290
2016-2017	86,766	206
2017-2018	46,899	260
2018-2019	46,345	426

Source: CIPAM

50. Also, under Section 25(2), a total of 28 post-grant oppositions were filed during the year. Five post-grant oppositions were disposed of during the year.

51. While the pre-grant opposition adds time to the patent prosecution process, it is less time consuming and less expensive than defending the post-grant opposition proceedings. The pre-grant opposition provides an opportunity for the quick assessment of patentability for the patent applicant. Further, the Patents Act of India lays down measures in case delay is caused due to the pre-grant opposition. In such cases, a professed infringer will be accountable for the damages starting from the date of publication of the patent application. However, it may be noted that in the U.S., the right to sue for infringement commences only on grant of the patent.

52. India's patent law has provisions for both pre-grant and post-grant opposition. This provides an efficient and effective method for preventing or revoking the grant of a non-eligible patent. The procedure for pre-grant opposition has been useful in helping many applicants and companies to oppose patents on similar grounds on which a post-grant opposition is filed. Other jurisdictions have also introduced provisions similar to the pre-grant oppositions by allowing submission of '*third-party observations'* prior to the grant of a patent.

    The underlying principle remains the same, i.e., to help in the examination process and ensuring that unworthy patents are not granted. Countries like Australia, Israel, Portugal, and Zambia have provisions for pre-grant opposition, while countries like Denmark, other member states of European Union, Korea and the U.S. have provisions for post-grant opposition[11].

[11] WIPO - https://www.wipo.int/scp/en/revocation_mechanisms/opposition/index.html

53. Further, in December 2019, the Delhi High Court in its order laid down guidelines for Post-grant opposition. The Court held that an endeavour ought to be made by the Patent Office to ensure that post-grant oppositions are decided expeditiously as pendency of post-grant oppositions delays adjudication of infringement suits, if any, in respect of the patent and also keeps the rights of the patentee under a cloud or in doubt.

54. Due consideration should also be given to the fact that past delays in patent examination can also be largely attributed to the administrative and manpower limitations and not just to pre-grant oppositions. However, USTR may take note of the substantial increase in the number of the patent applications examined and disposed as indicated in the above sections which now addresses these limitations. In addition to this, it may be noted that failure on part of an applicant to submit the necessary information on time can also be attributed to the delays caused during the process.

55. In this regard, we request the USTR to closely look into the concerns raised by the U.S. companies and re-evaluate the concerns raised against India.

VI. Compulsory Licensing

56. Compulsory licensing is one of the notable flexibilities of TRIPS, for legitimate public health needs. Under TRIPS, a government can authorize the use of a patent of pharmaceuticals for its own purposes (government use), to address public health problems. This right was reaffirmed under the Doha Declaration on TRIPS and Public Health. Thus, Compulsory License (CL) of patented pharmaceuticals may be deemed essential as it is a last resort, limited governmental measure that can be used to intervene in the case of market failure.

57. We would like to urge USTR to take a note that, despite the aforementioned flexibilities afforded to member countries of WTO, the Indian Patent Office has so far granted only one Compulsory License - for producing the generic version of patented drug Nexavar. That judgement, in 2012, was supported by the public policy, and the fact that the patent holder could not make its invention available in India at an affordable price and commercial scale. Moreover, USTR may like to take note that the Indian Patents Office has displayed careful scrutiny and has rejected other applications for compulsory licenses, namely Dasatinib and Saxagliptin. This has been acknowledged by PhRMA as well, where they state that “the Indian Government continues to take a measured and cautious approach in responding to recent CL cases.”

58. The provisions for compulsory licenses have practically no effect on the patentee’s rights as the conditions for getting these licenses in India are strict. It falls within the sovereign rights of a nation to maintain adequate legal provisions to address unbalanced access to healthcare challenges that may have an adverse impact on large sections of the society.

    It is reiterated that CL provisions have been there in many patent laws across the globe and such provisions are in line with the TRIPS provisions. India is therefore justified in exercising its right to issue compulsory licenses.

VII. Patentability Exceptions: Section 3(d)

59. The TRIPS Agreement and Doha Declaration have provided policy space to member countries to suit the needs of a member country. Under Section 3 of Patents Act 1970, inventions based on traditional knowledge, patenting of animals, plants, plant variety and seeds etc. are not allowed.

60. To prevent patent 'ever greening' (extension of life of a patent over products that are about to expire, on account of minor and incremental improvements in the invention), Section 3 (d) of the Act provides that:
    - A mere discovery of a new form/use/property/process etc. of a known substance which does not result in enhanced efficacy is not patentable.
    - Salts, esters, ethers, polymorphs, etc. of known substances are to be considered to be the same substance until these differ significantly in properties with regard to efficacy.
    - Mere use of a known process, machine or apparatus is not patentable unless such known process results in a new product or employs at least one new reactant.

61. Section 3(d) is essentially an enabling provision - states that patent applications for certain types of inventions and satisfying the requirements laid down in the provision (for e.g., exhibiting enhanced therapeutic efficacy over the form from which it is derived) will be eligible for patent. It is for the patent holder to satisfy the patent office that the invention satisfies the requirements of this section. The argument that Section 3(d) impairs grant of patents to certain classes of invention is not correct. Patents have been granted to inventions claiming alternate polymorphic forms of several compounds which have satisfied the requirements of Sections 3(d). It is noteworthy that Section 3(d) does not discriminate between Indian and foreign applicants for patents.

62. In India, after the decision of the Supreme Court in *Novartis v. Union of India & others* of 2013, the law relating to the applicability of the section 3(d) has been well settled and is on par with the legal frameworks in other leading countries including the U.S. Therefore, the allegation that the section 3(d) limits the innovation is misplaced and without any quantitative data as to the harm done to the patentees due to this provision.

63. In some countries, features of patent legislation are similar to India's Section 3(d). These are given below:

    - Philippines - To toughen the criteria of patentability, had proposed to amend its laws.
    - Brazil - Patent Office drafted guidelines to restrict patentability of new forms of compounds (polymorphs) or new property or new use of a known process unless this known process resulted in a new product.
    - Japan - Patent legislation mentions the subject matter as new use of a drug can be patented if the usage is absolutely novel over the original and its use must be clearly differentiated.
    - European Patent Office has also given guidelines regarding patentability of polymorphs. As per these guidelines, for polymorphs to be considered as inventive it must produce extraordinary technical effect compared to already known effects.

    Thus, other countries have also been taking measures through their patent system to stop the process of evergreening which significantly hampers access to affordable medicines.

64. The TRIPS requirements under Article 27 are: invention must be *new*, involve an *inventive step*, and be capable of *industrial application*. However, none of these terms used in this provision have been defined, leaving some flexibility in the hands of signatory members to introduce a deeming provision such as section 3(d), provided it is not entirely arbitrary. More specifically, it may be argued that a claimed substance that does not satisfy criteria in the section 3(d) threshold is not an 'invention' within the meaning of Article 27. Thus, India's Section 3(d) is TRIPS-compliant.

VIII. Customs duties directed to IP-intensive products

65. USTR in the 2019 and 2020 Reports has raised concern over high custom duties on IP intensive products. IPA's 2020 submission has already mentioned that the custom duties have been the same from the last few years. The customs duties have remained the same in 2020. Further, the custom duties for both patented as well as generic drugs are also the same.

IX. Covid-19 – Need for greater Global Cooperation

66. As Covid-19 grappled the world since December 2019, nation states, international organizations, and other groups came together and worked on a strategy to address the issues emerging from this public health crisis. When the World Health Organisation (WHO) declared the Covid-19 outbreak as a global pandemic, countries started responding immediately according to their capacity. However, the disruption of supply chains brought out the nuances of the interconnected world. Not only was there a problem in access to food supply for countries but it created a huge demand for diagnostic kits, personal protection equipment, medical products, among others to tackle the situation. As the situation worsened in the middle of 2020, it clearly indicated the need to produce a safe and effective vaccine at the earliest. During the pandemic, Indian pharmaceutical industry has demonstrated its commitment to supply life- saving drugs uninterruptedly to the U.S. and across the globe.

67. At the international level, Costa Rica along with the WHO and its partners launched the Access to COVID-19 Tools (ACT) Accelerator to coordinate the global efforts in finding a solution to this health crisis. Scientists, pharmaceutical companies, funding agencies and private bodies turned their focus towards developing a vaccine. In the meantime, it also highlighted the range of barriers to afford medical products, particularly those of low and middle income countries. Given this scenario, it became imperative to ensure the availability and affordability of vaccines for countries across the globe.

68. In order to ensure the access to medical products, diagnostic kits, vaccines, and other items, one of the barriers identified was intellectual property rights. Although a provision exists in the TRIPS Agreement, it may not be sufficient for countries that do not have manufacturing, distribution, or logistical capacities. In other words, the right to issue compulsory license and issue permit without the patentee consent for manufacturing may be met with legal and institutional challenges and cause delay when time is the essence of treatment. Besides, it requires time for the countries to leverage this licensing mechanism.

    Also, the procedural aspects required to leverage waiver provided with Article 31bis of the TRIPS Agreement would be cumbersome to countries.

69. In this context, any leniency in adhering to IP rights at the WTO level in terms of TRIPS Agreement was perceived to enable countries at varying capacities to deal with this pandemic in their country. Hence, India and South Africa communicated a joint proposal to the WTO TRIPS Council regarding a grant of waiver of IP rights, for a limited period, from complying with the TRIPS Agreement for the prevention, containment, and treatment of Covid-19.Such a waiver has been sought so that production of products related to Covid-19 treatment may be scaled up rapidly and such medical products may reach the patients on time. India is a proponent of global cooperation in these challenging times.

70. In addition to the discussion on TRIPS Waiver, voluntary licensing becomes important for addressing the challenges of pandemic. For instance: vaccine Covishield resulted from the partnership of Serum Institute of India (SII) with Oxford University and AstraZeneca. The positive results from this partnership are evident and have brought certain relief to the ongoing crisis situation not for India alone but to countries across the world. Given this situation, it becomes imperative to also have provisions to use voluntary licensing mode as it would hold the mechanism of reward for all the stakeholders involved in the process of developing the medical products. In other words, the voluntary licensing would allow the manufacturing and distribution of such COVID-related products at affordable rates, thereby ensuring the patent rights in all terms of the patentee. Hence, due consideration may be given to voluntary licensing terms as it may become a balancing act and facilitate consensus between the concerned stakeholders of all levels in addressing the IP issue.

71. Currently, multiple vaccines have received regulatory approvals and vaccination has begun across the globe. Although the proposal has been discussed and received support from certain members at the WTO, a consensus is yet to be reached among the member countries. Uncertain times call for drastic measures and hence, the countries with manufacturing base, affordability and the wherewithal to preferential access may need to consider the possible ways to ensure accessibility for countries featuring in the lower stratum of developmental scale. It would also assist the highly advanced countries to lead, contribute and shape the world in addressing global health crisis at this unprecedented level.

72. In this humanitarian health crisis , we support global cooperation and need to facilitate trade of these products as it will help to address public health crisis and patients across the globe.

a. Discriminatory and Non-Transparent Pharmaceutical Pricing Policies

73. In India, the National Pharmaceutical Pricing Authority (NPPA) is authorised to fix, revise the ceiling prices /retail prices under paras 4, 10, 11 and 14 of Drug Price Control Order (DPCO) 2013, only for the Scheduled Formulations, barring exceptional circumstances, where it considers it necessary in public interest as under para 19 of DPCO 2013. Thus, it is very clear that NPPA is legitimately following its roles and the responsibilities in a transparent manner, with no biases or discretion between domestic and foreign companies.

X. Enforcement

a. Enforcement against Counterfeit Medicines

74. The 2020 Report has referred to a report by the Organization for Economic Co-operation and Development (OECD), “Trends in Trade in Counterfeit and Pirated Goods” and raised concern that India’s border enforcement against counterfeit and pirated goods is ineffective. However, this publication also concedes that the General Trade-Related Index of Counterfeiting and Piracy (GTRIC) methodology used, “does not provide a direct measure of the overall magnitude of counterfeiting” but rather that it establishes relationships which “may be useful”.

75. IPA would like to reiterate the findings of the Survey of Extent of Problems of Spurious and Not of Standard Quality Drugs in the Country (National Drugs Survey), a survey conducted by the National Institute of Biologicals across India during 2014-2016. According to this survey, the proportion of substandard drugs has been pegged at about three percent of the total drugs sold, while about 0.28 percent was found to be spurious. The study also noted that “None of the samples drawn from air/sea ports were found to be of Not of Standard Quality (NSQ) or Spurious.”

76. Furthermore, the Union Government made it mandatory for all drug manufacturers to upload the details of their manufacturing licenses and list of products being manufactured to their online portal ‘SUGAM’. This information is directed to be updated regularly and verified by the concerned licensing authorities.

77. The Central Drugs Standard Control Organisation (CDSCO) publishes lists of drugs, medical devices and cosmetics that are evaluated and declared as not of standard quality/ spurious/ adulterated/ misbranded. Further, only registered pharmacists may deal with the supply and storage of medicine for distribution to retail pharmacy outlets. In addition to this, the number of National Accreditation Board for Testing and Calibration Laboratories (NABL) accredited labs for drug testing has been increased.

78. India currently has a Drug Authentication and Verification Application (DAVA) system for tracking and tracing manufactured medicines for export during their complete supply chain. The Directorate General of Foreign Trade (DGFT) shall launch the Integrated Validation of Exports of Drugs from India and its Authentication (iVEDA) portal for drug authentication and tracking and tracing of the drug supply from 1 April 2021. This updated mechanism shall replace the DAVA system and continue to assist in gaining real-time visibility of pharmaceuticals produced and exported from India.

79. Under iVEDA, the manufacturers and exporters would be required to barcode their products using GS1 standards along with the batch number and expiry date to facilitate authentication of exported drugs. Exporters shall also be required to upload data on barcode on secondary and tertiary packaging of exported drugs.

    Thus, active steps are being undertaken to ensure the continued absence of counterfeit drugs from the Indian market.

b. Other enforcement actions

80. The Ministry of Health and Family Welfare (MoHFW) has amended the Drugs and Cosmetics Rules, 1945 – rules framed under the Drugs and Cosmetics Act, 1940, India's primary drug control legislation – to require manufacturers to use brand names that are not similar to other brand names or trade names of drugs already in existence as a condition for obtaining the manufacturing license. The amendment also requires manufacturers to provide an undertaking to the relevant authority to the effect that the manufacturer has already undertaken a search of the proposed brand name in the trademarks registry, the central database maintained by the drug regulator, literature, and reference books on drug formulations as well as the internet and is not aware of the existence of any drug with the same or similar proposed brand name.

81. The amendment follows another circular issued by the DCGI directing all drug controllers in India to take strict action against manufacturers who change the underlying formulation of a drug without changing the brand name of the drug, to prevent patients from being confused about the composition of a drug marketed under a brand name.

c. Protection of Trade Secrets

82. The 2020 Report mentions "Companies also continue to face uncertainty caused by insufficient legal means to protect trade secrets in India". In this regard, we would like to submit that India has been working constantly in this area, which was also mentioned in our 2020 Submission[12]. CIPAM has in place a guide, 'A Guide to Protecting Trade Secrets: How to protect the confidential business information that provides businesses a competitive edge'. This toolkit aims to guide Indian businesses especially MSMEs and start-ups regarding protection of trade secrets. It also explains what trade secrets are, why they are important to business, and the practical and legal steps you can take to protect them.

83. We would also like to bring it to notice that due consideration has been given to protection of trade secrets in the National IPR Policy, 2016. Protection of trade secrets has been mentioned as one of the important areas of study and research for future policy development.

84. It may also be noted that India covers trade secrets under the common, civil, and criminal laws. In addition to remedies such as injunctions or damages available under the Information Technology Act, India allows for criminal remedies under the Indian Penal Code 1860, such as for criminal misappropriation, breach of trust and theft of property.

[12] IPA 2020 Submission-Para 8(iii)

d. Sensitization of Enforcement Agencies & Judiciary for effective enforcement

85. Several steps have been taken by the Government of India to increase awareness among the police and the judiciary. This includes Police Training Programs to aid in familiarity with investigation techniques. So far, more than one hundred programs on IP enforcement have been conducted for various law enforcing agencies (police, judiciary, and customs) by CIPAM, pan India in association with IP experts from law firms and the industry. CIPAM has continued to conduct training programmes for customs officials across India in collaboration with National Academy of Customs, Indirect Taxes & Narcotics (NACIN); 26 such training programmes have been organised till date. A few of such initiatives are stated below.

    a. DPIIT has been organizing National IP Enforcement Workshops to increase awareness amongst officials of enforcement agencies (police/customs) and to help sensitize enforcement agencies country-wide on their importance as IPR enforcers. The events provide a platform for police officials from across the country to share experiences and exchange views on best practices, thereby creating opportunities to forge inter-agency coordination.

    b. DPIIT prepared an “IPR Enforcement Toolkit for Police”. Subsequently, capacity building programs were organized for police officials on enforcement of IPRs nationwide. The toolkit (updated in November 2019) has been distributed widely to police departments across the country to help them deal with IP crimes, specifically counterfeiting and piracy. IPR modules for customs and judiciary have also been developed by DPIIT in association with other industry bodies.

    c. IPR Cells were created under police departments in Karnataka, Punjab, and Jammu & Kashmir.

    d. Advisory was issued by the Ministry of Home Affairs to all State police departments and Union Territories to include IPRs in the training curriculum.

    e. Training programs for Police officials on IP enforcement have been conducted by CIPAM, in association with law firms and industry, in states of Andhra Pradesh, Uttar Pradesh, West Bengal, Madhya Pradesh, Telangana, Haryana, Jharkhand, besides several rounds of training in North-East Police Academy and Sardar Vallabhbhai National Police Academy, Hyderabad.

    f. Training of Judges on IP enforcement and adjudication was undertaken by CIPAM.

    g. Two colloquiums on commercial laws for High Court judges were held at National Judicial Academy, Bhopal to sensitize judges on IPR policies. Programs have also been conducted in conjunction with National Judicial Academy (NJA) & the State Judicial Academies of Meghalaya, Uttarakhand, and Kerala.

    h. DPIIT, WIPO & NJA conducted a three-day IPR Program for High Court Justices.

    i. CIPAM, in association with Korea Trade Investment Promotion Agency (KOTRA) - IP Desk organised two webinars with respect to IPR. An IP awareness webinar for Korean companies was organised in September 2020. Further, a Counterfeit Product Identification webinar was organised for Indian police and customs officials in November 2020.

e. Copyright Policies

92. IPA's 2020 submission pointed out that DPIIT has issued draft Copyright (Amendment) Rules, 2019 which amends the Copyrights Rules, 2013. Thus, the highlighted amendment rules expand the scope for statutory licensing, code of conduct for copyright societies, provision for undistributed royalties and provision of an Annual Transparency Report.

93. USTR has stated that "In 2019, the Department for Promotion of Industry and Internal Trade (DPIIT) proposed draft Copyright Amendment Rules that would broaden the scope of statutory licensing to encompass not only radio and television broadcasting but also online broadcasting, despite a high court ruling earlier in 2019 that held that statutory broadcast licensing does not include online broadcasts. If implemented, the Amendment Rules would have severe implications for Internet content-related right holders."

94. As per the office memorandum issued by DPIIT on 5 September 2016, concerning copyright section, internet broadcasting has been under the scope of statutory licensing under 31D section of Copyright Act, 1957 of India.[13] This ensures that the copyright policy is also applicable to internet broadcasting. Further, the amendment replaces words "by the way of radio broadcast or television broadcast", with "for each mode of broadcast", thus including every type of broadcasting service under the scope of statutory licensing. This broadens the copyright framework and will definitely protect the interest of 'internet content-related right holders. Thus, USTR's concerns that implementation of Amendment Rules would have severe implications for Internet content-related right holders, is nullified.

95. The amendment rules are still at a draft stage and the technical members are likely to be appointed as soon as the Amendment rules are adopted. Hence, the concern related to non-functionality of the board will be addressed as soon the rules will be adopted.

f. Effective Use of Commercial Courts Act

96. Judicial enforcement is essential to support legislative measures for safeguarding and promotion of IPR. Indian courts have played an instrumental role in the development of an effective IP jurisprudence in India. The Commercial Courts Act, 2015 was enacted to establish Commercial Courts for the adjudication of commercial disputes in order to reduce the pendency of cases and bolster India's ranking in the Ease of Doing Business Index.

97. The Act stipulates stringent timelines for the disposal of appeals within a period of six months from the date of filing. Because of these timelines, the time spent litigating IP cases has been reduced. Furthermore, in order to alleviate concerns regarding delay in judgements, the establishment of exclusive IP courts is under consideration.

98. The Case Management Hearing system enables the Court to decide and fix a timeline for completion of various stages of trial, like *inter alia* recording of evidence, commencement, and conclusion of oral arguments. The Court has wide powers under this provision to dismiss applications, foreclose right to file pleadings, order payment of costs, etc. These provisions along with the Delhi High Court Rules (2018) have resulted in substantially reducing the time spent in cross-examination.

[13] https://dipp.gov.in/sites/default/files/OM_CopyrightAct_05September2016.pdf

99. In 2018, the Commercial Courts (Amendment) Act, 2018, was passed with the following features:

    a. The pecuniary jurisdiction of commercial courts has been reduced from INR 1 Crore to INR 3 lakhs. This has allowed for the establishment of commercial courts at the district court level in India.
    b. In territories where the high courts do not exercise original jurisdiction, the State Governments have been empowered to designate commercial courts at the District Judge level to exercise powers as mentioned under the Act;
    c. The Amendment mandates pre-institution mediation in cases where no urgent interim relief is sought.

100. This amendment has resulted in increasing the number of commercial courts which are available to parties, thereby reducing the number of cases being handled on a daily roster by judges. This in turn facilitates the speedy disposals of IP cases.

101. Some examples of proactive and positive decisions taken by the Indian Judiciary in IPR cases are listed below:
    a. UTV Software Communication Ltd. v. 1337x.to and OINR
    b. FeridAllani v. Union of India
    c. Monsanto Technology LLC &OINR v. Nuziveedu Seeds Ltd.
    d. Communication Components Antenna Inc. v. Ace Technologies Corp. and OINR

102. Furthermore, arbitration, mediation, settlement, and conciliation are some of the models which are the alternatives to court-based litigation. The Indian judiciary has effectively tried to bring mediation and settlement for intellectual property disputes in the traditional model of litigation, through Section 89 of the Civil Procedure Code, 1908. Even where the alternative dispute resolution methods fail to be the effective choice for the determination of disputes related to intellectual property rights, they can be used for narrowing down the issues for contestability in a traditional model of litigation. Mediation centres have been established at levels from high courts to district courts. Samadhan, a mediation centre of the Delhi High Court, has settled around 660 IPR cases since its establishment in 2006.

103. In view of the increasing number of patent infringement suits filed with the Delhi High Court in the last decade and the technical subject involved, the Delhi High Court has proposed to frame “The High Court of Delhi Rules Governing Patent Suits, 2020”. The proposed Rules aim to streamline the procedure for filing and adjudication of all patent suits and set the contents of the pleadings including the plaint, written statement, counterclaim, and replication. The Rules also prescribe the documents which are required to be filed with the plaint and written statement including the expert reports and laboratory analysis relied upon by the parties. The proposed Rules also set three case management hearings leading the final arguments in the suit and the first case management hearing is proposed for framing of issues based on claim construction briefs, invalidity, and infringement briefs, filed by the parties. The proposed Rules aim to align the Indian suit procedures with international standards.

XI. Concluding Comments

104. India is committed to a strong IP ecosystem and over the years it has taken steps towards strengthening it. The 2020 Report has recognised and acknowledged the progress made by India in its commitment to promote IPR and enhance enforcement. In summary:

- India has consistently been modernizing its IP ecosystem, legislation and has revised the patent rules in 2020. The latest amendments are related to the submission of Priority Documents and Form-27 related to the Statement of Working for a granted patent. The changes have served to streamline the process of patent application with a view of ease of doing business.

- Extensive initiatives have been undertaken by the Government of India to strengthen the significance of IPR in the country through various knowledge sharing platforms, awareness programmes.

105. India has continued to take considerable steps to minimise the time for patent and trademark application. There has been augmentation in technical manpower which has resulted in substantial decline in pendency of IP applications. Examination of patent applications saw an increase to more than four times in FY 2019-20 as compared to FY 2015-16, and a three-fold increase in grants and near two-fold increase in disposal of applications was observed.

- India's judicial system has taken major strides in providing fair and quick justice in IPR cases.

- **Regulatory Data Protection:** India is fully consistent with the TRIPS requirement by protecting undisclosed test or other data which does not require an exclusivity period. We have mentioned that "lack of protection against unfair commercial use" does not make a materialistic difference to US based pharmaceutical companies and suggested that an authentic data driven estimate of extent of actual and potential injury incurred by lack of system against unfair commercial use is required before stating that India does not protect intellectual property rights of US based companies. An exclusivity provision would cause unnecessary delays in patient access to life saving drugs at affordable prices and thus would impact the patient's treatment.

- **Pre-grant Opposition**: We have explained that while the pre-grant opposition adds time to the patent prosecution time, it is less time consuming and less costly than defending the post-grant opposition proceedings. Out of the 426 pre-grant oppositions received, 399 pre-grant oppositions were disposed of during the year showing that the prompt judicial disposal of application is in place. We therefore submit that the concern of pre-grant opposition raised by U.S. companies requires closer inspection.

- **Compulsory Licensing:** There has been no grant of a compulsory license in the last eight years in India. A judicious approach has been maintained by the IP machinery in this regard as the conditions for obtaining these licenses in India are strict. Furthermore, granting of compulsory licenses is in line with the provisions of the TRIPS Agreement. India is therefore justified in exercising its right to issue compulsory licenses.

- **Section 3(d):** Section 3(d) of the Patents Act only limits secondary patents that do not enhance efficacy and typically result in evergreening. Evergreening of patents delays the entry of generic drugs which in turn adversely impacts the accessibility of drugs to the patients across the world.

106. We submit that India has demonstrated strong commitment to IP laws and has been consistently up- grading IPA ecosystem keeping ease of doing business in perspective. There exists a compelling case for the removal of India from the Special 301 Report's Priority Watch List, as India complies with all international obligations related to intellectual property rights. We urge the USTR to consider the removal of India from the Priority Watch List.

107. We thank you for the opportunity to make this submission.