



USTR: 2020 Special 301 Submission

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Submission by

INDIAN PHARMACEUTICAL ALLIANCE

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CONTENTS

	Page No
I. Introduction	1
II. The IPR Environment	
a. Accession to WIPO Treaties	2
b. New Patent Rules	2
c. Positive indications from the Judicial system	3
d. Awareness building initiatives	3
III. Speeding up of Patent and Trademark applications	4
IV. International Co-operation	
a. WIPO treaties	7
b. PPH with Japan Patents Office	8
V. Enforcement	
a. Enforcement actions taken	9
b. Copyright policies	10
c. Online and broadcast piracy	10
d. Border enforcement	11
VI. Regulatory Approvals	
a. Regulatory data protection	13
b. Marketing approvals for follow-on pharmaceuticals	13
VII. Pre-grant opposition	15
VIII. Compulsory Licensing	16
IX. Section 3(d) of the Indian Patents Act	18
X. Other issues	
a. Pharmaceutical pricing policies	20
b. Environment for clinical research	20
XI. Concluding Comments	21

I Introduction

1. This submission is on behalf of the Indian Pharmaceutical Alliance (IPA). IPA's membership consists of twenty five large pharmaceutical companies which collectively account for about 85 per cent of private sector investment in pharmaceutical research and development in India, more than 80 per cent of the country's exports of pharmaceuticals and related services and over 57 per cent of the domestic market. IPA therefore, has a vital interest in the protection of innovations, not only for developing cost-effective and useful improvements to 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. Today, one out of every three tablets sold in the U.S. is supplied by an Indian pharmaceutical company. This sale of generic medicines has resulted in significant savings for the American consumers and the U.S. The use of generics resulted in savings of USD 292.6 billion in 2018. In 2017, the contribution made by Indian companies to these savings was about USD 80 billion.
3. This submission addresses the patent issues relevant to the pharmaceutical industry, which have been noted in the 2019 Special 301 Report prepared by the United States Trade Representative (USTR) (2019 Report). India is one of the 11 countries placed on the Priority Watch List in the 2019 Report. This document seeks to submit information and perspectives that may aid the USTR in determining whether India provides adequate and effective protection of Intellectual Property Rights (IPR) as also fair and equitable market access to the U.S. pharmaceutical industry.

II The IPR Environment

4. The 2019 Report acknowledged a number of key developments and reforms in the field of intellectual property in India. Importantly, India has continued these efforts and made significant progress in the last year towards achieving effective protection of IPR. Some of these developments are: initiatives undertaken by the Department for Promotion of Industry and Internal Trade (DPIIT), Government of India, continued efforts of the Indian Patents Office (IPO) to improve operational efficiency, accession to World Intellectual Property Organisation (WIPO) treaties, and the overall commitment of both government and industry to spread awareness of the value of IPR. These developments are briefly discussed below.

a. Accession to WIPO treaties

5. In 2019, India ratified three WIPO treaties namely the Vienna, Nice and Locarno Agreements¹. These treaties are designed to ease the search for trademarks and industrial designs. This intends to help brand owners and designers in their efforts to obtain protection for their own work.

b. New Patent Rules

6. The Indian Government, over the last several years, has taken numerous steps to revamp the IPR system. There has been a persistent improvement in recent years and further strides have been taken in 2019. DPIIT published the revised Patents (Amendment) Rules on 17 September 2019² based on the suggestions received from the public in respect to the amended draft rules as issued on 5 December 2018. A draft of Patents 2nd Amendment Rules, 2019 was also published for public comments on 18 October 2019³.

The major changes in the Patent (Amendment) Rules are the following:

- (i) The rules mandate the patent agent to file, leave, make or give all documents only by electronic transmission duly authenticated. Further to this, if required, the original document shall be submitted within a period of 15 days. This amendment removes the additional burden of submitting scanned copies of documents that were required to be submitted in original.
- (ii) The rules widen the scope of applicants eligible to file a request for expedited examination. This amendment is an expansion of Rule 24C of Patent Rules, 2003. The IPO through this amendment allows both Indian and foreign applications to apply for expedited patent examinations. Some of the categories added post amendment include small entities; a natural person or in the case of joint applicants, all the applicants are natural persons, then the applicant or at least one of the applicants is a female; departments of the Government; institutions owned or controlled by the Government; institutions wholly or substantially financed by the Government; and those who are eligible for processing a patent application pursuant to an arrangement between the Indian Patent office and the Foreign Patent office. The fast track examination of

¹https://www.wipo.int/portal/en/news/2019/article_0021.html

²https://dipp.gov.in/sites/default/files/Patents_Amendment_Rules2019_23September2019.pdf

³https://dipp.gov.in/sites/default/files/draft_PatentRules_2003_23October2019.pdf

patent applications and the early grant of patents will motivate applicants.

c. Positive Indications from the Judicial System

7. Indian courts have granted interim injunctions in the matters related to patents. In the 2019, Delhi High Court granted numerous injunctive reliefs to innovator companies. To name a few, injunctive relief was granted for AstraZeneca's blockbuster drug Ticagrelor, Novartis's globally used drug product for heart failure sold under the name of Entresto containing combination of Sacubitril/valsartan, Bristol Myers Squibb's multibillion generating product, Apixaban, and Lundbeck's antidepressant drug, Vortioxetine.

d. Awareness building initiatives

8. The 2019 Special 301 Report noted that "The Cell for Intellectual Property Rights Promotion and Management, established under the Department of Industrial Policy and Promotion to move forward implementation of the National Intellectual Property Rights Policy, continues to spearhead efforts successfully to promote IP awareness, commercialization, and enforcement throughout India and undertook new and collaborative efforts in 2018."

IPR promotion and awareness has been achieved by a number of initiatives in schools and colleges. Many of these were explained in the 2018 and 2019 submissions of IPA⁴.

Continuing these efforts to create a stronger ecosystem of IPR within India, some new initiatives undertaken are as follows:

- i. The IP processes have been restructured to facilitate the growth of innovative start-ups and to build a strong IPR ecosystem. An 80 per cent rebate is provided to start-ups on patent filing fees. There is also a provision to avail the special facility of expedited examination of their patent applications. As of 31 December 2019, 781 start-ups have submitted requests for expedited examination under Rule 24(C) of Patent (Amendment) Rules 2016. The first examination report has been issued in case of 667 applications and 268 patents have been granted.
- ii. The Cell for Intellectual Property Rights Promotion and Management (CIPAM), in collaboration with the Ministry of Micro, Small and Medium Enterprises (MSMEs), Government of India, organized five day intensive IPR trainings for MSME Officers across India. These trainings will enable

⁴IPA 2018 Submission paras 4-6 and IPA 2019 Submission paras 11-12

these officers to provide IPR related services to MSMEs. Five such trainings have been conducted so far.

- iii. CIPAM has prepared a Trade Secret Toolkit to guide Indian businesses especially MSMEs and Start-ups regarding protection of trade secrets.
 - iv. A scheme for facilitating Start-ups Intellectual Property Protection (SIPP) has been launched to encourage innovation and creativity of start-ups. The scheme is in force up to 31 March 2020.
 - v. A draft has been notified for public comments on “Model Guidelines on the Implementation of IPR Policy for Academic Institutions”.⁵ This is in line with the National IPR objective of encouraging the formulation of an IP Strategy in Higher Education, Research & Technical Institutions. The guidelines provide detailed provisions for ownership, commercialization and encourage entrepreneurship at the institutional level.
 - vi. Over 140 IPR awareness workshops for various MSME clusters have also been conducted by CIPAM.
 - vii. An online IP Learning Platform-L2Pro has been launched in collaboration with National Law University, Delhi and Qualcomm. This would provide students and industry (especially SMEs) an easily accessible IP learning forum.
9. Additionally, India advanced 5 spots in 2019 to be ranked 52nd out of 129 countries on the Global Innovation Index co-published by Cornell University, INSEAD, and WIPO⁶.

III Speeding up of Patent and Trademark Applications

10. The 2019 Special 301 Report acknowledged the progress India has made in speeding up of patent and trademark applications. However, the report also stated that “India has yet to take steps to address long-standing patent issues that affect innovative industries.” It goes on to state that “Furthermore, patent applicants face costly and time-consuming patent opposition hurdles, long timelines for receiving patents, and excessive reporting requirements including long timelines for receiving patents”.

⁵https://dipp.gov.in/sites/default/files/Draft_Model_Guidelines_on_Implementation_of_IPR_Policy_for_Academic_Institutions_09092019.pdf

⁶https://dipp.gov.in/sites/default/files/pressRelease_24July2019_0.pdf

11. In this regard, we submit that India continues to pursue significant steps in the administrative domain to reduce the time for processing patent and trademark applications and digitize the process for registering a copyright. We had outlined the key administrative measures that had been initiated in our 2018 Submission as well⁷. Technical manpower has been augmented manifold leading to a tremendous decline in pendency of IP applications. For instance, the number of patent applications pending for examination has gone down by over 42 percent in the past four years (from 197934 in March 2016 to 112856 in March 2019).

12. These steps have yielded tangible results as explained in the table below:

1. PATENT APPLICATION PROCESS

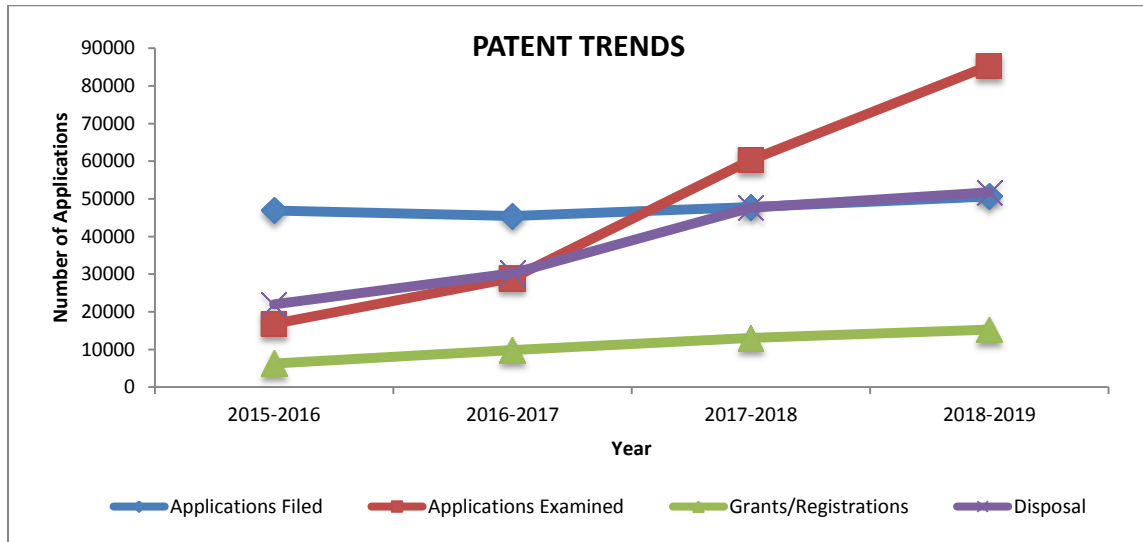
	FINANCIAL YEAR (FY)				% Change FY 2018-19 Vs 2015 -16
	2015- 2016	2016- 2017	2017- 2018	2018- 2019	
Applications Filed	46904	45444	47854	50688	8
Applications Examined	16853	28967	60330	85436	407
Grants/Registrations	6326	9847	13045	15284	142
Disposal	21987	30271	47695	51781	136

Source: CIPAM

The number of patent applications examined, increased substantially in FY 2018-2019 in comparison to FY 2017-2018. The number of applications filed i.e. 50688 kept pace with the number of applications disposed (grants, refusals, withdrawals, abandonments) i.e. 51781. Number of Grants/Registration increased to 15284 from 13045 in FY 2018-2019. The examination of applications has thus increased by more than 5 times whereas there has been a more than two fold increase in grants and disposal.

⁷ IPA 2018 Submission paras 12-18

13. The patent trend from 2015 to 2019 can be seen in the graphical representation given below.

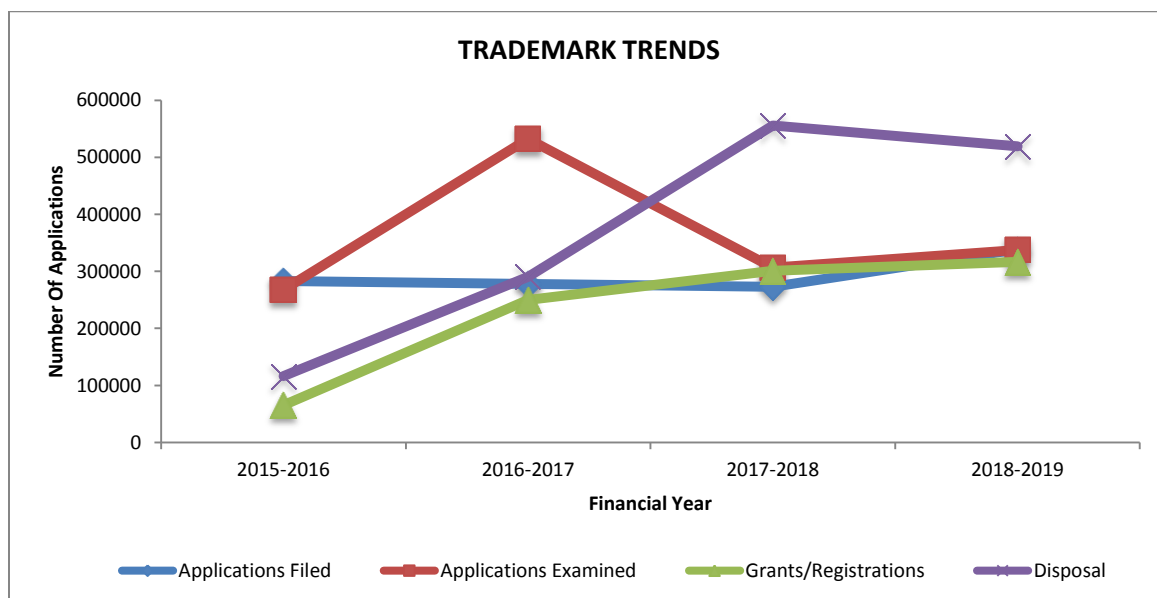


2. TRADEMARKS

	FINANCIAL YEAR (FY)				% Change FY 2018-19 VS 2015-16
	2015-2016	2016-2017	2017-2018	2018-2019	
Applications Filed	283060	278170	272974	338542	20
Applications Examined	267861	532230	306259	337541	26
Grants/Registrations	65045	250070	300913	316798	387
Disposal	116167	290444	555777	519185	347

Source: CIPAM

14. It was observed that the IPO examined nearly all applications filed in FY 2018-2019. The number of applications filed in FY 2018-2019 increased to 338542 from 272974 in FY 2017-2018 and the number of applications filed also increased considerably from 306259 to 337541 in FY 2018-2019. The disposal of application is up by more than four times.



IV International Co-operation

a. WIPO accession

15. In 2019, India ratified three WIPO treaties namely the Vienna, Nice and Locarno Agreements. The WIPO Director General appreciated India's decision and deep engagement in the WIPO and in the international intellectual property system. He also acknowledged that India has been extremely active in the field of intellectual property and in international cooperation in this field in recent years⁸. It is believed that this is a major step in improving India's IPR competitiveness. The three treaties are:

- i. Vienna Agreement establishing an international classification of the figurative elements of marks. This facilitates trademark anticipation searches and avoids substantial reclassification of work when documents are exchanged at the international level. India became the 34th member of this agreement.

⁸ https://www.wipo.int/portal/en/news/2019/article_0021.html

- ii. Nice agreement concerning the international classification of goods and services for the purposes of the registration of marks. It is a vital tool establishing a classification of goods and services for registering trademarks and service marks. India became the 88th member of this agreement.
- iii. Locarno Agreement establishing an international classification for Industrial designs. India became the 57th member of this agreement.

It is evident that these Agreements would enable the IP offices in India to harmonise the classification systems for examination of trademark and design application, in line with the international classification system. It is noteworthy that India has been increasingly taking steps to align itself with global templates such as WIPO, while the U.S is yet to accede to two of these three treaties (Locarno and Vienna Agreements).

b. PPH with Japan Patents Office

16. Patent Prosecution Highway (PPH) is a set of initiatives for providing accelerated patent prosecution procedures by sharing information between the patent offices of the signatory countries.
17. The 2019 Submission of IPA mentioned an agreement between the Japan Patents Office (JPO) and IPO in the second quarter of 2018 to start a bilateral Patent Prosecution Highway program on a pilot basis in certain identified fields of invention, subject to completion of necessary formalities.⁹The bilateral PPH commenced between the two offices on 5 December 2019. A procedure guideline document for patent prosecution highway has been published on the website of Controller General of Patents, Designs & Trade Marks.¹⁰ The guidelines address the procedures required to request expedited examination.
18. The IPA's 2019 submission also made a note of an amendment in the India's Patent Rules¹¹, which was the legislative change concerning expedited patent examination. To further facilitate in this process, Patent Rules have been suitably amended, in this regard.
19. We trust that the USTR has taken note of this development.

⁹ IPA 2019 Submission para 28

¹⁰http://www.ipindia.nic.in/writereaddata/Portal/News/591_1_PPH_Procedure_Guideline_combined_20191128_final.pdf

¹¹IPA 2019 Submission para 29

V. Enforcement

a. Enforcement actions taken

20. Customs officers in India have ex-officio authority to seize and destroy counterfeit goods, though rights holders must pay for storage and destruction of counterfeit materials. In the past few years, with regular training, customs and police enforcement has increased.
21. The new customs recording system allows trademark owners to record their brands and trademarks with the ministry and seek affirmative action in case of any counterfeit issue at the ports.
22. As per reports, customs departments across the Indian ports, seized fake goods worth USD 8million being imported from China last year.
23. To aid in capacity building for enforcement of IPR, the following steps have been taken:
 - i. So far, 87 training programs on IP Enforcement have been conducted by CIPAM for various law enforcement agencies (Police, Judiciary and Customs), across India in association with IP experts from law firms and the industry. In addition, an advisory has been issued by the Ministry of Home Affairs to all State Police Academies to incorporate IPR in their training curriculum for police officers.
 - ii. CIPAM is collaborating with National Academy of Customs, Indirect Taxes & Narcotics (NACIN) for training custom officials on 'Intellectual Property Rights: Scope, Importance and Objective'. In this regard, 13 training programs have been organized so far. Additionally, training of Judges on IP Enforcement and adjudication has also been undertaken in collaboration with the National Judicial Academy. CIPAM is also in touch with various State Judicial Academies for conducting training programs for Judges at district and lower courts.

b. Copyright Policies

24. In May 2019, DPIIT issued draft Copyright (Amendment) Rules, 2019¹² amending the Copyrights Rules, 2013. The key amendments made to the rule are the expansion of scope for statutory licensing, code of conduct for copyright societies, provision for undistributed royalties and provision of an Annual Transparency Report.
25. The draft replaces the 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 bring in more transparency and accountability in copyright issues.
26. USTR’s concern related to a ‘not fully functional’ copyright royalty board is also addressed in the rules. The amendment lays down the scheme for copyright society for undistributed royalties when the owner could not be identified or located.
27. Further, the rules require the copyright society to provide an Annual Transparency Report, which covers information on report on the activities in the financial year; refusals to grant a license, details of the structure of copyright society, financial information on royalties, and information on relationships with the foreign societies or organisation. The amendment will also digitize certain provisions like payment of fee, mode of communication and application which were carried out by only offline procedures earlier.

c. Online and broadcast piracy

28. In IPA’s 2019 submission, the concern of U.S. stakeholders regarding camcording originating in Indian cinemas was addressed by mentioning the draft amendment to the Cinematographic Act that was published for public comments in January 2019¹³. The Act establishes provisions for exacting penalties for offences like exhibition of a film that has not been certified for public exhibition and tampering with a film after it has been certified. In February 2019, the Union Cabinet approved the proposal of introducing the Cinematograph (Amendment) Bill, 2019. This Bill was introduced in the upper house of the Parliament (Rajya Sabha) on 12 February 2019. It was referred to a Parliamentary Standing Committee on 4 October 2019. Further action would be initiated after the

¹²https://dipp.gov.in/sites/default/files/Draft_Copyright_Amendment_Rules_2019.pdf

¹³IPA 2019 Submission Para 9

Committee submits its report.¹⁴ The Amendment Bill allocates for unauthorised recording and prohibits a person from using a recording device to make a copy or transmit a film, without written authorisation from the producer of the film. As per the Bill, the persons who make copies of a film without authorisation will be penalised with imprisonment of up to three years, or a fine of up to Rs 10 lakh, or both.

29. To counter online piracy, CIPAM collaborated with National Internet Exchange of India (NIXI) and Maharashtra Cyber and Digital Crime Unit (MCDCU), to suspend over 380 infringing websites on the basis of incomplete Know Your Customer (KYC) (or WHOIS norms).

d. Border enforcement

30. The 2019 Special 301 Report referred to two publications, “Trends in Trade in Counterfeit and Pirated Goods,” a 2019 publication produced by the Organisation for Economic Co-operation and Development (OECD), and “Mapping the Real Routes of Trade in Fake Goods,” a 2017 report from the OECD and the European Union Intellectual Property Office (EUIPO), when suggesting India’s border enforcement against counterfeit and pirated goods is ineffective.
31. The 2019 OECD publication, among other findings, states that India is among the top five provenance economies for counterfeit goods, while the second publication (from 2017), alleges India to be a key producer and exporter of counterfeit foodstuffs, pharmaceuticals, perfumes and cosmetics, textiles, footwear, electronics and electrical equipment, toys, games, and sporting equipment.
32. The 2017 publication also states that 55 percent of global seizures of counterfeit pharmaceuticals, by total value, originated in India and that these counterfeit pharmaceuticals are shipped “around the globe, with a special focus on African economies, Europe, and the United States.” We would like to submit that this statement is based on data gathered by OECD and EUIPO on global customs seizures between 2011 and 2013. India, on the other hand, has more recent data to suggest that only 3 percent of the total drugs sold which originate from India are of substandard quality.¹⁵ Furthermore, the 2019 OECD publication also mentions that between 2011-2013 and 2014-2016, the top 20 industries which are affected by counterfeiting changed. The new list no longer features pharmaceuticals (HS Code 30) among the top 20 affected industries. This also lends credence to the argument that the 2017 report and its claims may be disregarded as they are derived from old data.

¹⁴ The Cinematograph (Amendment) Bill, 2019 - PRS Legislative Research

¹⁵ The Survey of Extent of Problems of Spurious and Not of Standard Quality Drugs in the Country, 2014-2016

33. In addition to this, the 2019 OECD publication 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”.
34. According to 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 following the orders of the Ministry of Health and Family Welfare, the proportion of substandard drugs has been pegged at about 3 percent of the total drugs sold, while about 0.28 percent was found to be spurious. During the survey, about 47,954 samples were collected from the government hospitals, dispensaries, and pharmacies. According to the survey, there has been some improvement in the situation over the time.
35. Moreover, the findings of the survey clearly show that counterfeit drugs do not originate from India as has been alleged by Special 301 Report quoting the aforementioned OECD and OECD-EUIPO publications. The study notes that “None of the samples drawn from Air/Sea Ports were found to be of Not of Standard Quality (NSQ) or Spurious.”
36. Therefore, we suggest that the USTR to remove this language from 2020 Special 301 Report.

VI. Regulatory Approvals

37. PhRMA expressed concern in their 2019 Submission relating to Section 8 of the Indian Patents Act under the heading of ‘Administrative Burdens’:
 - i. ‘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.’
38. As discussed in our 2019 submission as well¹⁶, the requirements of Section 8 are applicable to all patentees, including Indian patentees. Furthermore, several countries have a requirement to furnish information on request, similar to

¹⁶IPA 2019 submission paras 39-40

Section 8(2). Therefore the concerns are not well founded. Furthermore, the Courts have held that non-compliance of Section 8 requirement will not lead to an automatic revocation of its patent under Section 64(1)(m).^{17 18} It is noteworthy that as per the decision, it is necessary to check whether the non-disclosure of information under Section 8 was deliberate/ intentional or whether it was a mere clerical/ bona fide error.

a. Regulatory Data Protection

39. The 2018 and 2019 Special 301 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’. Our previous submissions mentioned that, 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 such a system is required before stating that India does not protect intellectual property rights of US based companies.

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 test or other data which does not require an exclusivity period.

b. Marketing approvals for follow-on pharmaceuticals

41. The 2019 Report voiced concern over the alleged ‘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’. It has already been mentioned in IPA’s submission in previous years that India does not have analogous provisions like the Orange Book and the Hatch Waxman provisions whereby an applicant seeking marketing approval for a generic drug is mandatorily 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.

¹⁷ *Koninklijke Philips Electronics vs Maj. (Retd) Sukesh Behl & Anr.*, Delhi High Court, CS 2206/2012

¹⁸ *F-Hoffman-La Roche Ltd. v. Cipla Ltd.*, Delhi High Court, CS (OS) No.89/2008 and C.C. 52/2008

42. We have also pointed out in 2019 submission about many countries, like in the European Union that do not have a provision for ‘patent linkage’.¹⁹ There are considerable reasons for India to not follow the U.S. model. If a patent is eventually found invalid or non-infringed, the delays due to holding up marketing authorization of generics during the term of the patent would cause injury to patients which cannot be compensated. Also, there have been a few instances where any Indian company seeking to launch a generic version before the patent term is over has been challenged and the Courts have intervened to ensure that the patent owner’s interests are adequately protected.
43. We submit that the USTR should reconsider whether ‘irreparable harm’ is being caused to the patent holder without a formal system of notification. In India, the pharmaceutical manufacturers are informed about the potential launches of generic drugs through routine commercial intelligence, thus in our understanding, lack of a formal system is of little significance.
44. The Indian system provides rights to a patent holder to sue a generic manufacturer who intends to manufacture a potentially patent-infringing commodity. 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. 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:
- i. In the year 2017, the pharmaceutical company Merck Sharp & Dohme Corporation & Anr. filed a case against Aprica Pharmaceuticals Private Limited for the infringement of their Indian Patent No.209816.²⁰ The patent was on drug “SITAGLIPTIN”. The plaintiff was against the launch of “ECOGLIPT” in the Indian market, which is the generic version of “SITAGLIPTIN”. Although at the time of filing the case, the infringing product “ECOGLIPT” was not commercially launched in the Indian market. The activities of defendant were prohibited under the Section 48, Indian Patent Act, 1970. The suit was in favor of plaintiff granting permanent injunction. The plaintiff was given addition liberty to file the exact amount of money incurred in the judgment process.
45. Thus, it is evident that the judicial system in India continues to enforce the IP Rights of the Patent holders and is considering various options to safeguard the interests of the patent holders.

¹⁹IPA 2019 submission para 79

²⁰ *Merck Sharp & Dohme Corporation & Anr. v. Aprica Pharmaceuticals Private Limited*, Delhi High Court, CS (OS) 1236/2013

VII. Pre-grant opposition

46. The 2019 Special 301 Report says that the ‘patent applicants face costly and time-consuming patent opposition hurdles’. This concern has been addressed by IPA in 2019 submission²¹. We have categorically cited provision in the legislation to this effect. Furthermore, if pre-grant oppositions continue to be characterized as a concern by U.S. industry in their 2020 Submissions, we submit that the issue calls for further 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. We had cited examples of this in IPA’s 2019 submission²² - “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”.
47. It is therefore reiterated that the India’s Patent Act has been amended several times in order to make the rules TRIPS compliant. The Act has been upheld by the Supreme Court of India as being compliant with the provisions of TRIPS.
48. 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. Pre-grant opposition provides opportunity of quick assessment for patentability for the patent application. The Patents Act of India has provisions for the delay caused due to the pre-grant oppositions, where a professed infringer will be accountable for the damages from the date of publication of the patent application. Whereas, in the U.S., the right to sue for infringement commences only on grant of the patent.
49. There is a possibility rather than pre-grant oppositions, delays in patent examination times can be attributed more to manpower and administrative limitations. However, as these limitations were addressed, there has been a substantial increase in the number of patent applications examined and disposed.

²¹ IPA 2019 Submission para 31

²² IPA 2019 Submission para 34

It may also be noted that the delays are not only on account of the government and may also be due to a failure on part of applicants to provide necessary information. We therefore submit that the concern of pre-grant opposition raised by U.S. companies require closer inspection.

VIII. Compulsory Licensing

50. The IPO has so far granted only one Compulsory License (CL) to Natco Pharma Ltd. for producing the generic version of Bayer Corporation's 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.
51. We urge USTR to take note that the Indian Patents Office, displaying careful scrutiny, 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."
52. The controller has so far rejected the grant of compulsory licenses on various grounds; first, failing to prove prima facie case, second, not applying for a license of patent prior to applying for compulsory license and the third, failure to prove public use of the product sought to be used by the compulsory license.
53. Patents on pharmaceutical products allow for monopolistic pricing, which often puts them out of reach of those who need them the most. Moreover, India has an international obligation to ensure that all its citizens are guaranteed the right to health set out under Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR). Consequently, compulsory licenses may prove to be a useful tool for ensuring access to affordable life-saving drugs.
54. It is imperative to note here that the practice of compulsory licensing is prevalent in foreign jurisdictions as well. CLs have been used as a tool against anti-competitive activities & enforcement of affordable commodities globally. Countries like Canada, Germany, Malaysia, Thailand, Brazil and Ecuador, among others have all been known to issue CLs. India, has actually been extremely judicious in the use of this flexibility granted under the TRIPS Agreement. This is to demonstrate that the use of compulsory license as a tool to achieve universal health coverage is definitely a global practice and the argument is not meant to be construed as justification for widespread use of compulsory licensing unlike how originator industry associations such as PhRMA interprets in its 2019 submission.

55. As per a High-Level Panel on Access to Medicines constituted by the UN in November 2015 to review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies, some recommendations have been made²³. The recommendations are as follows:

- i. WTO members must make full use of TRIPS flexibilities as confirmed by the Doha Declaration to promote access to health technologies when necessary.
- ii. WTO members should make full use of policy space available in Article 27 of TRIPS agreement by adopting and applying rigorous definitions of invention and patentability that are in interests of country's public health and its inhabitants. This includes amending laws to curtail patents ever-greening & awarding patents only when genuine innovations occur.
- iii. Governments should adopt or implement legislation that facilitates issuance of CLs. The use of CL should be based on provisions found in Doha Declaration and grounds for issuance left to discretion of the governments.
- iv. Governments engaged in bilateral and regional trade and investment treaties should ensure that these agreements do not include provisions that interfere with their obligations to fulfil the rights to health.
- v. Governments and the private sector must refrain from explicit or implicit threats, tactics or strategies that undermine the right of WTO Members to use TRIPS flexibilities.

56. 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.

²³<https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf>

IX. Section 3(d) of the Indian Patents Act

57. The 2019 Special 301 Report states that, “In the pharmaceutical sector, Section 3(d) of the India Patents Act restricts patent-eligible subject matter in a way that fails to properly incentivize innovation that would lead to the development of improvements with benefits for Indian patients.”

58. Section 3(d) reads as follows:

“The following are not inventions within the meaning of this Act:

(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.”

59. This provision aimed at weeding out the practice of ‘evergreening’, an egregious industry trend of effectuating trivial tweaks to patented drugs, and then claiming secondary patents on such tweaks to prolong the patent monopoly. The extent of evergreening being practiced by the innovators can be gauged from a report published by I-MAK (Initiative for Medicines, Access, and Knowledge) in 2018 on the patent estate covering Humira®(adalimumab) by AbbVie.

According to the report,

“For Humira specifically, development began in 1993 through a joint venture, with initial patents filed in 1994. The biologic was subsequently approved by the FDA in 2002. To date, Humira is covered by 247 total patent applications in the United States. The report notes that 89% of these applications were filed in the United States after Humira was already on the market, and 49% were filed after the first patent expired in 2014.”

Interestingly, the report also found that - “Comparatively, the number of patent applications filed on Humira to date at the European Patent office is only 76. “What is noticeable from the European Patent Office data compared to the [United States] is that a number of AbbVie’s patent applications after 2002 that would have significantly extended its monopoly were either withdrawn, refused during examination, or revoked after patent challenge,” said the report.

60. Thus, other countries have also been taking measures through their patent system to stop the process of evergreening which seriously hampers access to affordable medicines.
61. The section 3(d) was effectively derived from a European drug regulatory directive. Part II, Annex 1 to Directive 2001/83/EC states that generic substances must also contain the same therapeutic moiety as the innovative substance. If that is not the case, the substance shall be considered a new active substance.
62. PhRMA, in its 2019 submission also noted with concern “the expanded application of patentability exceptions” (restrictive patentability criteria). It states that “Section 3(d) of the Indian Patents Act as amended by the Patents (Amendment) Act 2005 adds a criterion of “enhanced efficacy” to the TRIPS requirements”. The TRIPS requirements referred to here are: invention must be *new*, involve an *inventive step*, and be capable of *industrial application* (Article 27). However, none of these terms used in this provision have been defined, leaving some flexibility in the hands of signatory members to suitably provide for balancing innovation and access to affordable medicines. More specifically, it may be argued that a claimed substance that falls foul of the section 3(d) threshold is not an ‘invention’ within the meaning of Article 27.
63. India understands that Intellectual property regimes are meant to capture a careful balance between a private monopoly right that incentivises innovation, and an equally compelling public interest in accessing the innovation at affordable rates. However, considering the political and socio-economic climate of India, the provision of 3(d) is necessary to prevent the practice of evergreening.
- Furthermore, it is important to note that concerns about evergreening in the United States have prompted Democratic and Republican lawmakers to consider reforms to U.S. patent law that would inhibit this process²⁴.
64. Section 3(d) is essentially an enabling provision in that it states that patent applications for certain types of inventions and that satisfy the requirements laid down in the provision (for e.g. exhibiting enhanced therapeutic efficacy over the form from which it is derived) will be patent eligible. It is for the patent holder to demonstrate to the patent office that the invention satisfies the requirements of this section. So, the argument that Section 3(d) impairs grant of patents to certain class of invention is not correct. For example, patents have been granted to inventions claiming alternate polymorphic forms of several compounds which have satisfied the requirements of Sections 3(d).
65. Consequentially, we submit that the India’s Section 3(d) is TRIPS-compliant.

²⁴ <https://www.cornyn.senate.gov/content/news/cornyn-blumenthal-introduce-bill-prevent-drug-companies-abusing-patent-system>

X. Other issues

a. Pharmaceutical Pricing Policies

66. Concerns have been raised over the “broad authority granted to National Pharmaceutical Pricing Authority (NPPA)”, stating that it does not adhere to the need for transparency, predictability, and trust in the decision-making process. 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 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. Thus these concerns are misplaced.

67. Further, their concern over these decisions hindering investment in India is unfounded as the FDI flows into the pharmaceutical sector has increased in 2019 as compared to the previous year. The FDI inflow in 2018 was USD 266 million, while in 2019 it was USD 297 million, and it is among the sectors witnessing the highest FDI equity inflows in India.²⁵

Customs duties directed to IP-intensive products

68. The 2019 Special 301 Report raised concern for high custom duties on IP intensive products. The issues was not mentioned in earlier reports, however the custom duties have been the same from last few years. Further, it has been same for the patented as well as well the generic drugs.

b. Environment for clinical research

69. In March 2019, the Ministry of Health and Family Welfare, Government of India (MoHFW) issued “New Drugs and Clinical Trials Rules”, 2019²⁶ with an aim to promote clinical research in the country. The following provisions has been made in this rule:

70. The new rule will allow the organization intended to conduct clinical trials to make an application to Central Licensing Authority (CLA). The decision (regarding the acceptance/rejection/need to rectify) will be communicated to the concerned person in 90 working days from the day of receipt of application.

²⁵ https://dipp.gov.in/sites/default/files/FDI_Factsheet_September2019_01January2019.pdf

²⁶ https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf

71. Additionally, for drugs discovered in India and research and development being done in India, the decision will be passed in 30 working days from the day of receipt of application. It has been clearly stated in the rule that if the decision is not provided in the specified time period, then the permission is deemed to be granted by CLA and the organization is legally authorized to initiate clinical trials with the prior information provided to the CLA.
72. This new rule addresses concerns over uncertainty related to definition of “trial related injury,” “standard of care,” and “medical management”. As per the new rule, financial compensation will be made to the trial subject in case of any injury (permanent or temporary) or death by the sponsor or representative who has obtained permission to conduct the clinical trial. In addition to this medical management expenses will also be incurred by the sponsor.
73. The issue of clinical trial waiver has also been addressed under rule 24 of chapter V of the new rules. The stated rule will consider the drug for waiver of local clinical trials if already approved and marketed outside India in the countries mentioned in rule 101.

XI. Concluding comments

74. Based on the information provided above, it is clear that India has made significant progress in establishing a strong IP- ecosystem. In view of this, we respectfully submit that there is a case for reviewing the continuance of India on the Priority Watch List. In summary:
 - i. **Administrative improvements in patent issue:** 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. The examination of patent applications has increased by more than five times and there has been a more than two fold increase in grants and disposal. In the past four years, the number of patent application pending for examination has been brought down by over 42 percent. Nearly all the trademark application filed in FY 2018-2019 were examined. The disposal of trademark applications has been up by more than four times.
 - ii. **Developments in Patent regime:** Revised Patent Amendment Rules, 2019 have been published by DPIIT which have widen the scope of applicants who can request expedited examination. This amendment has also removed the additional burden of submitting scanned copies of documents that were required to be submitted in original.

- iii. **Pre-grant opposition:** Pre-grant opposition is less time consuming than defending the post-grant opposition proceedings. There is a possibility rather than pre-grant oppositions, delays in patent examination times can be attributed more to manpower and administrative limitations. It may also be noted that the delays are not only on account of the government and may also be due to a failure on part of applicants to provide necessary information. We therefore submit that the concern of pre-grant opposition raised by U.S. companies require closer inspection.
- iv. **Compulsory Licensing:** There been no grant of a compulsory license in the last seven years in India and the IPO has maintained a judicious and cautious approach in its decisions on applications for compulsory licenses. Nevertheless, 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.
- v. **Section 3(d):** It has been made clear that Section 3(d) of the Patents Act only limits secondary patents that do not enhance efficacy and typically result in 'evergreening'.
- vi. **Regulatory Data Protection:** It has been explained that India is fully consistent with the TRIPS requirement by protecting undisclosed test or other data which does not require an exclusivity period. We have also 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.
- vii. **Copyright Policy:** DPIIT, Government of India has issued a draft Copyright (Amendment) Rules, 2019. This amendment will expand the framework for statutory licensing and thus will bring in more transparency in copyright issues. The issues like non- functionality of royalty board, have been resolved as the rules lays down the whole scheme for the undistributed royalties. The provision of providing Annual Transparency Report will further allow for a review of the activities of copyright society.
- viii. **Pharmaceutical Pricing Policies:** NPPA's role and responsibilities have been properly explained, and it has been established that it is functioning in a transparent manner. Furthermore, the data of FDI inflows makes it

evident that there is no hindrance to investment in India because of the pricing decisions in India.

- ix. **Environment for clinical research:** MoHWF, Government of India issued “New Drugs and Clinical Trials Rule”, 2019 with an aim to promote clinical research in country. The new rule will help the organization to get faster approval to conduct clinical trials. The concerns over uncertainty related to the definitions for “trial related injury,” “standard of care,” and “medical management” is addressed in the rule. Furthermore, the issue of clinical trial waivers has also been addressed in the rule.

75. We therefore submit that a compelling case already exists for the removal of India from the Special 301 Report’s Priority Watch List as India complies with all international obligations on intellectual property rights. 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.

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