USTR: 2022 Special 301 Submission

(Docket No. USTR-2022-0016)

Submission by

INDIAN PHARMACEUTICAL ALLIANCE

Mumbai

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1. INTRODUCTION

1.1 This submission is being made on behalf of the Indian Pharmaceutical Alliance (IPA). IPA is an association consisting of twenty-four leading Indian pharmaceutical companies, which account for more that 85 percent of India's private sector investment in pharmaceutical research and development. Further, IPA member companies contribute to more than 80 percent of the exports of drugs, and services over 60 percent of the domestic market in India. IPA therefore has a vital interest in the protection, promotion and the perseverance of innovations. The focus of IPA is not only the development of cost-effective and useful improvements to existing medicines, but it also extends to the discovery of novel medicines.

1.2 IPA member companies are committed to providing safe and effective drugs to all consumers in the U.S. and across the globe in an efficient manner. The U.S. and India are both manufacturing hubs for the member companies of IPA. During the Covid-19 pandemic, IPA member companies have shown commitment by continuously supplying quality-assured medicines both in domestic as well as international markets. The Indian pharmaceutical industry is contributing approximately 40 percent of the generics in the U.S[1]. These large Indian pharmaceutical companies have played a critical role in U.S. healthcare in the past few years.

In the year 2021, generics and biosimilars accounted for 91 percent of prescriptions filled in the U.S., at only 18.2 percent of the drug expenditure, and 3 percent of the overall healthcare expenditure[2].

1.3 As mentioned above, in the past few years, the trade with respect to pharmaceuticals between India and the U.S. has been of great significance. Especially during the Covid-19 pandemic, India has been instrumental in providing affordable and quality-assured medicines and vaccines throughout the world, so much so that it has been continually dubbed the pharmacy of the world. Indian pharmaceutical companies have worked to develop generic drugs which has helped the U.S. and cater to the demand of the U.S. healthcare. As a result of generic medicines, consumers in the U.S. have a better and wider access to affordable medicines and pharmaceuticals, helping the U.S. Healthcare system save approximately USD 2.6 trillion over the last decade, with USD 373 billion savings in 2021 alone. Yearly savings due to generics have consistently increased by 7 to 10 percent[3].

1.4 Furthermore, the Special 301 Report is a system that was established before the adoption of the World Trade Organizations (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement). India has over the years, vide various amendments to its Intellectual Property Rights (IPR) laws, ensured that they are conforming to the provisions of TRIPS.

[1] https://www.ibef.org/industry/indian-pharmaceuticals-industry-analysis-presentation
[2] 2022, Generic Drug & Biosimilars Access & Savings in the U.S. Report
[3] 2022, Generic Drug & Biosimilars Access & Savings in the U.S. Report

1.5 IPA has been making submissions to the United States Trade Representatives (USTR) with respect to the Special 301 Report for several years, highlighting India's effective IPR ecosystem, and the progress of the IPR regime in India. The present Special 301 Report (Special 301 Report, 2022) raises concerns with respect to the time-consuming process of patent grants in India, narrow patentability criteria, the protection and enforcement of IPR, and issues relating to counterfeit goods among others. This year, India is one of 7 countries on the Priority Watchlist.

1.6 The present submission to the Special 301 Report, 2022, addresses the issues raised by the United States Trade Representative (USTR) which are particularly relevant to the pharmaceutical industry, and touches upon other IPRs relevant to the pharmaceutical industry such as patents. The submission addresses and summarizes a range of important developments undertaken by the Government of India, the Indian judicial system and other stakeholders to strengthen and modernize India's intellectual property ecosystem. It seeks to submit information and perspectives that articulate that India provides adequate and effective protection of IPR, and fair and equitable market access to the U.S. pharmaceutical industry. Hence, the IPA submits that India should no longer be placed on the Priority Watch List through the Special 301 Report process.

2. DEVELOPMENTS IN THE IPR SYSTEM IN INDIA

2.1 GENERAL DEVELOPMENT

2.1.1 There have been various developments in the past few years with respect to intellectual property law enforcement and protection in India.

2.1.2 It is pertinent to note that the Patents Act, 2005, (Indian Patents Act) and the Patent Rules, 2003, (Patent Rules) have undergone various amendments throughout the years in order to align Indian patent practices with the international standards. The amendments that have taken place have significantly shortened the disposal process and expedited the grant and examination process. In the last five years, the Patent Rules have been amended thrice, in 2019, 2020, and 2021. In 2019, the amended Patent Rules mandated that all documents to be filed were to be in electronic form and expanded the categories of applicants that were eligible to file requests for expedited examination, including Indian and foreign small entities, start-ups, and so on. Further, in 2020, the Patent Rules were amended to include a six-month period from the end of each financial year, wherein the filing of patent information under form 27 of the Indian Patents Act (Form-27) has to be completed. The latest amendment to the Patent Rules came into force on 21 September 2021, wherein educational institutions were made eligible for reduced fees, thereby promoting creation and innovation in the educational sector.

2.1.3 The Indian Patent Office (IPO) recently issued a public notification dated 16 January 2023[4], stating that in order to expeditiously dispose of pre-grant oppositions as well as post-grant oppositions, no party shall be given more than two adjournments of hearings, and that each adjournment shall be for not more than 30 days, whereas the inner limit for adjournments has been fixed at 10 days. Another public notification published on the same day, i.e., 16 January 2023[5], states that no adjournment can be sought by any party without mentioning "reasonable cause" for the same, and that adjournments filed without reasonable cause will not be entertained. In accordance with the aforementioned, it can be clearly seen that the IPO is taking adequate steps in order to ensure that patent proceedings that have been pending disposal are sped-up, and that the issues relating to hearings and adjournments are streamlined.

2.1.4 As mentioned in IPA's submissions to the USTR in 2021, the Intellectual Property Appellate Board (IPAB) was abolished. The same was due to operational difficulties faced by the IPAB, which consequently resulted in some delays.

2.1.5 Due to the abolishing of the IPAB, various IPR appeals were transferred to the High Courts. In order combat the cases, the Hon'ble Chief Justice of Hon'ble Delhi High Court announced the creation of the Intellectual Property Division (IPD) which would solely deal with IPR matters. The IPD has delivered various important decisions since its establishment. Some of these decisions are highlighted as below:

2.1.5.1. *Agriboard International vs. Deputy Controller of Patents and Designs*

2.1.5.1.1. In this case, the Deputy Controller of Patents and Designs ("**Controller**") cited several instances of prior art documents an refused the patent application at the stage of examination on the ground of lack of inventive step. However, the Controller did not elaborate the reasons for his decision.

2.1.5.1.2. The IPD held that in order to reject a patent application, the Controller was required to give a detailed reasoning to explain how a person skilled in the art would arrive at the teachings of the patent application.

[4] https://www.ipindia.gov.in/writereaddata/Portal/News/869_1_Public_Notice_3.pdf.
[5] https://www.ipindia.gov.in/writereaddata/Portal/News/868_1_Public_Notice_2.pdf.

2.1.5.1.3. The Controller's decision was therefore set aside, and the matter was remanded back to the IPO for fresh consideration.

2.1.5.2. *Nippon A&L vs. The Controller of Patents*

2.1.5.2.1. In the past, the IPO has stated that when amending the claims of a patent, no additional features from the description can be added in the claims.

2.1.5.2.2. In this case however, the IPD held that the amendment of claims of a patent specification before the grant of a patent ought to be construed liberally and not narrowly.

2.1.6 The Hon'ble Delhi High Court has been particularly vigilant in protecting and enforcing the rights of IPR owners. The IPD, in February of 2022, has notified its own comprehensive rules and specific rules governing patent suits, being the Intellectual Property Division Rules, 2022 (IPD Rules). The IPD Rules were intended to streamline the process for resolving IPR disputes in India and includes rules that assist the IPD in the disposing of scientific and technical matters. One such rule requires the filing of a technical primer by the parties for the Court to understand the basic technology components in the patents. The IPD Rules under rule 31 also require the Hon'ble Delhi High Court to create a panel of scientific advisors in order to assist the judges if required.

2.1.7 Further, the success of the IPD at the Hon'ble Delhi High Court was so vast, that the April 2022 Parliamentary Committee Report recommended and encouraged High Courts across the country to establish their own IPDs. The Delhi High Court, on 18 May 2022, nominated three judges to who would exclusively be dedicated to the IPD.

2.1.8 Furthermore, IPR matters are now classified as "commercial cases" under the Commercial Courts Act, 2015, which are subject to strict timelines and procedures under the law in order to shorten the amount of time for litigation. The intention behind the introduction of the Commercial Courts Act, 2015, was to enable speedy redressal of commercial disputes in India. Some of the stringent timelines under the same include the following – written statement to the plaint is to be filed within 120 days of the service of the summons; within 30 days of the filing of the written statement, the parties must complete inspection of all the documents disclosed in the proceedings; within 4 weeks of the filing of affidavits of admission or denial of documents, the court must hold a case management hearing and pass an order framing the issues. Further, in various litigations, the courts have specifically ordered for the same to be speedily disposed.

For example, in the past year, the Hon'ble Delhi High Court ordered that the cases of Interdigital Technology Corporation & Ors. Vs Guangdong Oppo Mobile Telecommunications Corp. Ltd. and Ors.[6] and Koninklijke Philips N.V. vs Vivo Mobile Communication Co. Ltd.[7] be disposed of vide a speedy trial. Hence, it is clear that the Indian courts are taking material steps to implement such legislations and practises.

2.1.9 The Government of India has also made efforts to spread awareness of IPR throughout the country. The Cell for IPR Promotion and Management (CIPAM) has specifically been active in providing awareness to different stakeholders and the public in general. CIPAM's main aim is to enhance creativity, innovation, competitiveness and economic growth in India, and spreading awareness thereof. The Special 301 Report, 2022, raises concerns regarding the enforcement of IPR, specifically citing weak enforcement by the police department. CIPAM, in its National IPR Policy, emphasizes on the need to build the capacity of enforcement agencies at various levels, including the strengthening of IPR cells in State police forces. CIPAM, in collaboration with the Federation of Indian Chambers of Commerce and Industry (FICCI) has prepared an IPR enforcement toolkit for the police. This toolkit, comprising of information regarding legal provisions relevant to IPR crime, checklists for registering a complaint and search and seizures, and suggestive guidelines for search and seizure, is effective in dealing with IPR crimes, such as trademark counterfeiting. This toolkit has been distributed to all state police departments across the country. CIPAM also conducts training programmes for police officials from time to time, sensitizing the police about their role, duties and powers in enforcement of IPR.

2.1.10 CIPAM has also, in coordination with WIPO and the National Judicial Academy, India, organised sensitization programs on IPR for the judiciary. In 2022, a day-long conference was organised by CIPAM and FICCI on the topic of "Leveraging India's Demographic Dividend through IP". Further, CIPAM being the nodal point for the Technology and Innovation Support Centre (TISC) program in India, has conducted eight online sessions with the Indian TISC network on IPR commercialization, its importance, challenges relating to the same, and the way forward. Around 122 programs on IPR enforcement have been conducted by CIPAM for law enforcement agencies such as the Police, Judiciary and Customs, in association with IPR experts from the industry.

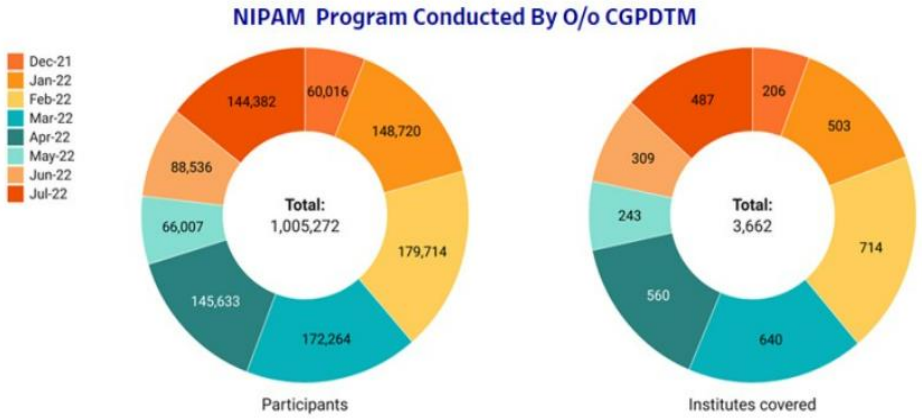
6 CS(COMM) 692/2021
7 CS(COMM) 349/2022

2.1.11 CIPAM, in collaboration with the National Academy of Customs, Indirect Taxes and Narcotics (NACIN) has also conducted training programs for Customs officials on "Intellectual Property Rights: Scope, Importance and Objective". Till date, 328 training programs have been organised for customs officials.

2.1.12 Some other categories of IPR awareness campaigns include schools and universities. CIPAM has conducted around 447 awareness campaigns in more than 4600 academic institutions till date. During innovation week in India, i.e., 10th to 16th January, CIPAM conducted awareness sessions with National Institutes of Design to spread awareness among 500 students. Online programs were also conducted with Atal Innovation Mission, which covered over 200 schools. Further, on the occasion of World Intellectual Property Day, CIPAM, in collaboration with Atal Innovation Mission and NITI Aayog conducted an insightful YouTube live session, highlighting the importance of Intellectual Property Rights in the innovation ecosystem today and motivating the students of Atal Innovation Mission to think differently.

2.1.13 It is pertinent to note that CIPAM has also engaged with various international bodies, such as its collaboration with the Danish Trademark and Patent Office and the Danish Embassy wherein a joint workshop on IP Exchanges was conducted with participation by Accelerating Growth of New India's Innovations (AGNii), and the Danish Inventor Advisory Services. Another example of increased alignment with international authorities is collaboration with the Japan External Trade Organization and Japan Patent Office to organize a product design seminar which was attended by top companies and designers from both Japan as well as India. Furthermore, the Department for Promotion of Industry and Internal Trade (DPIIT) has entered into a memorandum of understanding (MOU) with various countries in order to establish a wide ranging and flexible mechanism for cooperation in the field of IPR and information technology services related to the same. These MOUs lay a foundation for technical cooperation between countries with the aim of strengthening the protection of IPR for the benefit of innovation as well as for sustainable economic growth. In 2022, MOUs have been signed with Taiwan and the European Union (EU).

2.1.14 The Government of India launched the National Intellectual Property Awareness Mission (NIPAM) as a flagship program in order to impart IPR awareness to students across the country on 8 December 2021. NIPAM has successfully conducted various awareness programs and achieved its target of imparting IPR awareness to 1 million students on 31 July 2022.



Source: NIPAM

2.1.15 It is also pertinent to note the IPR trends in the past year. The Global Intellectual Property filings statistics released by WIPO on 21 November 2022, has found that patents filings in India have frown 5.5% in 2021, thereby propelling the share of Asian filings to cross the two-thirds threshold[8]. The patent Office is working effectively and has been clearing the pending application making it one of the fastest IP offices in the world. Some key trends on the filing and grant of patents is enumerated in the table below:

Patent Trends	**Financial Year (FY)**					**% Change FY 2021-2022 vs. 2017-2018**
	2017-2018	**2018-2019**	**2019-2020**	**2020-2021**	**2021-2022**	
Applications Filed	47854	50659	56284	58502	66440	39
Grant/ Registrations	13045	15283	24936	28391	30074	131

Source: CIPAM

[8] Worldwide IP Filings Reached New All-Time Highs in 2021, Asia Drives Growth, WIPO, 2022.

2.1.16 The Economic Survey of 2021-22 published by the Department of Economic Affairs of the Government of India in January 2022 ("**Economic Survey**"), demonstrated that in the past five years, the filing of patents in India has risen to 30%, while the number of patents that have been granted in the same period has tripled. This analysis data from the Economic Survey shows that the share of patent applications filed by start-ups has risen by over five times since the survey of 2016-17[9].

2.1.17 Further, the Government of India, vide its Scheme for Intellectual Property Protection (SIPP), aims to protect and promote IPR of start-ups and to encourage innovation and creativity among them. The SIPP aims to facilitate start-ups to file and process IPR including patents, designs and trademarks by engaging IPR facilitators, whose fees is borne by the Office of the Controller General of Patents, Designs and Trademarks. As on 30 September 022, INR 380.81 Lakhs have been disbursed vide the SIPP as fees to the facilitators assisting the start-ups in IPR fillings. The patent applications filed by start-ups have increased to 1649 in the year 2021-2022, and as on 31 December 2022, the patent applications filed by start-ups in the year 2022-2023 is 1610. Further, trademark applications filed by start-ups have increased to 8649 in the year 2021-2022. Since the launching of the SIPP in 2016, 7430 patent applications and 28749 trademark applications have been filed by start-ups.

2.1.18 With effect from November 2, 2022, the SIPP has been revised to increase the fees of the IPR facilitators substantially, thereby further encouraging them to provide quality services to start-ups.

2.1.19 India has risen to the 40th rank in the Global Innovation Index in 2022 among over 131 global economies and has overtaken Vietnam becoming the leader of the lower middle-income group. As mentioned in the previous submissions, India was at rank 81 in 2015, therefore, jumping 41 ranks in the last 7 years.

2.1.20 India has also been entering into different trade agreements with countries in order to promote trade and development. In the year 2022, two such notable agreements are as follows:

2.1.20.1 In 2022, India entered into a free trade agreement (FTA) with Australia, known as the India-Australia Economic Cooperation and Trade Agreement (ECTA), which came into force on 29 December 2022. The ECTA aims to provide trade and investment opportunities between India and Australia.

[9] Economic Survey, 2021-2022

The ECTA also aims to facilitate trade in prescription generic and biosimilar medicines and have agreed to a separate annex on pharmaceutical products under this agreement, which would enable fast-track approval for patented, generic, and biosimilar medicines.

2.1.20.2 On 17 June 2022, the EU relaunched its negotiations with India for an FTA[10]. The EU is India's third largest trading partner and accounted for 88 billion Euros worth of trade in 2021 and 10.8% of total Indian trade. The trade negotiations between the two aim to remove barriers and help smaller EU firms to export more. The FTA also aims to facilitate the production, provision and commercialisation of innovative and creative products and services between the parties, and to ensure an adequate and effective level of protection and enforcement of IPR. The third rounds of the FTA negotiations took place in December 2022. This shows faith of countries in India and India's business ecosystem and environment.

2.2 LANDMARK JUDGMENTS IN IPR

2.2.1 The year 2022 has been instrumental from the standpoint of IPR in India with numerous landmark judgments on the same. The developments are laid down in this section.

2.2.2 *Sun Pharmaceutical Laboratories vs. Hetero Healthcare Ltd. And Anr.*

2.2.2.1. The High Court of Delhi, in this case held that there is no infringement of trademarks when the marks are derived from the active ingredient of a drug, which was used to manufacture the products of both the parties.

2.2.2.2. Both the products contained the active ingredient "Leterozole". While deciding the case, the High Court noted that one of the parties cannot monopolize the International Non-Proprietary Name (INN) "Leterozole".

2.2.2.3. The INN of an active ingredient is a name used throughout the pharmaceutical industry for that active ingredient. Therefore, no one company can claim monopoly over the same, as it is not a coined or unique trademark, but is derivative.

[10] https://policy.trade.ec.europa.eu/eu-trade-relationships-country-and-region/countries-and-regions/india/eu-india-agreement_en

2.2.3 *Gogoro Inc. vs The Controller of Patents*

2.2.3.1. The High Court of Delhi reiterated that while rejecting an application for the lack of inventive step, discussion on the prior art, the subject invention and the manner in which the subject invention is obvious to a person skilled in the art is mandatory.

2.2.3.2. The provision of pre-grant oppositions has been under scrutiny many a times, including through the Special 301 Report, 2022. A misconception regarding the same is that patents can be easily rejected under this provision. However, it has been specifically reiterated in this High Court case that in order for a patent to be rejected, there has to be sufficient grounds to do so. The opponent, in the present case, when claiming the ground of lack of inventive step, has to prove that the alleged invention would be obvious to a person skilled in the art.

2.2.4 *ITC Ltd. vs. Central Part Estates Private Ltd.*

2.2.4.1. This case is considered to be a landmark case since it ascertains the importance of well-known marks as per the Indian law, while drawing a parallel with the principle of territoriality and famous marks doctrine under US law.

2.2.4.2. Contrary to the territoriality marks doctrine as per American trademark law, in India, ITC's trademark enjoyed substantial goodwill and reputation among Indians as well as foreigners. India recognized its transborder reputation, and thereby the mark was determined to be well-known.

2.2.4.3. IPR is inherently a territorial right and is therefore limited only to the jurisdiction in which it is granted. A trademark is an indication of recognition and goodwill of the proprietor of the same, however, the same is usually restricted jurisdictionally.

2.2.4.4. Today, the world has become a smaller place owing to the extent of trade and communication between countries. In the present case, the Court held that owing to the same, ITC's trademark transcended borders and was recognized outside the jurisdiction it enjoyed protection in. This case shows that under the Indian IPR laws, a trademark that has garnered vast goodwill in another country/jurisdiction would be able to use the same in order to strengthen his trademark in India.

2.2.5 *Dr. Reddy's Laboratories Limited & Anr. vs. The Controller of Patents and Ors.*

2.2.5.1. In the above case, the Hon'ble Delhi High Court debated whether in the case of revocation applications under section 64 of the Indian Patents Act, a party could approach any High Court as opposed to the High Court in the corresponding jurisdiction of the patent office which granted the patent.

2.2.5.2. The Court stated that a revocation petition can be filed wherever the effect of the patent revocation is felt. The grant of a patent effects not only a specific jurisdiction of the country, but the dynamic effect of the same is felt nationwide. The Delhi High Court therefore held that a petitioner could file a revocation petition in any High Court of India as the "cause of action" would have to be decided on the basis of both static as well as the dynamic effect of the grant of a patent.

2.2.5.3. Post the abolition of the IPAB, all IPR matters were transferred to the High Courts. However, questions arose with respect to the jurisdiction of the High Courts, and whether all High Courts could entertain proceedings for revocation of patent. The present case clarifies this position and gives parties wider avenues with respect to initiating revocation proceedings.

3 PATENTS

3.1 PRE-GRANT OPPOSITIONS

3.1.1. The Special 301 Report, 2022, raises issues regarding the process of pre-grant oppositions dubbing the same as time consuming and leading to long waiting periods to receive patent approval. This issue has been addressed in all our prior submissions including those to the Special 301 Reports of 2020 and 2021[11].

3.1.2. Section 25(1) of the Indian Patents Act provides a process for the filing of a pre-grant opposition against a patent application. Under this provision, interested parties as well as third parties or the Government can challenge the application for the grant of a patent after the same has been published, but before the grant of the patent. The intent for the introduction of Section 25 through the Indian Patent (Amendment) Act, 2005, was to ensure the quality of patents and to eliminate frivolous applications, if any.

3.1.3. As mentioned above, the pre-grant opposition process mainly ensures the quality as well as the genuineness of patents. The provision also ensures that the patents for salts, crystals, polymorphs that enter the market are those which have enhanced therapeutic efficacy.

[11] https://www.ipa-india.org/wp-content/uploads/2022/02/IPA-Submission-USTR-2021-Special-301-report.pdf (2021) & https://www.ipa-india.org/wp-content/uploads/2021/01/IPA-Submission-USTR-Special-301-Report.pdf (2020)

This provision therefore provides an important and additional layer of scrutiny when deciding the patentability of an invention. During the insertion of this provision in 2005, the legislation made a conscious decision to adapt the World Trade Organization (WTO) mandated patent system to the situation in India. In a developing country like India, the major focus was to balance the rights and monopolies of patent holders with the health needs of the public at large, who require access to affordable generic medicines. On the other hand, the patent systems in other countries are designed to protect the rights and interests of the patent holders. Further, it is pertinent to note that although the pre-grant opposition adds to the time of the granting of the patent, it is more cost-effective as well as less time-consuming than a post-grant opposition.

3.1.4. The result of pre-grant oppositions are that companies have been able to launch generic equivalents of the patented drugs upon expiry of the product patent, helping patients not only in India but also as stated above, patients in the U.S. gain access to quality affordable medicines. The pre-grant opposition process weed out applications that are not innovative enough to merit patent protection and are essentially attempts at evergreening.

3.1.5. It is safe to say that the effect of the pre-grant opposition procedure being followed is that, if the controller finds the opposition relevant, the controller may direct the applicant to restrict the claims, thereby granting a robust patent which is enforceable. It is interesting to note that for a lot of patents that are in fact granted for a new chemical entity (NCE) in Indian jurisdiction, it becomes difficult for a competitor to launch generic and claim non-infringement.

3.1.6. Further, in order to quash the trend of filing pre-grant oppositions by strawman, the Hon'ble Bombay High Court in a Writ Petition (Dhaval Diyora v/s Union of India and Others) filed before it questioned the filing of such oppositions by front men. The Hon'ble Bombay High Court questioned the credentials of the front man opponent and stated that the opponent could not establish intricate knowledge of the field of the patent application, as is essential. The Hon'ble High Court held that the purpose of pre-grant opposition, was not to create individual rights, but to assist the patent office in examination of the patent application and that such rights cannot be used to abuse the process of law. The Hon'ble High Court-imposed costs in view of such conduct of the Opponent.

3.1.7. The erstwhile Intellectual Property Appellate Board in its order in the matter of Pfizer Products v. The Controller of Patents & Designs in OA/2/2016/PT/MUM had also expressed concern over the rising tendency to file unnamed/unknown oppositions by imposters that are unaccounted for and emphasized that only genuine oppositions should be entertained.

3.1.8. Additionally, even at the patent office front, in the matter of pre-grant opposition filed against Indian Patent Application Number 2706/DEL/2009, it was held that the opposition is an abuse of the process of law considering that the opponent failed to provide his credentials and/ or expertise in the field of the invention. The patent office made observations regarding the conduct of the Opponent and held that the opposition was filed with a view to delay/stall the grant of the patent and therefore dismissed the opposition.

3.1.9. Further, the provision of pre-grant opposition is not unique to India and such proceedings are employed in most cases only to test the continuing patentability/validity of the inventions as opposed to their threshold patentability/validity.

3.1.10. The new patent rules have provided timelines for completing the pre-grant process. Today, the time prescribed for patent prosecution in India is one of the shortest. It is pertinent to note that the purpose for the examination procedure is to ensure that the Examiner gets adequate time to scrutinize the application, thereby ensuring that only genuine inventions are granted.

3.1.11. Further, although the pre-grant oppositions may delay the grant of a patent, it is pertinent to note that as per the Indian Patents Act, on and from the date of publication of the patent application and until the grant of the same, the applicant shall have all the privileges and rights as if the patent was granted. Therefore, although the applicant can sue for infringement only after the grant of the patent, the infringer can be held accountable for damages from the date of the publication of the patent application itself, and the damages would not be calculated from the date of grant.

3.1.12. Pre-grant oppositions further prevent the practice of evergreening of patents. In 2005, the first pre-grant opposition was filed by a cancer patient group, the Cancer Patient Aid Association (CPAA) against a pending claim on imatinib mesylate, which is a lifesaving drug for the treatment of cancer, filed by Novartis AG. The claimed invention is a salt of an already known medicine, and the pre-grant opposition was filed on the ground that the selection of a salt of an existing compound is a common practice in the industry and thereby not patentable. The IPO rejected the patent application, and the same was upheld by the Supreme Court of India. The CPAA, through this pre-grant opposition, aimed to protect the price reduction of the medicine.

This helped advance access to general imatinib for patients for many years, whereas if the patent was granted, Novartis would have had monopoly over the medicine until 2017. On the other hand, Novartis held the patent for almost 30 years in the U.S., constantly driving the cost of the same higher, and rendered a lifesaving cancer drug unaffordable under monopoly.

3.1.13. With respect to the concerns raised by the Special 301 Report, 2022, regarding excessive reporting requirements under the Indian patent regime, we submit that the same has been dealt with in our previous submissions as well. The Indian Patents Act requires all applicants, irrespective of their nationality, to disclose particulars of applications made for the same subject matter in different jurisdictions. The intent of the legislature in inserting this provision in the Indian Patents Act was to ensure that the patent examiners in India are aided in their examination process by the information disclosed. Further, the provision requiring disclosure of information, i.e., Section 8 of the Indian Patents Act, ensures that there is sufficient transparency with respect to patents filed in India, and that crucial information regarding the same is made available to the examiner and the public at large, which in turn results in weeding out and identifying any frivolous party in this regard.

3.2 SECTION 3(D) OF THE INDIAN PATENTS ACT

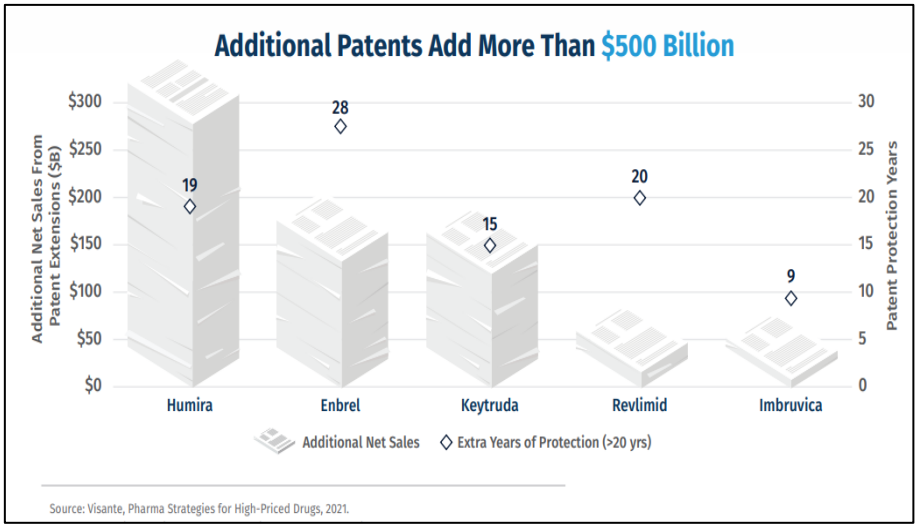
3.2.1 Section 3(d) of the Indian Patents Act ("**Section 3(d)**") is a provision which enables the grant of patents to new forms of known substances that demonstrate enhanced efficacy. The Special 301 Report, 2022, expresses concerns about the section, dubbing the same as restrictive and narrow. The new forms mentioned in Section 3(d) refer to salts, esters, esthers, polymorphs, etc. of the already known compounds/substances and are denied patents only if and when such new forms fail to meet the requirement of increase in the therapeutic efficacy over the already known substances/compounds.

3.2.2 IPA has made submissions regarding this issue in the past. It is reiterated that secondary patents, i.e., those being for new forms of known substances, are often attempts to evergreen patents by extending the term of the patents and thereby delaying the entry of affordable generics.

3.2.3 Evergreening is an issue in the pharmaceutical industry globally, and most countries, including the U.S. are affected by it. In fact, the restrictions under Section 3(d) have the same effect as the Hatch-Waxman Act in the U.S. with respect to curbing the practice of evergreening. The Hatch-Waxman Act governs the procedures through which a potential generic drug manufacturer may obtain FDA marketing approval on a drug that has been patented by a brand name manufacturer. Prior to the 2003 amendment to the Hatch-Waxman Act, brand name firms were able to obtain multiple stays on their patents, thereby resulting in the evergreening of a patent.

On recognition of this issue, 2003 amendments to the Hatch-Waxman Act stipulate that only one 30-month stay can be filed by the patent owner, thereby reducing the extent to which a patent owner can ever-green his patent.

3.2.4 Even with the existence of the Hatch-Waxman Act, brand-name pharmaceutical companies have continued applying for an excessive number of patents with no significant innovation in the U.S., and thereby extending their monopoly rights for years together. This phenomenon of filing several frivolous patents with no significant innovation is known as a patent thicket. A patent thicket results in the staving off of competition from generics by blocking the same for a long period of time. This further results in the prices for these drugs to skyrocket and remain high, therefore becoming unaffordable. According to the Pharmaceutical Care Management Association, for 5 of the highest selling U.S. drugs, such as Humira and Revlimid, 584 patent applications were submitted after the initial FDA approval, thereby enhancing their prices and adding around $500 billion in additional sales. These 5 drugs, as is shown in the table below, have acquired around 20 extra years of protection.



3.2.5 In fact, USFDA has raised concerns regarding evergreening in its letter to USPTO dated 10 September 2021.[12] The letter also stated "…One study of which we are aware found that 78 percent of the drug products for which new patents were listed in the Orange Book from 2005-2015 were existing drug products, not new drugs entering the market.." It is clear from this that the large pharmaceutical companies are engaging in practices that are putting patients at disadvantage and depriving them of timely access to medicines.

3.2.6 As stated in the congressional letter to the U.S. Patent and Trademark Office (USPTO) dated 16 September 2021, without a strong patent system to serve as a check against questionable patents, brand manufacturers would continue to form patent thickets. In India, owing to the provisions of Section 3(d), patent thickets can be avoided and therefore evergreening, and monopoly of a brand-name manufacturer can also be avoided.

[12] https://www.fda.gov/media/152086/download

3.2.7 India's patent laws are compliant with TRIPS and represents a balance between the incentive to innovate and public health. As mentioned above, Section 3(d) is not a blanket restriction, and only prohibits the grant of patents for new forms of known substances which do not have enhanced efficacy. Therefore, if a patent that is applied for a new form of a known substance can establish that it is a novel and useful invention which involves a technical advancement to the art, the same is patentable. Through this provision, India safeguards public health by prohibiting the grant of secondary patents which would extend the monopoly of the patent owner unless there is evidence of increased therapeutic efficacy.

3.2.8 The interpretation of Section 3(d) was explained in the matter of Novartis AG vs. Natco Pharma Limited & Anr., which held that that the bioavailability of a compound may be relevant while assessing the therapeutic efficacy of the said compound. If when administered, the bioavailability of the active pharmaceutical ingredient is increased, the therapeutic efficacy of the compound could also be increased. This judgment was further discussed in the case of FMC Corporation and Anr. vs. Best Crop. Science LLP and Anr. before the Delhi High Court wherein it was held that in any application wherein the claimed compound is a salt or polymorph or any new form of a known substance, the enhanced therapeutic efficacy was required to be shown.

3.2.9 Section 3(d) does not prohibit the grant of patents for all incremental inventions. It is an enabling provision for incremental inventions with enhanced therapeutic efficacy. As has been clarified above, the provision is extremely helpful in discouraging/preventing the evergreening of patents, patent thickets, and monopolisation of patents.

3.3 WORKING OF PATENT [FORM-27]

3.3.1. Patents are granted in India in order to encourage inventions. However, it is also important to ensure that the patents that have been granted are worked commercially to the fullest extent, as a patent that is not being commercially used does not contribute to the society in any way. Due to this, the Indian Patents Act and the Patent Rules prescribe the filing of Form-27, which is a statement from the patentee that the invention that has been patented is being worked commercially in India.

3.3.2. The Special 301 Report, 2022, expresses concerns about Form-27, and that confidential and sensitive business information is required to be filed in Form-27. It is pertinent to note that the required information under Form-27 is general in nature and cannot be treated as confidential. The aforementioned relevant information includes the approximate revenue/ value accrued in India through manufacturing in India/import into India of the patented invention.

Further it is pertinent to note that some of the commercials sought to be disclosed in this form are already available in the public domain.

3.3.3. At this juncture, it is important to highlight the following revisions that were made in Form-27 by way of the Patent (Amendment) Rules 2020:

3.3.3.1. The revised Form-27 enables the patentee or the licensee to file one form in respect of multiple patents, provided all of them are related patents, wherein the approximate revenue/value accrued from a particular patented invention cannot be derived separately from the approximate revenue/value accrued from related patents, and all such patents are granted to the same patentee.

3.3.3.2. The revised Patent Rules have extended the timeline for filing of the statement of working from within 3 months from the end of calendar year to within 6 months from the end of the financial year.

3.3.3.3. In the earlier Form-27, it was mandatory to provide the quantum and value of the patented product manufactured/imported, if the invention has been worked. In the revised Form-27, approximate revenue/value accrued in India to the patentee or the licensees furnishing the statement from patented invention(s) manufactured/imported can be stated. The revised Form-27 also includes a column to give a brief (of a maximum of 500 words) of the above. This allows the patentee or the licensee to provide an explanation when the approximate value and revenue are difficult to estimate. The revised Form-27 does not require the quantum of the patented invention manufactured/imported to be stated. Only value accrued of the patented invention manufactured/imported is to be submitted.

3.3.4. In order to maintain moderate confidentiality, the revised Form-27 does not require country-wise details to be given if the patented product has been imported from other countries. The revised Form-27 has also removed the requirement of disclosure of licenses and sub-licenses granted in respect of the patented product during the year. Additionally, it no longer requires a categoric statement of whether the public requirement of the patented product has been met partly/adequately/to the fullest extent at a reasonable price.

3.3.5. The Indian Patents Act allows for the grant of compulsory licenses of Indian patents under certain conditions, one of which is that the patented invention is not being commercially utilised in India. Therefore, under the Indian Patents Act, the filing of Form-27 is essential. The importance of Form-27 is that patents that are filed are done so in order to utilise the same instead of patents that are filed with the mere intention of attaining monopoly over the invention.

We therefore are of the view that the existing Form-27 requires only essential information from the patentee that can be used by interested persons to seek compulsory licenses in case the patentee is not utilising the invention. This gives third parties the opportunity to develop and commercialize patents that have been filed with no intention of using the same.

4 COUNTERFEIT DRUGS

4.1 The Special 301 Report, 2022, has yet again raised issues regarding counterfeiting in the pharmaceutical sector. In the past few years, especially amidst the Covid-19 pandemic, India has played a vital role in providing vaccines and medicines around the world. In fact, as mentioned above, it has been dubbed the pharmacy of the world. The Indian pharmaceutical industry is a highly regulated one and has been taking various steps over the years in order to battle challenges regarding counterfeiting of drugs. It is pertinent to note that counterfeit drugs is a global issue and is not limited to India, and no country is left unaffected by it. However, the Indian Government and the stakeholders of the pharmaceutical industry have been working together in order to eliminate spurious and counterfeit drugs from the market. One of the latest developments in this field is the decision to implement a QR code system that would assist in tracking and tracing active pharmaceutical ingredients in medicines that are manufactured in India as well as those that are imported, thereby ensuring the quality of the medicines.

4.2 Further, the Indian Government has over the years conducted various awareness programs to spread awareness about the menace of counterfeit medicines among the general public. The World Health Professions Alliance (WHPA), which is an organization representing millions of healthcare professionals like pharmacists, nurses, physicians, has collaborated with healthcare professionals in India, specifically the Indian Medical Association (IMA) and the Indian Nursing Council (INC) to help develop a campaign raising awareness about the public threats associated with spurious/counterfeit medicines in India[13].

4.3 PROPOSED CHANGES IN LEGISTATION:

4.3.1. The Central Government of India constituted an eight-member committee for the framing of the New Drugs and Cosmetics and Medical Devices Bill, 2022 (Draft Bill). The new Draft Bill released by the Government on July 31, 2022, is intended to replace the Drugs and Cosmetics Act of 1940. The definition of spurious drugs has been updated in the Draft Bill to include any drug which does not contain an “active pharmaceutical ingredient”, thereby broadening the already existing definition of “spurious drugs”, in order to enforce higher quality standards on drugs that are manufactured and imported into the country.

[13] https://www.ima-india.org/ima/left-side-bar.php?pid=325

Further, the Draft Bill implements revised the penalties for the offences under the Act. The use of imported spurious drugs would lead to imprisonment of a term not less than 10 years and which can extend to life imprisonment along with a penalty of an amount not less than 10 lakh rupees or three times the value of the drugs confiscated, whichever is more[14]. Section 104 of the Draft Bill also provides a comprehensive guide to punishments and penalties for the sellers of spurious allopathy drugs. The Draft Bill further intends to bridge the gap in the regulation of online pharmacies by mandating licenses required for the sale of drugs and medical devices over the internet.

4.3.2. The Ministry of Health and Family Welfare released a draft notification on January 18, 2022, with respect to the New Drugs (Amendment) Rules, 2022, to further amend the Drugs Rules, 1945. The amendment, as per the gazette notification mandates that every active pharmaceutical ingredient must contain a QR code on each level of packaging. The QR code, as per this draft amendment rules, would have to contain essential data that can be read through a computer software for efficient tracking and tracing. In furtherance to this, the government has identified 300 top selling drugs on which the QR codes would be mandatory.

4.4 The Government has also set up a portal called iVEDA which stands for the Integrated Validation of Exports of Drugs and its Authentication. This portal facilitates the uploading of the tertiary and secondary level barcoding data for the authentication of drug packages exported from India.

4.5 As aforementioned, there have been steps taken by the Government and stakeholders in the pharmaceutical industry have worked towards the eradication of the menace of counterfeit and spurious medicines in India.

5 PROTECTION OF TRADE SECRETS

5.1. The Special 301 Report, 2022, has raised concerns relating to the insufficiency to protect trade secrets in India. Although there is no specific legislation in India regarding the protection of trade secrets, it is imperative to note here that in so far as enforcement is concerned, both civil and criminal actions are available for trade secret misappropriation. An injunction granted by courts can restrain the wrongdoer from disclosing trade secrets and further, damages can also be sought by the trade secret owner. Other civil actions which the courts can grant to the trade secret owner in case of trade secret leakage is return of trade secrets or materials containing trade secrets.
On the other hand, fine or imprisonment can be granted by courts under penal code, copyright and information technology law. Indian courts have recognised the importance of protection of trade secrets and have based the same on equity principles and common law remedies for breach of confidence and contracts.

[14] Section 27(a), Draft New Drugs and Cosmetics and Medical Devices Bill

5.2. Specifically, section 27 of the Contract Act, 1872, states that contracts shall be structured in a way that they protect the firms' confidentiality. It is pertinent to note, however, that the Hon'ble Delhi High Court, in the case of Richard Brady vs Chemical Process Equipment Pvt. Ltd.[15] invoked a broader equitable jurisdiction and thereby passed an injunction order even in the absence of a contract. The court, in this case recognised that client information kept in databases and not made available to the public is copyrightable material under the Copyright Act, 1957, thereby implying that confidential information can be protected from disclosure or infringement as trade secrets even in the absence of a contract. It is pertinent to note, through this landmark case, that India has recognised the importance of trade secrets for decades, and courts have constantly endeavoured to protect the same.

5.3. Further, it is pertinent to note that clauses protecting trade secrets have been incorporated in different statutes including the Information Technology Act, 2000 (IT Act), the Indian Penal Code, 1860, the Code of Civil Procedure, 1908, and the Securities Exchange Board of India Act, 1992 (SEBI Act). Section 43A of the IT Act provides for compensation when an entity handling personal and sensitive information causes wrongful loss or wrongful gain. Similarly, section 72 of the IT Act ensures criminal liability for breach of secrecy and trust. It is also pertinent to note that under the SEBI Act use of insider information and publication of sensitive information is a punishable offence.

5.4. Thus, there are sufficient provisions in existing laws to protect trade secrets in the system. Trade secrets in the pharmaceutical industry is an alternative protection to patents. While patents require the patentees/applicants to disclose sufficient information while filing the same, information that is not disclosed through the patent and is not made available to the public in any manner can be protected as a trade secret.

6 CUSTOMS DUTIES DIRECTED TO IP-INTENSIVE PRODUCTS

The Special 301 Report, 2022, has yet again raised concerns relating to high customs duties on IP intensive products such as medical devices. We would like to reiterate that the rates of customs duties have remained the same for these goods since 2017. It is pertinent to note that despite the pandemic and general inflation, the customs duties for medical devices and pharmaceutical products have not increased for the past 5 years even though there has been an increase in customs duties for other imported products.

[15] AIR 1987 Delhi 372

7 DATA PROTECTION AND DATA EXCLUSIVITY

7.1 The Special 301 Report, 2022, raises concerns about the protection of data and unauthorized disclosure of data generated to obtain marketing approval for pharmaceutical and agricultural chemical products. As under the Article 39.3 of the TRIPS Agreement, member States are bound to protect undisclosed data which is required to be submitted for the approval of pharmaceutical and agricultural chemical products against commercial use. However, it is pertinent to note that this provision refers to situations wherein the pharmaceutical and agricultural chemical products are "new chemical entities".

7.2 Therefore, from a plain reading of Article 39.3 of the TRIPS agreement, it is clear that the TRIPS Agreement does not require member States to grant data exclusivity. In fact, the EU has acknowledged that "*It must be admitted that the following Article 39.3 does not, from a prima facie reading, appear to impose data exclusivity during a certain period of time.*"[16] Specifically, if a subsequent application for a previously approved drug is approved on the basis of the the data submitted for the first applicant, it cannot be regarded as unfair commercial use.

7.3 According to experts when studying the TRIPS Agreement, was of a view that data exclusivity is a TRIPS plus measure,[17] meaning that member states may opt to, but are not obliged to grant TRIPS-plus protection. Further, in a developing country such as India, the implementation or adoption of a TRIPS-plus measure such as data exclusivity has to be weighed with the impact it would have to the access to medicines and public health.

7.4 In 2004, an independent commission established by the WHO stated that "Developing countries need to decide in the light of their own circumstances, what provisions, consistent with the TRIPS Agreement, would benefit public health, weighing the positive effects against the negative effects".[18]

7.5 As mentioned above, data exclusivity is a TRIPS-plus measure, and India is not required under the TRIPS Agreement to adopt the same.

[16] European Union, Questions on TRIPs and data exclusivity, An EU contribution, Brussels, 2001, p 19.
[17] Correa CM, Protection of data submitted for registration of pharmaceuticals: Implementing the standards of the TRIPS Agreement, South Centre, 2002 Geneva, 2002, p 46.
[18] WHO, Public health, innovation and intellectual property rights, Report of the commission on Intellectual property rights, innovation and public health, Geneva, 2006, p 126.

8 CONCLUSION

8.1 India is committed to a strong IP ecosystem and over the years, it has taken various steps towards strengthening the same. The Special 301 Report, 2022, has recognized the progress made by India in its commitment to promote IPR and enhance its enforcement.

8.2 The Government of India has undertaken various initiatives to review and strengthen the IPR regime in India and to strengthen the awareness amongst the stakeholders including general public with respect to IPR.

8.3 India has continued take steps in order to minimise the time for patent applications, while simultaneously ensuring that the quality of patents being granted are those of the utmost standard as set by the Indian Patents Act. We therefore submit that the concern of pre-grant opposition raised by U.S. companies requires closer inspection.

8.4 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.

8.5 The Government of India as well as stakeholders of the pharmaceutical sector have ensured that steps are being taken in order to reduce and eradicate the menace of counterfeit pharmaceuticals by introducing draft amendments to address the same, as well as creating awareness among the public.

8.6 We submit that India has demonstrated strong commitment to IPR laws and has been consistently upgrading the IPR ecosystem keeping the ease of doing business in perspective. Therefore, there is already a compelling case for the removal of India from the Special 301 Report, 2022's Priority Watch List. Further, India is compliant with all international obligations related to IPR and is taking steps to make the Indian ecosystem an IP friendly one. We urge the USTR to consider the removal of India from the Priority Watch List.

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