USTR: 2023 Special 301 Submission

(Docket Number USTR-2023-0014)

Submission by

INDIAN PHARMACEUTICAL ALLIANCE

Mumbai

30 January 2024

INDEX

1. INTRODUCTION

1.1 This submission is on behalf of the Indian Pharmaceutical Alliance (IPA), an association comprising of twenty-five prominent research based Indian pharmaceutical companies. These companies collectively contribute to over 85 percent of India's private sector investment in pharmaceutical research and development. Additionally, IPA's member companies play a significant role, accounting for over 80 percent of drug exports and serving more than 60 percent of the domestic market in India. Given these substantial contributions, IPA strongly supports the delicate balance between innovation and access. Specifically, IPA is deeply invested in safeguarding, promoting, and preserving innovations, striving to create a collaborate environment for the Indian pharmaceutical industry to discover, develop, and deliver quality assured medicines equitably. IPA is dedicated not only to developing cost-effective and beneficial enhancements to existing medicines but also to exploring and introducing novel medications.

1.2 India is a major player on the global stage, exporting drugs to over 200 countries. Among these, the U.S. stands out as a key market. As the "Pharmacy of the World," India is ranked as the third largest worldwide for pharmaceutical production by volume, and fourteenth largest by value. India's contribution to the global supply of generic drugs is impressive, accounting for approximately 20 percent of total exports. It is particularly noteworthy is the role India plays in the U.S. healthcare system. Nearly 40 percent of generic pharmaceuticals in the U.S. are supplied by India, a figure that speaks volumes about the industry's significance and reliability.

1.3 India's impact extends to other parts of the world as well. The country meets over 50 percent of Africa's requirements for generic pharmaceuticals and about 25 percent of the U.K.'s medicinal needs. This wide-reaching influence underscores the crucial role Indian pharmaceutical companies play in global healthcare, especially in recent years. They have become indispensable in ensuring the availability of affordable and quality medicines across various continents.

1.4 The U.S. and India are major manufacturing hubs for these companies. During the Covid-19 pandemic, IPA members have exemplified their dedication by consistently supplying quality-assured medicines in both domestic and international markets. Their efforts during this critical period further demonstrate how IPA companies have been, and will continue to be, America's Medicine Partner.

Access to affordable HIV treatment from India is one of the greatest success stories in medicine worldwide. India is one of the biggest suppliers of reasonably priced vaccines in the world, and due to the quality medication provided by India , Indian medicines are preferred worldwide, therefore rightfully earing the aforementioned title of the "Pharmacy of the World".

Generic pharmaceuticals are of immense importance throughout the world. In the year 2022, generics and biosimilars constituted 90 percent of prescriptions filled in the U.S., accounting for only 17.5 percent of drug expenditure and 1.5 percent of the overall healthcare expenditure[1]. Generics and biosimilars have led to savings of $408 billion in the year 2022, which is $35 billion more than the amount saved in 2021. This figure indicates continued savings for the U.S. healthcare system, including patients and taxpayers. Over the last decade, these savings amounted to approximately USD 2.9 trillion. Yearly savings due to generics have consistently increased by 7 to 10 percent[2].

1.5 As a member of the World Trade Organization (WTO), India has conscientiously aligned its patent laws, particularly, i.e., The Patents Act, 1970, in order to be compliant with the standards of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). This alignment was achieved through, the Patents (Amendment) Acts of 1999, 2002, and 2005. It is crucial, however, to recognize that the TRIPS Agreement provides certain flexibilities, especially for developing countries, to tailor their laws to address specific public health needs. India judiciously adopted flexibilities granted under the TRIPS Agreement. These adaptations are instrumental in ensuring access to affordable medicines and to curb the certain monopolistic practices of pharmaceutical companies, thereby prioritizing public health in India. This approach aligns with the ethos of the Doha Declaration, formally known as the Declaration on the TRIPS Agreement and Public Health, adopted by WTO members in November 2001. The declaration underscores the primacy of protecting public health over intellectual property rights (IPR) and reaffirms the importance of these flexibilities for responding to public health concerns in developing countries.

1.6 Furthermore, it's important to contextualize the Special 301 Report within the broader framework on international trade and IPR agreements. The Special 301 Reports issued by the United States Trade Representatives (USTR) was established prior to the adoption of the TRIPS Agreement. This practice, as seen in the 2023 and preceding reports, often overlooks the critical balance between protecting IPRs and addressing urgent public health needs through flexibilities, a balance that the TRIPS Agreement and the Doha Declaration strive to maintain.

1.7 IPA has consistently engaged with the USTR through annual submissions addressing the Special 301 Report over several years. These submissions emphasize India's intellectual property rights (IPR) ecosystem and the significant strides made in enhancing the IPR regime in the country. Despite these advancements, the Special 301 Report of 2023 has flagged concerns regarding the time-consuming process of patent grants in India, narrow patentability criteria, potential threats of patent revocation the protection andenforcement of IPR, and issues relating to counterfeit goods, custom duties, and trade secrets, among others. Notably, India is one of seven countries on the Priority Watchlist.

[1] 2023, Generic Drug & Biosimilar Access & Savings in the U.S Report.
[2] 2023, Generic Drug & Biosimilar Access & Savings in the U.S Report

1.8 This submission to the Special 301 Report of 2023 aims to address the concerns raised by USTR, particularly those pertaining to the pharmaceutical sector and extends to other relevant intellectual property rights such as patents. This document sets forth a series of significant initiatives undertaken by the Government of India, the Indian judiciary, and other stakeholders. These concerted efforts have been directed at not only strengthening but also thoroughly modernizing India's intellectual property framework.

1.9 The array of actions and developments outlined in this submission clearly shows India's unwavering commitment to enhancing its IPR regime. These strides extend beyond mere compliance; they exemplify a proactive and strategic approach to aligning with international standards, particularly those set forth in the TRIPS Agreement and underscored by the Doha Declaration.

1.10 In view of these substantial and meaningful advancements, the Indian Pharmaceutical Alliance (IPA) strongly contends that India's continued placement on the Priority Watch List in the Special 301 Report process is unjustified. The current categorization overlooks and undervalues the remarkable progress and dedicated efforts made by India in the realm of intellectual property rights. Therefore, with compelling evidence and firm conviction, IPA urges the reconsideration of India's position, advocating for its removal from the Priority Watch List. This call for action is grounded in the belief that India's achievements in IPR protection and enforcement deserve recognition and respect on the global stage.

2. DEVELOPMENTS IN THE IPR SYSTEM IN INDIA

2.1 GENERAL DEVELOPMENT

2.1.1 In recent years, India has undertaken substantial steps to modernize its IP system, aligning it more closely with global standards and enhancing the enforcement and protection of IP laws. Key to these reforms is the comprehensive amendment of the Patents Act, 2005, (Indian Patents Act) and the Patent Rules, 2003, (Patent Rules). The amendments have streamlined the patent process, considerably reducing the time for the disposal process and expedited the grant and examination process. Notably, the Patent law has been revised three times in quick succession - in 2019, 2020, and 2021 – each time making substantial improvements.

2.1.2 The 2019 amendments marked a shift to electronic filing for all documents, increasing the scope for expedited examination requests to include various categories like Indian and foreign small entities and startups. Further, in 2020, the Patent Rules were amended, the focus was on timely compliance, introducing a six-month window post each financial year for, wherein the filing of patent information under Form 27 of the Indian Patents Act (Form-27). The 2021 amendments further reduced fees for educational institutions, thereby promoting creation and innovation in the educational sector.

2.1.3 Recently, a draft Patent (Amendment) Rules, 2023 are proposed by the Department for Promotion of Industry and Internal Trade (DPIIT). These draft patent rules propose significant reductions in various procedural timelines, such as period for requesting patent examination and filing opposition statements and evidence. The draft patent rules aim to curb frivolous opposition filings by empowering the Controller of Patents in most instances to pre-assess the maintainability and increasing the statutory fees to be paid by the opponent to file a representation. The draft patent rules also seek to simplify the format for the working of patents, eliminating the need for detailed revenue/value information (/value accrued from manufacturing and/or the importation to India, or the reason for the non-working of the patent.) Lastly, the draft patent rules reduces the frequency of required working statement from annually to every three years. These significant reforms demonstrate India's dedication to modernizing its IP system, ensuring efficiency, and aligning with international standards, reinforcing its commitment to a robust and responsive intellectual property environment.

2.1.4 Building on the momentum of these reforms, the Indian Patent Office (IPO) made a significant move by releasing a public notice dated January 2023[3], introducing measures to expedite both pre-grant and post-grant opposition proceedings. The notice brings about a notable change to the handling of adjournments in patent hearings. It stipulates that no party will be granted more than two adjournments, with each adjournment limited to a maximum of 30 days, and a stricter inner limit set at 10 days. This policy aims to minimize delays and ensure a more efficient resolution of patent disputes.

2.1.5 Additionally, IPO issued another public notice[4] on the same date, which emphasizes the need for "reasonable cause" to be provided for adjournment requests. It explicitly states that requests lacking a valid reason - reasonable cause - will not be entertained. This directive serves to discourage unnecessary postponements and emphasizes the importance of maintaining the integrity and pace of the patent adjudication process. These announcements from IPO clearly indicate its commitment to expediting pending patent proceedings and streamlining issues related to hearings and adjournments. This approach aligns with the broader efforts of the Indian government to modernize its IP framework, reflecting a commitment to a robust and effective intellectual property environment.

2.1.6 As mentioned in IPA's 2021 submission to the USTR, the Intellectual Property Appellate Board (IPAB) was abolished. Following the dissolution of the IPAB, a large number of IPR appeals were transferred to the High Courts. In response to this transition, proactive measures were taken to effectively address these

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

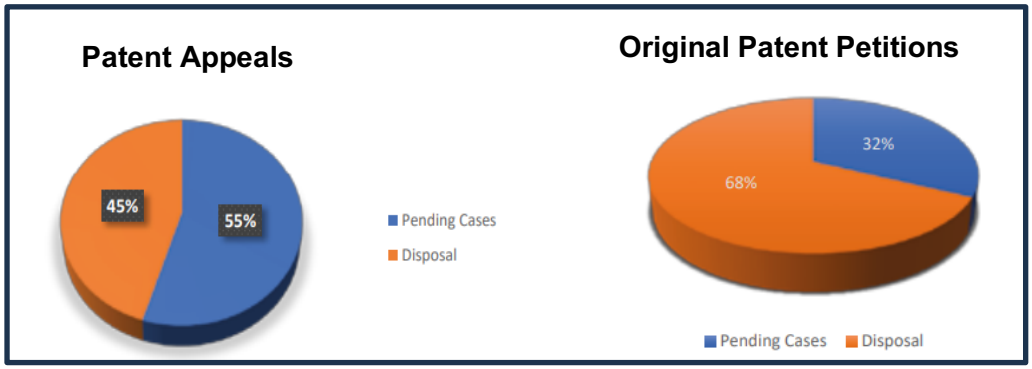
cases. Moreover, A noteworthy initiative in this regard was undertaken by the Delhi High Court. The Hon'ble Chief Justice of the Delhi High Court announced the creation of the Intellectual Property Division (IPD). This special division within the court is dedicated solely to handling of IPR matters. Since its inception, the IPD has been instrumental in delivering several important decisions, showcasing its effectiveness in managing the the IPR caseload. The creation of the IPD is a testament to the Indian judiciary's adaptability and commitment to ensuring timely and effective resolution of IPR disputes.

2.1.7 The Hon'ble Delhi High Court has displayed particular diligence in safeguarding and upholding the rights of intellectual property rights (IPR). In February 2022, the IPD introduced comprehensive regulations, specifically addressing patent litigation, known as the Intellectual Property Division Rules, 2022 (IPD Rules). These rules aimed to streamline the resolution of IPR disputes and encompass provisions facilitating the IPD in addressing scientific and technical aspects. Notably, the IPD Rules incorporate several innovative provisions to aid the court in handling complex scientific and technical aspects of IPR cases. One key feature of these rules is the requirement of litigants to submit a technical primer, which apprises the Court of the fundamental technological elements of the patents involved in the litigation. Additionally, Rule 31 of the IPD Rules mandates the establishment of a panel of scientific advisors to aid the judges in technical matters.

The effectiveness of these measures is evident in the outcomes achieved by the IPD.

2.1.8 The Hon'ble Delhi High Court has been extremely successful in other ways as wellThe IPD judges have actively encouraged parties to explore alternate dispute resolution mechanisms, leading to a higher number of cases being expeditiously resolved. Mediationhas been extremely suc

2.1.9 The Hon'ble Delhi High Court has been extremely successful in other ways as well. The IPD judges have actively encouraged parties to explore alternate dispute resolution mechanisms, leading to a higher number of cases being expeditiously resolved. Mediation has been extremely successful with an impressive rate of over 80 to 85 percent of referred cases at the Delhi High Court Mediation and Conciliation Centre have been settled. The annual report of the Hon'ble Delhi High Court's IPD for 2022-2023 provides evidence of these achievements. It shows that more than 45% of all patent appeals were resolved, and over two-thirds of all the original patent petitions transferred from the IPAB have been disposed of. These figures highlight the IPD's efficiency and its crucial role in expediting the resolution of IPR disputes, further reinforcing India's commitment to a robust and responsive intellectual property ecosystem.



Source: Delhi High Court Intellectual Property Division Annual Report 2022-23, 26 April, 2023.

Further, the Hon'ble Delhi High Court has established a dedicated IPR appellate division, which has further streamlined the disposal of appeals arising from cased handled by the IPD.

2.1.10 The success of the IPD at the Hon'ble Delhi High Court was so extensive that it prompted the April 2022 Parliamentary Committee Report to recommend that other High Courts across India establish their own IPDs. In response to this recommendation, the Delhi High Court, on May 2022, appointed three judges to exclusively oversee the IPD. Accordingly, in April 2023, the Hon'ble Madras High Court inaugurated its Intellectual Property Division, becoming the second High Court in India to establish as dedicated division for IPR disputes.

Following suit, the Hon'ble Calcutta High Court has recently made strides towards establishing its own IPR division. It notified the proposed draft rules, the "Intellectual Property Rights Division Rules of the High Court at Calcutta" through a gazette notification dated December 19, 2023. Therefore, High Courts around the country have stepped up to establish IPR divisions that will exclusively deal with IPR cases as a means to overcome the backlog due to the IPAB being abolished

2.1.11 Of great relevance is the fact that IPR matters are now classified as "commercial cases" under the Commercial Courts Act, 2015, marking a significant shift in how these cases are handled in India. This designation is critical as it subjects IPR disputes to the strict timelines and procedures outlined in the Act, aimed at streamlining the judicial process. The intention of the Commercial Courts Act, 2015 is to enable speedy resolution of commercial disputes in India. Under this framework, IPR cases benefit from stringent timelines that facilitate quicker legal proceedings. For instance, a written statement in response to a plaint must be filed within 120 days of the service of the summons. Following this, parties have 30 days to complete the inspection of all disclosed documents. Moreover, within 4 weeks of filing 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, courts have specifically ordered the expedited disposal of cases. This directive further underscores the judiciary's commitment to ensuring timely adjudication in IPR-related matters.

2.1.12 The Government of India, recognizing the importance of IPR, has undertaken several initiatives to promote IPR awareness nationwide. The Cell for IPR Promotion and Management (CIPAM) be plays a central role in these efforts, actively engaging in the dissemination of information to stakeholders and the general public. CIPAM's primary objective is to foster creativity, innovation, competitiveness, and economic growth in India through increased awareness.

2.1.13 Addressing concerns raised in the Special 301 Report, 2023 about IPR enforcement, specifically police department effectiveness, CIPAM, in its National IPR Policy, underscores the necessity of enhancing the capabilities of enforcement agencies including strengthening IPR cells in State police forces. Collaborating with the Federation of Indian Chambers of Commerce and Industry (FICCI), CIPAM has developed an IPR enforcement toolkit for the police, covering . legal provisions for combating IPR crimes, checklists for filing complaints and conducting search and seizures, along with recommended guidelines for these actions. Particularly effective in addressing trademark counterfeiting, this toolkit has been distributed to all state police departments nationwide. Additionally, CIPAM also organizes training programs for police officials periodically, aiming to raise awareness about their roles, responsibilities, and powers in IPR enforcement.

2.1.14 CIPAM has also, in coordination with WIPO and the National Judicial Academy, India, organized sensitization programs on IPR for the judiciary. In 2022, a day-long conference was organized 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 402 awareness programs were conducted for industry particularly MSMEs and 135 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.Further, IPR awareness programs have been conducted in various educational institutions including the Atal Tinkering Labs. Through around 447 programs conducted, more than 4,600 academic institutions have been covered by CIPAM till date[5].

S. No.	Target Group	No. of Programs
1.	Academic Institutions (Schools, Colleges, Universities, TISCs)	447
2.	Industry including MSMEs and Start-ups	402
3.	Enforcement Agencies and Judiciary	135

Source: DPIIT Annual Report 2022-23

[5] Department for Promotion of Industry & Internal Trade, Annual Report 2022-23

2.1.15 Further, FICCI successfully hosted its ninth edition of its annual conference, i.e., the Movement Against Smuggled and Counterfeit Trade (MASCRADE) in September 2023, on the socio-economic impact of illicit trade on global and Indian economies and the way forward. Further, the National Institute of Science Communication and Policy Research (NIScPR), a constituent institute of the Council of Scientific Industrial Research, conducted a boot-camp on IPRs in July 2023, with the goal of creating awareness and enhancing the understanding about IPRs among research scholars, scientists, and the youth.

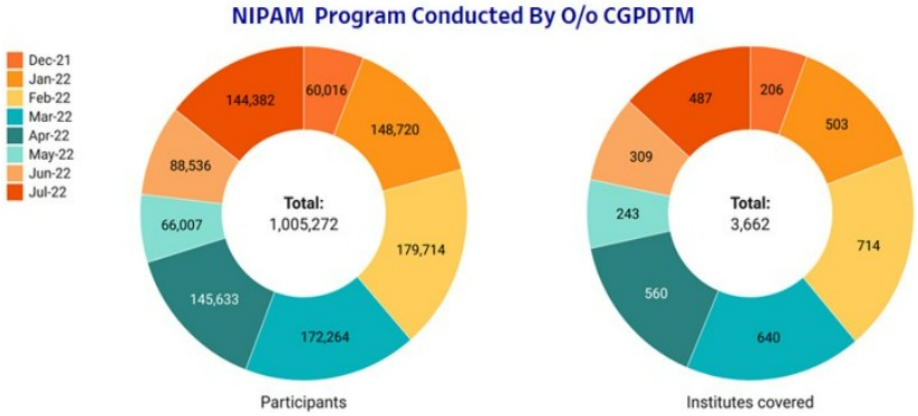
2.1.16 CIPAM, in collaboration with the National Academy of Customs, Indirect Taxes and Narcotics (NACIN) has also conducted training programs for Customs officials on "Intellectual Property Rights: Scope, Importance and Objective". Till date, 328 training programs have been organised for customs officials.

2.1.17 CIPAM's IPR awareness campaigns also extend to schools and universities. CIPAM has conducted around 447 awareness campaigns in more than 4600 academic institutions. During innovation week, CIPAM conducted sessions with National Institutes of Design, reaching 500 students, and conducted online programs with Atal Innovation Mission, covering over 200 schools. Further, on 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.

2.1.18 The WIPO Director General visited India in October 2023, where he met with senior government officials, business and academic representatives as well as other stakeholders from the innovation ecosystem. The Director General observed that India's initiatives to promote innovation among its youth and its large and vibrant start up community can be an inspiration to other developing countries. The Director General met with the Commerce and Industry Minister to discuss the role of innovation which has helped India become the fastest movers in Global Innovation Index.

2.1.19 During his visit, the Director General signed several agreements including the WIPO-India Action Plan to deepen strategic ties, an agreement with the Department of Biotechnology formalizing a collaboration to support 4 WIPO funded fellows to participate in the "Biodesign Program", an agreement to include India's collection of relevant judicial decisions into the WIPO Lex Judgements database, and a letter of intent to establish a Joint Masters in IPR with the National Law University, New Delhi. The Director General also launched an India-customized version of WIPO's IP Diagnostic tools which will be translated into six languages. The Director General delivered a keynote speech pdf at the National IP Conference entitled "Nurturing Growth of IP for Knowledge Economy," noting India's ascension in the GII rankings, climbing from position 81 to 40 in eight years.

2.1.20 The National Intellectual Property Awareness Mission (NIPAM), initiated by the Government of India as a flagship program, was launched in December 2021, with the primary goal of disseminating intellectual property rights (IPR) awareness among students nationwide. NIPAM has effectively executed diverse awareness programs and accomplished its objective of imparting IPR awareness to one million students by July 2022.



Source: NIPAM

2.1.21 Further, in order to overcome the current limitations in innovation ecosystem, the Kalam Program for IP Literacy and Awareness (KAPILA) was launched by the Indian Government in 2020. The primary objective of KAPILA is to increase understanding of IPRs and recognizing and fostering innovation in IPR in Higher Educational Institutions. KAPILA in collaboration with the Ministry of Education and NIPAM, and the Ministry of Commerce and Industry, has organized IPR awareness programs in various Higher Education Institutions across India.

2.1.22 **Patent Trends**: Most importantly, USTR should not overlook the tremendous IPR trends in India. As reported by The World Intellectual Property Indicators, 2023[6], patents filings have surged in India. This trend is not just a measure of quantity but also a strong indicator of the growing culture of innovation and confidence in intellectual property (IP) protection within the country. The 25.2% rise in patent filings in 2022, the sharpest since 2005, and the record number of over 82,000 patent filings in the financial year 2022-23, with 58% contributed by domestic firms[7]., reflect this trend.

2.1.23 This surge in patent activity suggests a deepening trust in the Indian IP system. Inventors and firms are increasingly inclined to seek patent protection as they recognize the country's commitment to upholding and enforcing IP rights. The rationale is clear: entities would not invest their time and resources in the patent application process unless they had confidence in the system's ability to protect

[6] World Intellectual Property Indicators 2023.
[7] https://www.cnbctv18.com/india/india-witness-highest-patent-filings-in-fy23-domestic-firms-cii-japan-16509531.htm

their innovations. The effectiveness of the Indian patent office in swiftly clearing pending backlog of applications and keeping pace with the growing demand further reinforces this trust. Its efficiency in processing these filings positions it among the fastest IP offices worldwide, underlining India's dedication to fostering an environment where innovation is not only encouraged but also sufficiently protected.

In summary, the enhanced patent filings are a testament to the burgeoning innovation in India and deeper system trust.

2.1.24 The table below provides an overview of key trends in patent filings and grants, underscoring the significant progress and momentum in India's IPR landscape:

Patent Trends	Financial Year (FY)						% Change FY 2022-2023 vs. 2017-2018
	2017-2018	2018-2019	2019-2020	2020-2021	2021-2022	2022-2023	
Applications Filed	47854	50659	56284	58502	66440	90310	89
Grant/ Registrations	13045	15283	24936	28391	30074	76053	483

Source: CIPAM

Further, in the year 2023 itself, there have been 90310 patents filed and 76053 patent that have been granted. In comparison with the figures mentioned in the table hereinabove, there has been an 89% increase in patent filings since the financial year 2017-2018, and a 483% increase in the number of patent grants since the financial year 2017-2018. This is significant since the same emphasizes the increase in innovation in India as well as the rate of patent registrations in India.

2.1.25 The Economic Survey of 2022-23 published by the Department of Economic Affairs of the Government of India in January 2023 ("Economic Survey"), demonstrated that over 2016-2021, the filing of patents in India has risen to 46%. The analysis data from the Economic Survey shows that the shareof patent applications filed by start-ups has risen by over five times since the survey of 2016-17[8].

2.1.26 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 September 30, 2022, INR 380.81 Lakhs have been disbursed vide the SIPP as fees to the facilitators assisting the start-ups in IPR fillings.

[8] Economic Survey, 2021-2022

2.1.27 With effect from November 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.

2.1.28 India has risen to the 40th rank in the Global Innovation Index in 2023 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 8 years.

2.1.29 Free Trade Agreements (FTA) have shown to impact biosimilars and generic medicines. The EU-Andean agreement is estimated to have resulted in lost cost savings of approximately USD 5.4 million for prescription medicines in Equador and Peru, and a lost cost savings of approximately USD 10.7 million for prescription medicines in Colombia. Similarly, the EU-Korea FTA, which was ratified in 2015, is estimated to have resulted in lost cost savings of approximately USD 592 million for prescription medicines[9]. India has also been entering into different trade agreements with countries in order to promote trade and development. Some of the notable updates in this regard are as follows:

2.1.29.1. India is in negotiations with the UK with respect to a free trade agreement. The 14th and concluding round of negotiations for the same commenced in January 2024, focusing on resolving remaining issues such as business mobility, Scotch whiskey, automobiles, farm products, pharmaceuticals, rules of origin, and a separate agreement to enhance bilateral investments.

2.1.29.2. In April 2023, the Department of Commerce of the Government of India and the Ministry of Foreign Trade of the Republic of Costa Rica decided to establish the India – Costa Rica Joint Economic and Trade Committee (JETCO) which aim to meet regularly to discuss matters of concern and interest in trade and direct investments. The pre-existing trade agreement between India and Costa Rica has led to exports of packaged medicaments and pesticides from India to Costa Rica, among others.

2.1.29.3. In June 2023, a Memorandum of Understanding (MOU) was signed between the Indian Pharmacopoeia Commission, the Ministry of Health and Family Welfare, Government of India, and the Ministry of Health, Government of Suriname for Recognition of Indian Pharmacopoeia (IP) in Suriname. The aforementioned MOU

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

recognizes the importance of developing close cooperation and exchanging information in the field of regulation of medicines in accordance with their respective laws and regulations to boost the export of Indian pharmaceutical products to these countries[10].

2.1.30 Further, India held Presidency of the Group of Twenty (G20) forum for international economic cooperation from December 1, 2022, to November 30, 2023. The G20 declaration under the theme 'Vasudhaiva Kutumbakam', or the New Delhi Leaders' Declaration, not only underscored India's commitment to strong and sustainable growth but also addressed critical aspects of intellectual property (IP) rights. The declaration emphasized the significance of protecting intellectual property and highlighted concerns regarding over-commercialization and misappropriation of living heritage. It recognized the need for balanced IP frameworks that foster innovation while safeguarding cultural heritage. Moreover, the declaration acknowledged the role of intellectual property in promoting economic growth, fostering innovation, and enhancing competitiveness in the global market. It called for cooperation among G20 members to address challenges related to IP rights enforcement and protection, ensuring a conducive environment for innovation and creativity. The New Delhi Leaders' Declaration thus reaffirmed India's dedication to preserving its cultural heritage while promoting innovation and sustainable development on the global stage.

2.1.31 The Department of Biotechnology (DBT) under the Ministry of Science and Technology in September 2023, issued the DBT Intellectual Property Guidelines. These Guidelines regulate ownership, transfer/commercialization of intellectual properties from DBT-funded (extra-mural and intra-mural) institutions. The Guidelines seem to have the dual objectives of commercialization of technology for societal impact and to disseminate knowledge for the "public good". With regard to licensing, the Guidelines suggest that for research leads with lower Technology Readiness Levels (TRLs) a mode of exclusive licensing may be considered by the institutions, whereas for the institutions with higher TRLs, non-exclusive licensing may be preferred. For exclusive licensing, the Guidelines clarify that the same shall be subject to the irrevocable, royalty-free right of the Government to practice or mandate the licensee to sublicense to fulfil the health, safety, or security needs of the country.

2.2 LANDMARK JUDGMENTS IN IPR

2.2.1 The year 2023 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.

[10] https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1949414

2.2.1.1. *Afga NV & Anr. Vs. The Assistant Controller of Patents and Designs & Anr.*

The Hon'ble Delhi High Court observed that there was an imminent need to update the "Manual of Patent Office Practice and Procedure" so that examiners and controllers can receive better guidance on dealing with intricate matters related to complex inventions. The Hon'ble Delhi High Court has held that such updation would be particularly useful when dealing with patents involving Artificial Intelligence systems, machine learning functions, agro chemicals, pharmaceuticals, and manufacturing methods.

2.2.1.2. *Allergan Inc Vs. Controller of Patents*

The Hon'ble Delhi High Court held that while examining the scope of the amended claims, the court cannot eschew, from consideration, the complete specification in the pre-amended claims. Where every detail of the implants, as contained in the amended claims, was in fact disclosed in the original claims as filed, it would be a travesty to shut out the Appellant from seeking a patent in respect of the implants merely on the ground that the amendment is not permissible under Section 59(1) of the Act. The Court then proceeded to allow the amended claims, and remanded the matter back to the Respondent for consideration of the patentability of the invention afresh.

2.2.1.3. *Novozymes Vs. Assistant Controller of Patents and Designs*

The patentability of a process for creating a variation of a known protein was the primary point of dispute. The court determined that because the method included a novel and inventive step, it qualified for patent protection under Section 3(d) of the Indian Patents Act. The verdict's ratio said that while a newly discovered form of a known chemical does not automatically qualify as an invention, one that has a markedly improved level of efficacy may be eligible for patent protection. This lawsuit established a precedent in India on the patentability of breakthroughs in biotechnology.

2.2.1.4. *F Hoffmann-La Roche Ltd. & Ors. V/S Drugs Controller General Of India & Ors.*

The Delhi High Court in a recent judgement, recognized the doctrine of extended passing off in relation to an expired patent. F Hoffmann-LA Roche Ltd. ("Plaintiff") filed a suit seeking a declaration that the approval granted to 'Cadila Healthcare Limited' ("Defendant 1") and 'Hetero Drugs Limited' ("Defendant 3") by 'the Drugs Controller General of India' ("Defendant 2") for manufacturing authorization under the Drugs and Cosmetics Act, 1940, was invalid. The Plaintiff alleged that Defendant 1 and Defendant 3 were conducting clinical trials and marketing a drug purported to be biosimilar of the Plaintiffs'

product. The suit specifically invoked the action for extended passing off pertaining to the characteristic, composition, and quality of a product named 'Trastuzumab', which was earlier protected under a patent that expired in 2013.

3 PATENTS

3.1 PRE-GRANT OPPOSITIONS

3.1.1. The Special 301 Report, 2023, 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, 2021, and 2022[11].

3.1.2. Section 25(1) of the Indian Patents Act establishes a structured process for lodging a pre-grant opposition against a patent application. This provision enables interested parties, third parties, or the Government, to challenge a patent application after its publication but before the actual grant of the patent. The incorporation of Section 25 in the Indian Patent (Amendment) Act of 2005 was driven by the goal of ensuring the high quality of patents and curbing any potential submission of frivolous applications. This legislative initiative underscores India's commitment to maintaining the integrity and credibility of its patent system by allowing a comprehensive review before the actual grant of a patent.

3.1.3. As mentioned hereinabove, the pre-grant opposition procedure plays a pivotal role in ensuring the quality and legitimacy of patents. **It specifically ensures that patents covering salts, crystals, and polymorphs entering the market exhibit enhanced therapeutic efficacy.** This provision adds a crucial layer of scrutiny to the determination of an invention's patentability. When introduced in 2005, this legislation intentionally aligned India's patent system, mandated by the WTO, with the unique conditions of the country. In the context of India's status as a developing nation, the primary focus was on striking a balance between the rights and monopolies granted to patent holders and addressing the health needs of the broader public, facilitating access to affordable generic medicines. Therefore, India introduced the above provision under the flexibilities offered to developing nations under the TRIPS Agreement to emphasize the importance of public health. In contrast, patent systems in other countries primarily safeguard the rights and interests of patent holders. Specifically in the field of pharmaceuticals, this provision is extremely important in order to ensure access to generic medicines.

[11] https://www.ipa-india.org/wp-content/uploads/2023/02/ustr-2022-special-301-submission.pdf (2022), 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).

3.1.4. **It is crucial to emphasize that while the pre-grant opposition may extend the time required for patent grant, it proves to be less time consuming and better cost-effective compared to post-grant opposition.** During the amendments to the Patents Act, 1970, to comply with WTO requirements, India also incorporated flexibilities allowed under TRIPS as mentioned hereinabove. These flexibilities have substantial potential to make affordable and accessible medicines available in India, countering the monopolistic behavior of pharmaceutical multinational corporations. The outcome of pre-grant oppositions allows companies to introduce generic versions of patented drugs once the product patent expires, benefiting patients not only in India but also extending access to quality and affordable medicines for patients in the U.S. **This process effectively filters out applications lacking the necessary innovation deserving of patent protection, especially those attempting to extend patent exclusivity through evergreening strategies**.

3.1.5. It is safe to say that the pre-grant opposition procedure holds considerable weight. In the event that the controller finds the opposition to be relevant, they may instruct the applicant to refine the claims, resulting in the issuance of a patent that is both robust and enforceable. Notably, this process carries particular significance for numerous patents granted for new chemical entities (NCE) within the Indian jurisdiction. Competitors seeking to launch generic versions may encounter challenges, particularly in asserting non-infringement due to the stringent examination during the pre-grant opposition phase. This underscores the effectiveness of the procedure in ensuring the strength and exclusivity of patents for novel chemical entities, contributing to a more rigorous intellectual property landscape.

3.1.6. Moreover, in an effort to curb the practice of filing pre-grant oppositions through proxies, the Hon'ble Bombay High Court, in a Writ Petition (Dhaval Diyora v/s Union of India and Others), questioned the legitimacy of such oppositions lodged by intermediaries. The Hon'ble Bombay High Court scrutinized the qualifications of the intermediary opponent and emphasized the necessity for them to demonstrate intricate knowledge of the field pertaining to the patent application. The High Court asserted that the primary objective of pre-grant opposition is not to establish individual rights but rather to aid the patent office in the examination of patent applications. It emphasized that such rights should not be exploited to abuse the legal process. In response to such conduct by the opponent, the Hon'ble High Court imposed costs.

3.1.7. The former Intellectual Property Appellate Board, in its ruling on the case of Pfizer Products v. The Controller of Patents & Designs in OA/2/2016/PT/MUM, raised apprehensions about the increasing trend of submitting oppositions by unidentified individuals or imposters without accountability. The board underscored the need to only consider legitimate

oppositions. Further, as mentioned in paragraph 2.2.1.5 hereinabove, the Hon'ble Delhi High Court, in the case of Novartis vs Natco Pharma Limited & Anr., held that the right to hearing under rule 55(5) of the Patent Rules is limited to the representation for opposition and does not extend to the examination process. The abovementioned judgment ensures that the opposition proceedings are not abused or used frivolously. Additionally, the proposed increase in the statutory fees as per the proposed draft Patent (amendment) rules 2023 to be paid in order to file a pre-grant opposition would act as a deterrent against frivolous opponents.

3.1.8. Moreover, the pre-grant opposition provision is not exclusive to India, and in most instances, these proceedings are utilized to assess the ongoing patentability or validity of inventions rather than their initial patentability or validity. **Countries such as Australia, New Zealand, Portugal, and Colombia have pre-grant opposition provisions.**

3.1.9. The new patent rules have established specific timelines for completing the pre-grant process, making the patent prosecution timeline in India one of the shortest. It is important to highlight that the examination procedure's purpose is to provide the examiner with adequate time to scrutinize the application, thereby ensuring that only genuine inventions receive grants. Further, as mentioned hereinabove, the proposed draft Patent (amendment) rules 2023, seeks to further ensure that pre-grant oppositions are not abused or filed frivolously. The draft Patent (amendment) rules 2023 requires the Controller of Patents to first consider the opposition representation and only once the Controller is convinced that the same is maintainable will the opposition proceedings begin.

3.1.10. Additionally, despite the potential delays, it is crucial to note that under the Indian Patents Act, from the date of publication of the patent application until its grant, the applicant enjoys all the privileges and rights as if the patent were already granted. Although infringement lawsuits can only be initiated after the patent is granted, the infringer can be held accountable for damages from the date of the patent application's publication, not from the date of grant..

3.1.11. Moreover, pre-grant oppositions play a crucial role in preventing the practice of evergreening patents. In 2005, a significant pre-grant opposition was filed by the Cancer Patient Aid Association (CPAA), a group representing cancer patients, against Novartis AG's pending claim on imatinib mesylate, a vital cancer treatment drug. The opposition argued that the selection of a salt of an existing compound is a common industry practice and hence not patentable. The Indian Patent Office (IPO) rejected the patent application, a decision upheld by the Supreme Court of India. This pre-grant opposition by CPAA aimed to safeguard price reductions for the medicine, facilitating broader access to generic imatinib for patients for an extended period. If the patent had

been granted, Novartis would have maintained a monopoly on the medicine until 2017. In contrast, in the U.S., Novartis held the patent for almost 30 years, consistently driving up the cost of the drug and making a life-saving cancer treatment financially inaccessible under a monopoly. **Importantly it is noteworthy that the number of pre-grant oppositions is less than one percent of the total patent applications published or granted, as indicated in the annual reports from the Office of the Controller General of Patents, Designs, Trademarks, and Geographical Indications (CGPDTM) for the financial year 2021 - 22.**

3.2 SECTION 3(D) OF THE INDIAN PATENTS ACT

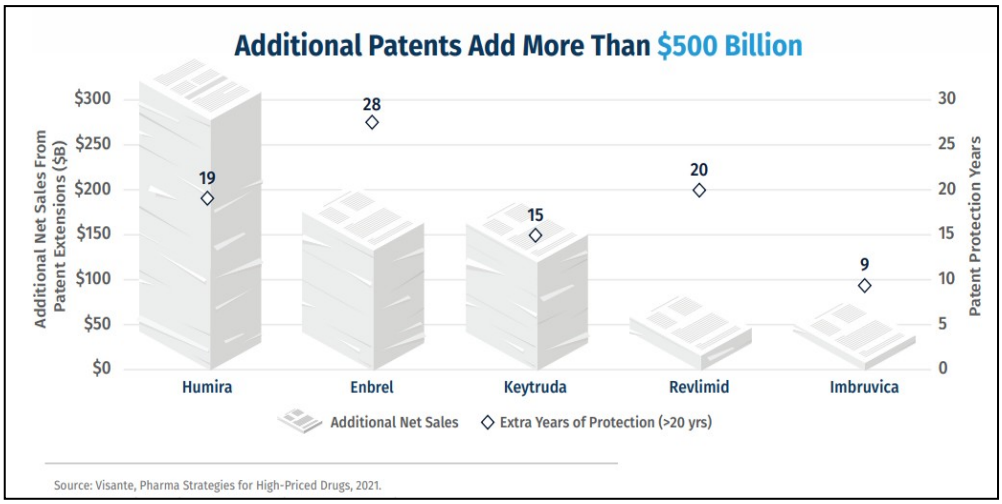
3.2.1 Section 3(d) of the Indian Patents Act (Section 3(d)) is a provision facilitating the grant of patents for new forms of known substances that exhibit improved efficacy. The Special 301 Report, 2023, expresses reservations about this section, characterizing it as restrictive and narrow. **The "new forms" mentioned in Section 3(d) encompass salts, esters, ethers, polymorphs, etc., of already known compounds/substances.** Patents for these new forms are denied only if they fail to meet the requirement of increased therapeutic efficacy over the known substances/compounds.

3.2.2 IPA has previously addressed this concern. It is reiterated that secondary patents, involving new forms of known substances, are often strategies aimed at evergreening patents to extend their term and consequently delay the introduction of affordable generics.

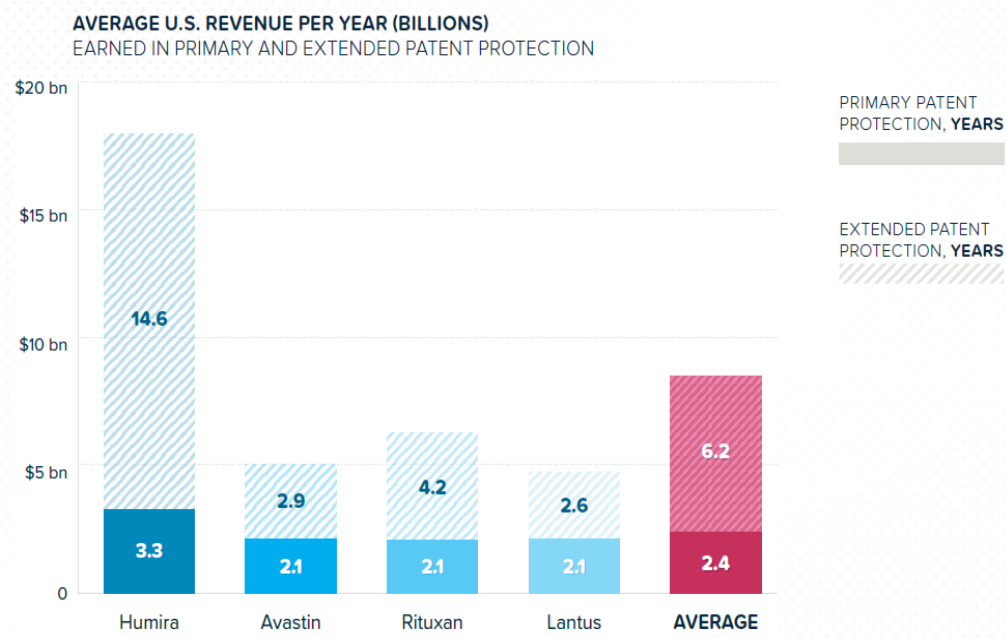
3.2.3 Evergreening is a global issue in the pharmaceutical industry, affecting numerous countries, including the U.S. Notably, the restrictions outlined in Section 3(d) have a similar effect to the Hatch-Waxman Act in the U.S. concerning curbing evergreening practices. The Hatch-Waxman Act governs procedures allowing potential generic drug manufacturers to obtain FDA marketing approval for a drug patented by a brand name manufacturer. Before the 2003 amendment to the Hatch-Waxman Act, brand name firms could secure multiple stays on their patents, contributing to patent evergreening. Recognizing this concern, the 2003 amendments stipulate that a patent owner can file only one 30-month stay, limiting the extent to which a patent owner can perpetuate evergreening practices. Further, the Biologics Price Competition and Innovation Act of 2009 was entered into law by the erstwhile President of the United States created an abbreviated approval pathway to help provide patients with greater access to biosimilars. The U.S. has, over the years realized the necessity for quality generic medicines and biosimilars. In furtherance to the same, the United States Patent and Trademark Office (USPTO) has recently begun collaborating with the U.S. Food and Drug Administration in order to further the Biden-Harris Administration's goal of facilitating access to affordable drugs[12].

[12] https://www.uspto.gov/sites/default/files/documents/PTO-FDA-nextsteps-7-6-2022.pdf

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., 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**. Apatent thicket results in the staving off of competition from generics byblocking the same for a long period of time. This further causes 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, more than 300 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 because of gaming the system by deploying patent thickets.



3.2.5 Further, the Initiative for Medicines, Access of Knowledge (IMAK), an organization focused on building a just and equitable medicines system, examined four of the leading biologic drugs that have had biosimilar competition introduced since 2019 – Humira, Avastin, Rituxan, and Lantus. For each of the aforementioned drugs, IMAK identified the remaining duration of the primary patent protection and the duration of the extended patent protection, and the U.S. revenue generated during these periods. The four drugs had an average of 19.4 years of market monopoly following their commercial launch, which included 13.2 years of remaining primary patent protection, plus an added 6.2 years of extended patent protection. IMAK discovered that all four drugs earned significantly more per year after the primary patent protection expired. The drugs averaged USD 6.2 billion per year in the extended period as compared to USD 2.4 billion per year in the primary period, thereby demonstrating the outsize cost to the system for each year of extended patent protection. All this at the cost of patient welfare.



Source: IMAK

During the period of extended patent protection for the aforementioned drugs, the total U.S. sales more than doubled in less than half the time.

3.2.6 Based on the information above, it is evident that certain practices adopted by innovator pharmaceutical companies are adversely affecting patients. These practices, geared towards maximizing revenues through patent thickets, are placing patients in challenging positions, often needlessly subjecting them to higher costs while depriving them of timely access to affordable medicines. Such actions have broader economic implications, impacting not only individual patients and their families, but also employers, state , and federal taxpayers in the U.S. They further escalate healthcare costs, placing an additional financial burden on stakeholders in the U.S. healthcare system. This situation underscores a critical overarching goal the need to secure the balance between innovation and accessibility. While innovation is essential for advancing medical science and developing new treatments, it is equally important to ensure that these advancements are accessible and affordable to those who need them. The current patent thicket practices of some innovator pharmaceutical companies, as highlighted, seem to tilt this balance unfavorably, prioritizing profits over patient accessibility and affordability.

3.2.7 Patent thickets, as has been explained hereinabove, are extremely detrimental to the public at large all over the world. 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.

3.2.8 **India's patent laws align with TRIPS, striking a balance between encouraging innovation and safeguarding public health**. As elucidated earlier, Section 3(d) is not an overarching restriction; it specifically disallows patents for new forms of known substances lacking enhanced efficacy.

Therefore, if a patent application for a new form of a known substance can demonstrate its novelty, utility, and technical advancement in the field, it qualifies for patentability. This provision serves to protect public health by preventing the grant of secondary patents that could prolong the monopoly of the patent owner unless a proven increase in therapeutic efficacy is established.

3.2.9 Section 3(d) is not a prohibition against granting patents for all incremental inventions; it serves as an enabling provision for incremental inventions demonstrating enhanced therapeutic efficacy. As clarified earlier, this provision is instrumental in discouraging and preventing practices like evergreening of patents, creating patent thickets, and monopolizing patents.

3.2.10 The interpretation of Section 3(d) was explained in the case of Novartis AG vs. Natco Pharma Limited & Anr., where it was established that the bioavailability of a compound could be pertinent in assessing its therapeutic efficacy. **If the administration of the compound results in increased bioavailability of the active pharmaceutical ingredient, it could also lead to an enhanced therapeutic efficacy.** This precedent was further discussed in the case of FMC Corporation and Anr. vs. Best Crop. Science LLP and Anr. at the Delhi High Court. The court emphasized that for applications involving claimed compounds like salts, polymorphs, or new forms of known substances, a demonstration of enhanced therapeutic efficacy was essential.

3.3 WORKING OF PATENT [FORM-27]

3.3.1. Patents are granted in India to encourage innovation; however, it is equally crucial to ensure that granted patents are commercially utilized to their fullest extent. A patent that remains unutilized commercially does not contribute to society. To address this, the Indian Patents Act and Patent Rules mandate the submission of Form-27. This form requires patentees to provide a statement affirming the commercial utilization of the patented invention in India.

3.3.2. The Special 301 Report, 2023, raises concerns about Form-27, claiming that it necessitates the disclosure of confidential and sensitive business information. It's essential to clarify that the information required in Form-27 is general in nature and cannot be treated as confidential. The details requested include approximate revenue/value generated in India through the manufacturing or importation of the patented invention. Notably, some of the commercial details sought in this form are already publicly available.

3.3.3. The Form-27 as it stands presently, allows the filing of a single form for multiple patents, provided they are related, and the revenue/value from a specific patented invention cannot be separately derived from related patents, all granted to the same patentee. The revised rules, i.e., as per the Patent (Amendment) Rules 2020, extend the timeline for filing the statement of

working from within 3 months from the end of the calendar year to within 6 months from the end of the financial year. Further, the current Form-27 no longer mandates the disclosure of the quantum of patented products manufactured or imported. Instead, it requires the submission of the approximate revenue/value accrued in India. A brief explanation (maximum 500 words) can be provided when estimating the value and revenue proves challenging. Neither does the current Form-27 necessitate country-wise details for patented products imported. It eliminates the requirement to disclose licenses and sub-licenses granted for the patented product during the year. Additionally, it no longer demands a categorical statement on whether the public requirement for the patented product has been met partly/adequately/to the fullest extent at a reasonable price.

3.3.4. In order to maintain a confidentiality, the revised Form-27 does not necessitate country-wise details for patented products imported. It eliminates the requirement to disclose licenses and sub-licenses granted for the patented product during the year. Additionally, it no longer demands a categorical statement on whether the public requirement for the patented product has been met partly/adequately/to the fullest extent at a reasonable price.

3.3.5. The Indian Patents Act permits the grant of compulsory licenses under specific conditions, one being non-commercial utilization of the patented invention in India. Therefore, the filing of Form-27 is imperative. This form ensures that patents are filed with the intent to utilize them rather than merely to obtain a monopoly over the invention. The existing Form-27 gathers essential information from patentees, enabling interested parties to seek compulsory licenses if the patented invention remains unused. This provision offers third parties the opportunity to develop and commercialize patents filed without the intention of utilization.

3.3.6. Nonetheless, as highlighted earlier, the proposed draft Patent (Amendment) Rules 2023 are set to further simplify the existing Form-27. According to the draft patent rules, a patentee is mandated to file a Form-27 to demonstrate whether the patent has been worked or not. This requirement is an integral part of ensuring compliance with patent law and monitoring the practical application of patented innovations.

3.3.7. Thus, India has successfully addressed the concerns raised in the Special 301 Report, 2023, regarding the confidentiality of sensitive information, through the draft Patent (Amendment) Rules 2023. The streamlined Form-27 focuses on the essential aspect of whether a patent is being utilized, without necessitating the disclosure of sensitive or confidential information that might be of concern to patent holders. These amendments are indicative of a thoughtful approach to balancing the need for transparency in the use of patented technology with the protection of proprietary information. This

alignment ensures that the confidentiality concerns raised in the Special 301 Report do not arise under the revised framework, thereby maintaining the integrity of both the patent system and the interests of patent holders.

4 COUNTERFEIT DRUGS

4.1 The Special 301 Report for the year 2023 has once again brought attention to concerns regarding counterfeiting in the pharmaceutical sector. In recent years, particularly during the Covid-19 pandemic, India has played a crucial role in supplying vaccines and medicines globally, earning it the recognition as the "pharmacy of the world." The Indian pharmaceutical industry operates under stringent regulations and has consistently taken measures to address challenges related to drug counterfeiting. It's important to highlight that counterfeit drugs pose a global issue affecting multiple countries, and India is actively collaborating with the government and pharmaceutical stakeholders to combat and eradicate counterfeit and spurious drugs from the market. A notable development in this endeavor is the decision to implement a QR code system. This system is designed to facilitate the tracking and tracing of active pharmaceutical ingredients in both domestically manufactured and imported medicines, thereby ensuring the overall quality of pharmaceuticals.

4.2 Additionally, the Government of India has undertaken various programs throughout the years to raise awareness among the general public about the perils of counterfeit medicines. The World Health Professions Alliance (WHPA), a global organization representing millions of healthcare professionals, including pharmacists, nurses, and physicians, has joined forces with healthcare professionals in India, specifically collaborating with the Indian Medical Association (IMA) and the Indian Nursing Council (INC). Together, they have initiated a campaign to enhance public awareness regarding the potential threats posed by spurious and counterfeit medicines in the country.[13]

4.3 PROPOSED CHANGES IN LEGISTATION:

4.3.1. The Central Government of India has established an eight-member committee to formulate the New Drugs and Cosmetics and Medical Devices Bill, 2022 (Draft Bill). Released in July 2022, the Draft Bill aims to replace the Drugs and Cosmetics Act of 1940. Notably, the definition of spurious drugs has been updated in the Draft Bill to encompass any drug lacking an "active pharmaceutical ingredient," thereby expanding the existing definition to ensure higher quality standards for drugs manufactured and imported into the country.

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

4.3.2. Additionally, the Draft Bill introduces revised penalties for offenses under the Act. The utilization of imported spurious drugs could result in imprisonment for a term not less than 10 years, extendable to life imprisonment, along with a penalty of not less than 10 lakh rupees or three times the value of the confiscated drugs, whichever is higher. Section 104 of the Draft Bill outlines comprehensive punishments and penalties for sellers of spurious allopathy drugs. Moreover, the Draft Bill addresses the regulation of online pharmacies by mandating licenses for the sale of drugs and medical devices over the internet, aiming to fill existing regulatory gaps in this domain.

4.3.3. The Ministry of Health and Family Welfare notified revised pharmaceutical manufacturing rules under Schedule M in order to ensure quality control. The revised Schedule M prescribes the Good Manufacturing Practices and requirements of premises, plant, and equipment for pharmaceutical products.

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 Further, in a stride towards eliminating counterfeit drugs, the Drugs Control General of India (DCGI), has decreed the mandatory application of barcodes or QR codes to the packaging of India's leading 300 medicine brands. The Central Drugs Standard Control Organization stated that any batch of the drug formulations that form a part of the aforementioned 300 medicine brands, manufactured on or after August 1, 2023, must mandatorily shave the barcode or QR code on its label. This regulation applies not only to the local pharmaceutical manufacturers, but also foreign manufacturers with respect to pharmaceuticals for the Indian market.

4.6 It is evident therefore that both the Government and stakeholders in the pharmaceutical industry have been actively working to eliminate the threat of counterfeit and spurious medicines in India.

5 PROTECTION OF TRADE SECRETS

5.1. The Special 301 Report for 2023 has expressed concerns regarding the inadequacy of trade secret protection in India. While there is no specific legislation dedicated to safeguarding trade secrets in the country, it is crucial to highlight that both civil and criminal remedies are available for addressing trade secret misappropriation. Courts can issue injunctions to prohibit wrongdoers from disclosing trade secrets, and the trade secret owner can seek damages as well. In cases of trade secret leakage, civil actions may include the return of trade secrets or materials containing such secrets. Additionally, courts have the authority to impose fines or imprisonment under penal code, copyright, and information technology law. Indian courts have acknowledged the significance of trade secret protection, grounding it in equity principles and common law remedies for breaches of confidence and contracts.

5.2. Section 27 of the Contract Act, 1872, specifically emphasizes the structuring of contracts to safeguard the confidentiality of firms. Notably, the Hon'ble Delhi High Court, in the case of Richard Brady vs. Chemical Process Equipment Pvt. Ltd., invoked a broader equitable jurisdiction and issued an injunction order even in the absence of a contract. In this case, the court recognized that client information stored in databases and not publicly disclosed is considered copyrightable material under the Copyright Act, 1957. **This implies that confidential information can be protected as trade secrets even without a contractual agreement.** Through this landmark case, it is evident that India has acknowledged the significance of trade secrets for an extended period, with courts consistently striving to ensure their protection.

5.3. Additionally, it is noteworthy that clauses designed to protect trade secrets have been incorporated into various 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 gain. Similarly, section 72 of the IT Act establishes criminal liability for the breach of secrecy and trust. Under the SEBI Act, the use of insider information and the publication of sensitive information constitute punishable offenses.

5.4. In essence, the existing laws contain sufficient provisions to protect trade secrets within the system. In the pharmaceutical industry, trade secrets serve as an alternative form of protection to patents. While patents necessitate the disclosure of adequate information during filing, data not revealed through the patent process and kept confidential from the public can be safeguarded as a trade secret.

6 CUSTOMS DUTIES DIRECTED TO IP-INTENSIVE PRODUCTS

The Special 301 Report, 2023, 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 due to geo-political events in the world, 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.

7 DATA PROTECTION AND DATA EXCLUSIVITY

7.1 The Special 301 Report, 2023 expresses apprehensions regarding the safeguarding of data and the unauthorized disclosure of data generated to secure marketing approval for pharmaceutical and agricultural chemical products. According to Article 39.3 of the TRIPS Agreement, member States are obligated to shield undisclosed data necessary for the approval of pharmaceutical and agricultural chemical products from commercial use. It is crucial to highlight that this provision specifically applies to cases involving "new chemical entities" in these products.

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.*"[14]. Specifically, if a subsequent application for a previously approved drug is approved on the basis of the data submitted for the first applicant, it cannot be regarded as unfair commercial use.

7.3 **According to experts, data exclusivity is a TRIPS plus measure[15], 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 exclusivityhas to be weighed with the impact it would have on the access to medicines and public health. 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"[16].

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

8 CONCLUSION

8.1 Over the years, India has actively pursued a robust intellectual property (IP) ecosystem, demonstrating its commitment through various initiatives. While the 2023 Special 301 Report, acknowledges the progress made by India in promoting and enforcing IPR. it's important to note that the extent of this progress may not be fully appreciated.

8.2 It has recently been noted that various countries are now understanding that the public's access to medicines is inhibited through stringent patent laws and they are thus taking steps now to introduce certain aspects in their local patent laws which would help in increasing the public's access. India, on the other hand, has always maintained an optimal balance between encouraging and protecting innovation along with the public's access to medicines not being hampered. This attribute goes to show that India's patent laws are adequately balanced and foremost amongst its peers. Equitable access to medicines is key and both India and US can play a greater role in this area of work.

8.3 The Government of India has implemented diverse measures to review and strengthen the country's IPR regime, fostering awareness among stakeholders, including the general public. In striving to expedite patent application processes, India ensures that granted patents adhere to the highest standards defined by the Indian Patents Act. In addition to these measures, it is crucial to acknowledge the significant surge in patent filings in India. This 89% increase, in 2023 from 2014-15, is not just a numerical growth

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

but represents a flourishing culture of innovation and a deep-rooted trust in the Indian patent system. This upsurge, which reflects the highest standards set by the Indian Patents Act, is indicative of a thriving environment conducive to intellectual creativity and protection.

8.4 Concerns raised by U.S. companies regarding pre-grant opposition, which account for a mere 1% of all patents, deserve a more nuanced examination. This small percentage of pre-grant patents reflects more of an efficient and balanced patent system, rather than a problematic one.

8.5 Section 3(d) of the Patents Act specifically targets secondary patents that lack efficacy enhancement, often leading to evergreening. This practice is not merely a legal or technical issue; it has broader implications for global healthcare. By potentially delaying the entry of generic drugs into the market, patent thickets can adversely affect patient access to essential medications worldwide and contribute to rising healthcare costs. This specific provision in the Patents Act underlines India's commitment to preventing such practices, thereby ensuring that patents serve their intended purpose of promoting genuine innovation while safeguarding public health interests.

8.6 India, both at the governmental level and within the pharmaceutical sector, actively addresses the issue of counterfeit pharmaceuticals. Draft amendments have been introduced to combat counterfeiting, accompanied by extensive public awareness initiatives.

8.7 The present submission emphasizes India's unwavering commitment to IPR laws, evident in continuous upgrades to the IPR ecosystem while prioritizing ease of doing business. This presents a compelling case for removing India from the 2023 Special 301 Report's Priority Watch List. India, in compliance with international IPR obligations, is diligently working towards establishing an IP-friendly ecosystem. For the reasons mentioned above, we strongly urge the USTR to consider removing India from the Priority Watch List.

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