USTR: 2024 Special 301 Submission

(USTR-2024-0023)

Submission by

INDIAN PHARMACEUTICAL ALLIANCE

Mumbai

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1. INTRODUCTION

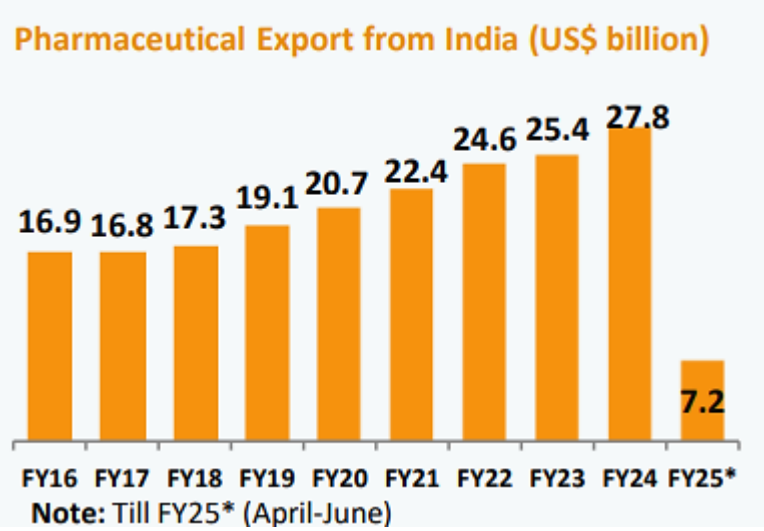
1.1 This submission is presented on behalf of the Indian Pharmaceutical Alliance (IPA), an esteemed association representing 23 of India's leading research-driven pharmaceutical companies with a portfolio of both brand and affordable medicines, committed to advancing global healthcare. Collectively, IPA members contribute approximately 85% of the private sector's investment in pharmaceutical research and development in India. Their significant contributions extend to over 80% of the country's drug and pharmaceutical exports, underscoring their pivotal role in bolstering India's reputation as a global pharmaceutical hub. Domestically, IPA member companies account for over 64% of the total pharmaceutical market sales reinforcing their commitment to ensuring the availability of affordable and essential medicines to the population. This extensive engagement reflects IPA's dedication to fostering a collaborative ecosystem within the Indian pharmaceutical sector to innovate, manufacture, and distribute high-quality medicines equitably. IPA's endeavours are rooted in making quality medicines accessible, affordable, and available globally. By sharing knowledge, adopting best practices, and engaging in policy dialogues, IPA actively contributes to addressing critical issues such as access, efficiency, and excellence of quality. Beyond its role in advocacy and collaboration, IPA is deeply committed to safeguarding and advancing pharmaceutical innovations. In addition to delivering cost-effective improvements to existing medicines, IPA and its member companies strive to pioneer the discovery and development of novel therapeutics. Their collective efforts exemplify a robust commitment to addressing both domestic and global healthcare challenges, ensuring that high-quality, affordable medicines reach those who need them most.

1.2 For IPA, ethics and business integrity of medicines is vital and the work put in this regard serves as a pivotal mechanism to safeguard public health interests and protect the intellectual property rights of national pharmaceutical companies.

1.3 IPA and its member firms are dedicated to furthering India's global pharmaceutical leadership by efficiently delivering safe, effective, and quality-assured medicines to consumers worldwide, with a significant presence in the U.S. and other major markets. Emphasizing innovation in novel and affordable product development, along with advanced manufacturing techniques, IPA members deploy state-of-the-art facilities to ensure the highest standards of quality and efficacy. As discussed below in more detail, IPA members provide 42% of the total U.S medicines, and 47% of the affordable medicines taken by Americans. Our partnership with the United States is underpinned by India's status as the country with the highest number of US FDA-approved manufacturing facilities outside the U.S.

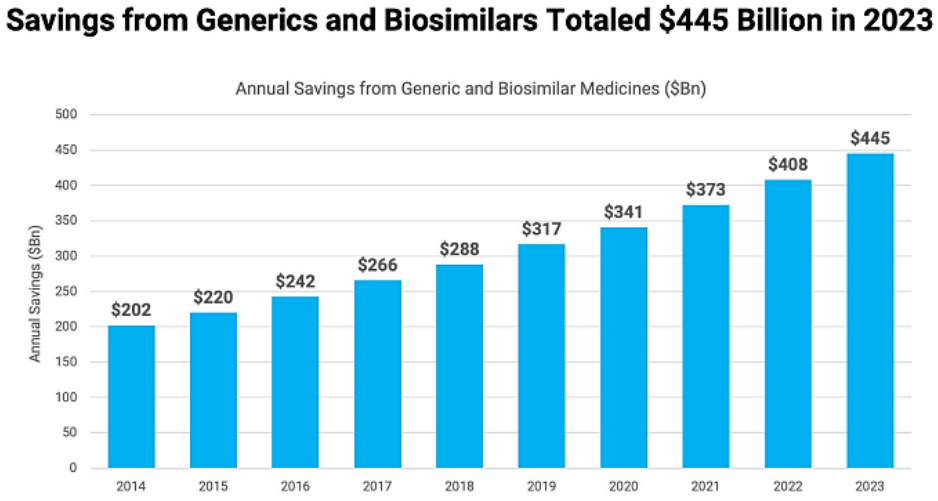
1.4 The Indian pharmaceutical industry has firmly established itself as a global leader, supplying affordable and essential medicines to over 200 countries. Aligned with the vision of 'Atmanirbhar Bharat,' meaning Self Reliant India, the industry continues to achieve remarkable milestones in its pursuit of self-reliance and global health contributions. Notably, India fulfils more than 60% of the global demand for various vaccines and stands as the largest provider of generic medicines. Recognized as the "Pharmacy of the World," the Indian pharmaceutical sector ranks third globally in pharmaceutical production by volume and fourteenth by value. With a 20% share in global supply volume and 60% in vaccines, India plays a pivotal role in addressing global healthcare needs, including leading the supply of vaccines like DPT, BCG, and Measles. The Indian vaccine industry developed a Covid vaccine with indigenous technology in collaboration with India's research institutions like Indian Council of Medical Research (ICMR) and the National Institute of Virology (NIV) effectively and expeditiously. India has provided 301 million doses of vaccines to more than 100 countries. Furthermore, India's pharmaceutical exports have seen a steady rise, being USD 27.9 billion during the financial year 2023-2024. These achievements underscore the pivotal role of IPA and its members in cementing India's position as a cornerstone of the global pharmaceutical ecosystem[1].

[1] https://pib.gov.in/PressReleasePage.aspx?PRID=2045238



Source: IBEF Pharmaceuticals Industry Report, 2024

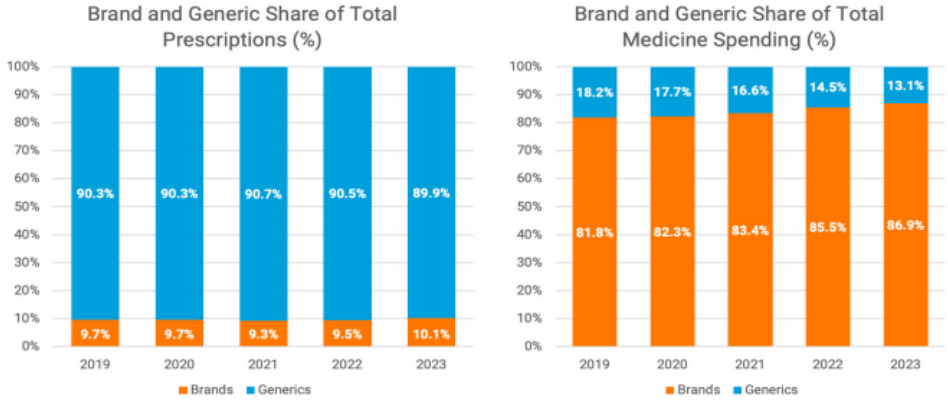
1.5 The pharmaceutical trade between India and the U.S. has been significantly impactful in recent years. Particularly during the Covid-19 pandemic, India played a crucial role in supplying cost-effective and quality-assured medicines and vaccines worldwide, earning it the consistent title of the 'pharmacy of the world'. Indian pharmaceutical companies have focused on developing generic drugs, contributing to the fulfilment of U.S. healthcare demands. The widespread availability of generic medicines in the U.S. has not only enhanced access to affordable pharmaceuticals for consumers but also delivered substantial financial benefits to the healthcare system. Over the past decade, these savings have totalled approximately USD 3.1 trillion, with USD 445 billion saved in 2023 alone, including over USD 12 billion attributed to biosimilar medicines[2]. Annual savings from generics have consistently grown by 7% to 10%, reflecting their increasing impact on cost-efficiency in the U.S. healthcare landscape. Additionally, under the new administration, the alignment of U.S.' policies aimed at reducing drug prices and promoting affordable healthcare solutions could significantly benefit the U.S. healthcare system through stronger collaboration with Indian pharmaceutical companies. With expertise in producing cost-effective generics and biosimilars, a cornerstone of India's pharmaceutical exports, Indian pharmaceutical companies are well-positioned to serve as critical partners in addressing U.S. healthcare challenges and ensuring wider access to affordable medicines for American consumers. This policy direction has the potential to deepen the bilateral trade relationship while reinforcing India's critical role as a key contributor to the global healthcare ecosystem.



Source: U.S. Generic and Biosimilar Medicines Savings Report 2024

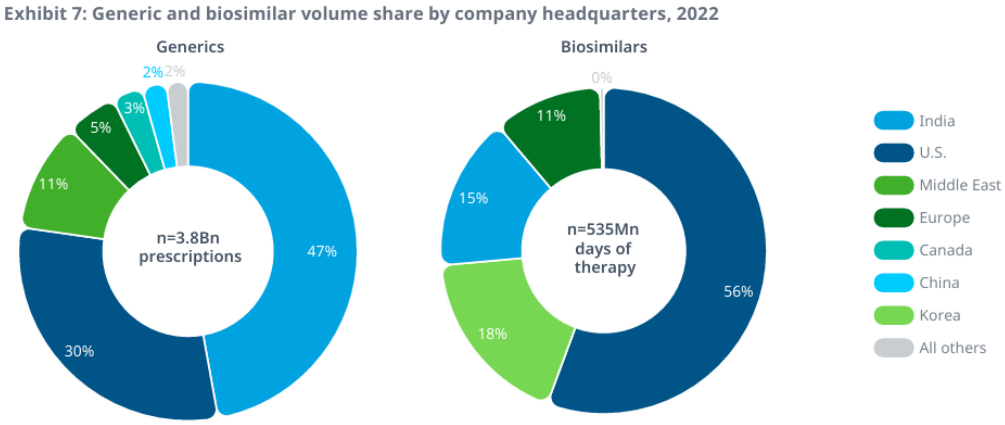
[2] 2024, Generic Drug & Biosimilar Access & Savings in the U.S Report

In 2023, generics and biosimilars reaffirmed their value by accounting for 90% of all prescriptions while representing only 13.1% of total prescription drug spending. The average out-of-pocket cost for a generic prescription stood at $7.05, significantly lower than the $27.10 average for brand-name drugs—nearly four times higher. This widespread adoption highlights the continued reliance on generics and biosimilars, which comprised 90% of all prescriptions dispensed during the year[3].



Source: U.S. Generic and Biosimilar Medicines Savings Report 2024

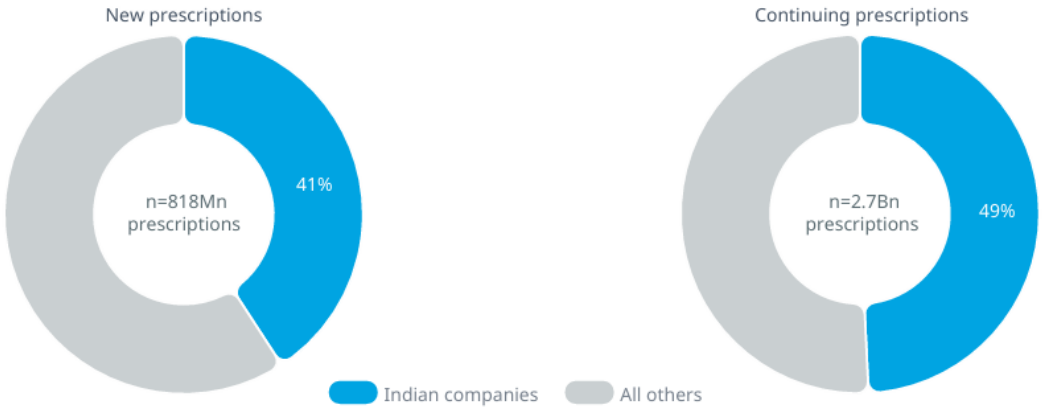
In 2022, Indian pharmaceutical companies played a pivotal role in supplying medications to U.S. residents. **They accounted for 42% of the total brand and generic prescriptions filled in the U.S**., amounting to 1.8 billion prescriptions that year. Indian companies are especially significant in providing affordable generic drugs, **contributing to 47% of generic prescriptions filled in the U.S.** This supply of cost-effective medications enhances access to critical treatments for patients. For instance, the case of Rosuvastatin highlights this contribution. After its generic entry in 2016, market competitiveness increased, as indicated by the Herfindahl-Hirschman Index (HHI). From 2019 to 2022, Indian companies held 80–90% of the drug's overall market share, underscoring their dominance and impact in this segment.



Source: IQVIA National Prescription Audit, IQVIA National Sales Perspective, Dec 2022; IQVIA Institute, Feb 2024.

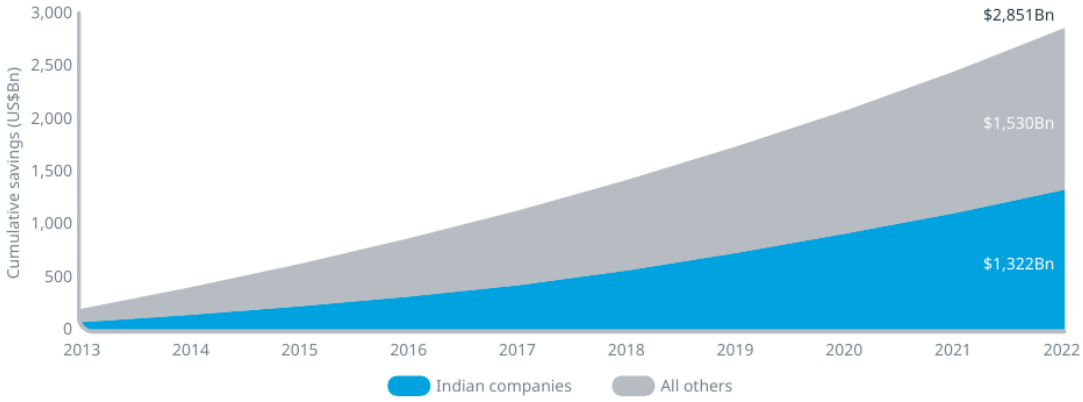
Patients refilling prescriptions are more likely to receive medications from Indian companies compared to those filling new prescriptions. While Indian companies supply 41% of first-time prescriptions, their share is slightly higher for refills. This trend indicates that patients relying on Indian companies for their prescriptions may demonstrate better adherence, likely linked to improved affordability of the medications they provide.

[3] 2024, Generic Drug & Biosimilar Access & Savings in the U.S Report.



Source: IQVIA National Prescription Audit: New to Brand, Dec 2022; IQVIA Institute, Feb 2024.

Indian pharmaceutical companies significantly contribute to cost savings in the healthcare system, bolstering its long-term sustainability. Generics, which introduce market competition and reduce costs, are central to these savings, with Indian companies playing a pivotal role. In 2022 alone, medications from Indian companies saved the U.S. healthcare system $219 billion, totaling $1.3 trillion in savings between 2013 and 2022. **Over the past decade, Indian companies accounted for 46% of the $2.9 trillion in generic drug savings, underscoring their critical role in ensuring affordable healthcare.**



Source: IQVIA National Sales Perspectives, Dec 2022; IQVIA Institute, Jan 2024.

1.6 On July 11, 2023, the U.S. Senate passed S. 150, the "Affordable Prescriptions for Patients Act of 2023," a bipartisan legislation aimed at addressing the challenges posed by "patent thickets" in the pharmaceutical industry. These thickets, often comprising numerous overlapping patents filed on minor variations of biologic drugs, significantly delay the entry of biosimilars into the market. The legislation restricts biologic patent holders from asserting more than 20 qualifying patents in infringement actions, particularly those filed long after the approval of the reference biologic drug. The Congressional Budget Office (CBO) scored the cost savings of this legislation at approximately $1.8 billion, underscoring its potential to foster affordability and accessibility in the U.S. healthcare system.[4] This legislative milestone reflects a broader trend of addressing monopolistic practices to ensure timely access to life-saving medications.

1.7 Given these developments, it is essential to recognize the strategic value of the ongoing collaborations between the U.S. and India in critical areas like energy, defense, and minerals. Medicines should naturally become the next area of focus, as both nations face significant national security concerns tied to the reliability and affordability of pharmaceutical supply chains. Establishing deeper partnerships in this domain would not only reinforce bilateral trade relations but also enhance global healthcare resilience.

[4] https://docwirenews.com/post/senate-passes-legislation-to-prevent-patent-thickets-lower-drug-costs

1.8 As a member of the World Trade Organization (WTO), India has aligned its patent laws with the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) by amending The Patents Act, 1970. These amendments were implemented through the Patents (Amendment) Acts of 1999, 2002, and 2005. It is important to highlight that the TRIPS Agreement includes provisions for certain flexibilities, allowing developing countries to tailor their laws to address specific public health needs. India, while amending provisions of the Patents Act, 1970, has adopted flexibilities allowed under the TRIPS Agreement which have immense potential to provide affordable access to medicines and to curb the monopolistic behaviour of pharmaceutical companies and in favour of the public health in India. The significance of these TRIPS flexibilities was further emphasized in November 2001, when WTO members adopted the Declaration on the TRIPS Agreement and Public Health, commonly known as the Doha Declaration. This landmark declaration reaffirmed the critical importance of prioritizing public health objectives over the protection of Intellectual Property Rights (IPR), particularly in addressing the healthcare challenges faced by developing countries[5].

1.9 Furthermore, the Special 301 Report is a system that was established much prior the adoption of the TRIPS Agreement. The Special 301 Reports issued by the United States Trade Representatives (USTR) for the preceding years, including the present Special 301 Report (Special 301 Report, 2024) has unjustly listed India on the watchlist for making use of flexibilities made available under the TRIPS Agreement.

1.10 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 and evolving ecosystem, and the robust progress of the IPR regime in India. The country has addressed and continues to address concerns previously raised by the USTR. Given the substantial progress discussed herein, along with the ongoing critical trade, energy, and defence partnership with the US, India should be removed from the USTR's 301 watch list.

1.11 The USTR 2024 Special 301 Report (Special 301 Report, 2024) unwarrantedly raises previous concerns with respect to the patent granting process in India, patentability and patent revocation criteria, along with concerns related to counterfeit goods and custom duties, among others. This year, India is one of 7 countries on the Priority Watchlist. Accordingly, this submission addresses the issues raised by the United States Trade Representative (USTR) in that Report 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 Several substantial steps have been taken in the last few years to modernize the IP system keeping with time and with respect to intellectual property law enforcement and protection in India.

[5] United States International Trade Commission, Covid-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities, October 2023

2.1.2 Importantly, the Patents Act, 2005, (Indian Patents Act) and the Patent Rules, 2003, (Patent Rules) have undergone various amendments 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. In 2021, the Patent Rules were amended to make educational institutions eligible for reduced fees, thereby promoting creation and innovation in the educational sector.

2.1.3 The latest development with respect to the Patent Rules is the Patent (Amendment) Rules, 2024 introduced by the Department for Promotion of Industry and Internal Trade (DPIIT) and notified on 15 March 2024 (Patent Amendment Rules). These amendments have brought significant changes to streamline processes and improve efficiency in patent prosecution and enforcement. Notable updates of the aforementioned Patent Amendment Rules include:

2.1.3.1. **Reduction of Timelines:**

2.1.3.1.1. The time to file a request for examination has been shortened from 48 months to 31 months from the earliest priority date, which would result in the acceleration of examination procedure, thereby, reducing the timeline for the subsequent grant of the patent.

2.1.3.1.2. Timelines for filing statements and evidence in opposition proceedings have been reduced.

2.1.3.2. **Measures to Discourage Frivolous Opposition Filings:**

2.1.3.2.1. The Controller of Patents now has the power to assess the maintainability of opposition representations prior to initiating the proceedings, thereby ensuring that only substantive oppositions are encouraged.

2.1.3.2.2. The statutory fees for filing opposition representations against a patent application have been increased, thereby deterring frivolous oppositions and serial oppositions.

2.1.3.3. **Simplification of Procedural Requirements:**

2.1.3.3.1. Patent applicants are now required to submit details of corresponding applications around the world via Form 3, only twice instead of multiple submissions.

2.1.3.3.2. The format of filing working statements via Form 27 has been simplified wherein the same are now to be filed once every three years instead of annually, and patentees are no longer required to disclose revenue/value from manufacturing or imports or reasons for non-working of the patent.

2.1.3.3.3. In rule 13 after sub-rule (2) which reads a specification in respect of a divisional application u/s16 shall contain specific reference to the number of the original application from which the divisional application is made , the following sub-rule is inserted (a more clarifying statement added) , namely, - "(2A) A patent applicant may, if he so desires, file one or more further applications under section 16, including in respect of an invention disclosed in the provisional or complete specification or a further application filed under section 16.

2.1.3.3.4. Rule 70A- Introduction of 'Certificate of Inventorship': To recognise inventors' contributions to patented inventions.

2.1.4 As mentioned in IPA's previous 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 **INTELLECTUAL PROPERTY DIVISIONS (IPD) AT HIGH COURTS:**

2.1.5.1 Following the abolition of the IPAB, numerous IPR appeals were transferred to High Courts across the country, necessitating measures to address these cases efficiently. To manage this transition, the Hon'ble Chief Justice of the Hon'ble Delhi High Court announced the establishment of the Intellectual Property Division (IPD), dedicated exclusively to handling IPR matters. Since its inception, the IPD has issued several significant rulings, reinforcing its pivotal role in adjudicating intellectual property disputes.

2.1.5.2 The Hon'ble Delhi High Court has demonstrated exceptional commitment to protecting and enforcing the rights of intellectual property (IP) owners. In February 2022, the Intellectual Property Division (IPD) introduced the Intellectual Property Division Rules, 2022 (IPD Rules), which provide a comprehensive framework for patent litigation. These rules aim to streamline the resolution of IPR disputes in India and include provisions to address complex scientific and technical issues. Notably, one such key provision requires litigants to submit a technical primer, providing the Hon'ble Court with an overview of the technological aspects of the patents in question. Furthermore, Rule 31 of the IPD Rules mandates the creation of a panel of scientific advisors to assist judges in understanding and adjudicating technical matters as needed.

2.1.5.3 The Hon'ble Delhi High Court has been extremely successful in this regard and has achieved notable success in resolving IPR disputes. The IPD judges have also encouraged parties to explore alternate dispute resolution mechanisms, such as mediation, leading to a significant increase in expeditious settlements and resolution. The mediation has been extremely successful with over 80 to 85 percent of referred cases at the Hon'ble Delhi High Court Mediation and Conciliation Centre have been successfully resolved through mediation. The annual report released by the Hon'ble Delhi High Court's IPD for the year 2023-2024 shows that more than 80% of all patent appeals were disposed of and more than 83% of all trademark appeals were disposed of, as of 30th June 2024[6]. More than two-thirds of all the original petitions concerning patents transferred from the IPAB have been disposed of.

[6] Delhi High Court Intellectual Property Division Second Annual Report 2023-24

Category	*Disposal rates (till 30th June, 2024)*
Patent Appeals	**80.8%**
Trade Mark Appeals	**83.02%**
Trade Mark Revocations/Cancellations	**48.9%**
Patent Revocation Petitions	**76.2%**
Copyright Revocations/Cancellations	**49.2%**
Overall	**60.10%**

Source: Delhi High Court Intellectual Property Division Second Annual Report 2023-24

2.1.5.4 According to the IPD's second annual report (2023-2024), the division disposed of over 60% of the 1,977 cases transferred from the IPAB as of June 2024, reflecting a robust effort to reduce pendency. Notably, 1,217 transferred cases were resolved during this period. Furthermore, the IPD demonstrated its efficiency in managing fresh filings, disposing of 2,026 new cases, surpassing the 1,917 cases instituted during the same period. These outcomes underscore the division's ability to maintain a higher disposal rate than the rate of new case filings[7]. Further, the Hon'ble Delhi High Court also has a dedicated IPR appellate division which has also resulted in disposal of appeals arising from the IPD.

2.1.5.5 The remarkable success of the IPD at the Hon'ble Delhi High Court prompted the April 2022 Parliamentary Committee Report to recommend the establishment of similar IPDs in High Courts across the country. In response, the Hon'ble Delhi High Court, in May 2022, designated three judges to focus exclusively on the IPD. Following this precedent, the Hon'ble Madras High Court launched its Intellectual Property Division in April 2023, becoming the second High Court in India to establish a dedicated division for IPR disputes. Mirroring Rule 31 of the Delhi High Court IPD Rules, Rule 13 of the Madras High Court Intellectual Property Rights Division Rules, 2022, allows the IPD to seek the assistance or opinions of experts with specialized knowledge or skills relevant to the case. The rule also provides for the creation of an expert panel, which can be maintained and updated periodically to support the division in its adjudication of complex IPR matters.

2.1.5.6 Following suit, the Hon'ble Calcutta High Court notified proposed draft rules being the "Intellectual Property Rights Division Rules of the High Court at Calcutta" vide gazette notification dated December 19, 2023. On September 20, 2024, the aforementioned "Intellectual Property Rights Division Rules of the High Court at Calcutta" were published via gazette notification[8], making it one of the newest High Courts, after the Hon'ble High Courts of Delhi and Madras, to have its own dedicated Intellectual Property Division.

[7] Delhi High Court Intellectual Property Division Second Annual Report 2023-24
[8] https://www.calcuttahighcourt.gov.in/Notice-Files/gazette-notification/12428

2.1.5.7 On July 8, 2024, the Hon'ble Himachal Pradesh High Court in Shimla introduced the Himachal Pradesh High Court Intellectual Property Rights Division Rules, 2022. With Himachal Pradesh accounting for 6% of India's pharmaceutical clusters and attracting significant investments in the pharmaceutical sector, the region is poised to see a rise in patent and pharmaceutical trademark disputes, potentially becoming a hub for IPR-related cases. This development makes the Hon'ble Himachal Pradesh High Court the fourth in India, following Delhi, Madras, and Kolkata, to establish a dedicated Intellectual Property Division.

2.1.5.8 Further, in an important development, the Hon'ble Karnataka High Court, on June 20, 2024, released a notification forming a sub-committee to draft rules for establishing an Intellectual Property Division[9].

2.1.5.9 Therefore, High Courts around the country have stepped up to establish IPR divisions which would solely deal with IPR related matters to overcome the backlog caused due to the abolishing of the IPAB.

2.1.6 The Government of India has launched multiple initiatives to enhance and promote awareness of intellectual property rights (IPR) nationwide. The Cell for IPR Promotion and Management (CIPAM) play a pivotal role in disseminating information to various stakeholders and the general public. CIPAM's primary objective is to foster creativity, innovation, competitiveness, and economic growth in India, with a focus on raising awareness to achieve these goals. CIPAM hosts multiple IPR awareness programs in various colleges around the country, some of which include an IPR awareness program in collaboration with Tamil Nadu State Council for Science and Technology and Loyola Institute for Frontier Energy on September 30, 2024, IPR training programme in collaboration with MR Nathwani College, Mumbai, IPR awareness programme at the National Institute of Ayurveda, Jaipur, in July 2024, wherein key aspects of IPR were highlighted. CIPAM has also held patent certification courses at the National Chemical Laboratory, Pune. IPR awareness programs have been conducted in over 10,000 academic institutions reaching over 2,00,000 students and approximately 100 IPR Cells have been established at various colleges across India[10]. The Special 301 Report, 2024 highlights challenges in IPR enforcement, particularly citing inadequate action by police authorities. To address this, the **National IPR Policy** emphasizes the need to strengthen enforcement agencies, including enhancing the capabilities of IPR cells within state police forces. In collaboration with the Federation of Indian Chambers of Commerce and Industry (FICCI), CIPAM has developed an IPR enforcement toolkit for police officers. This toolkit provides a comprehensive guide on relevant legal provisions, checklists for filing complaints, conducting search and seizure operations, and recommended practices, focusing on trademark counterfeiting. Distributed to all state police departments, this resource has been instrumental in improving enforcement. Additionally, CIPAM conducts periodic training programs for police personnel to build awareness about their responsibilities and authority in IPR enforcement, ensuring better implementation at various levels. CIPAM recently conducted several workshops on IPR at police academies, including but not limited to an IPR workshop at the Punjab Police Academy, Phillaur, in July 2024, a training program on the enforcement and adjudication of IPR in collaboration with the Rashtriya Raksha University was conducted with participation from Gujarat Police officers including constables, head constables, and sub-inspectors[11].

[9] https://karnatakajudiciary.kar.nic.in/noticeBoard/notfn-HCLC-59-2022-20062024.pdf
[10] Keeping Pirates at Bay – India's Anti-piracy Campaign, CIPAM
[11] https://pib.gov.in/PressReleseDetail.aspx?PRID=2068053&reg=3&lang=1

2.1.7 CIPAM, in collaboration with WIPO and the National Judicial Academy, India, has organized sensitization programs on IPR for the judiciary. CIPAM has conducted various training programmes in collaboration with the National Judicial Academy for civil judges on laws of IPR, including at the Kerala Judicial Academy in September 2024, at the Judicial Training Research Institute, Lucknow in August 2024, among many more. As the nodal agency for the Technology and Innovation Support Centre (TISC) program in India, CIPAM conducted eight online sessions with the Indian TISC network, focusing on IPR commercialization, its significance, challenges, and the way forward. Additionally, CIPAM has carried out 402 awareness programs for industries, especially MSMEs, and organized 135 IPR enforcement programs for law enforcement agencies like the police, judiciary, and customs in collaboration with industry IPR experts. Furthermore, CIPAM has extended its IPR awareness initiatives to educational institutions, including Atal Tinkering Labs. Through approximately 447 programs, CIPAM has reached over 4,600 academic institutions, significantly contributing to spreading knowledge about IPR across the country.

2.1.8 Further, FICCI has, over the years, actively spearheaded campaigns aimed at raising awareness among the general public about the detrimental effects of smuggling and counterfeiting, as a part of its broader mission to instigate societal change. A pivotal component of this initiative is FICCI's annual flagship international conference, i.e., the Movement Against Smuggled and Counterfeit Trade (MASCRADE). The 10th edition of MASCRADE was held in September, 2024, on "Building Resilient Economies and Implementing Robust Measures from a Global Initiative against Smuggling and Counterfeiting".

2.1.9 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, approximately 328 training programs have been organised for customs officials.

2.1.10 WIPO, in collaboration with the Hon'ble Delhi High Court, successfully organised the WIPO Master Class on Intellectual Property Adjudication, from March 7, 2024, to March 9, 2024. Held at the Hon'ble Delhi High Court, the event promoted transnational judicial exchange of IPR related experiences and jurisprudential developments. Judges from across the world, including India, Australia, the Unified Patent Court (UPC), the United Kingdom, and the United States of America comprised the distinguished faculty of the aforementioned Master Class. The faculty members guided the participating judges through a program of wide-ranging topics including the interplay of IP proceedings in different fora, current issues in patents, the territoriality of IP rights, frontier technologies, scientific evidence in emerging areas of technology, specialized rules of procedure, and injunctive relief. Recent court decisions from across the globe informed participant discussions, yielding exciting and productive insights into many of the key developments shaping IP adjudication today. Bringing together 37 experienced judges from 20 jurisdictions, the 2024 Master Class served as a global forum for leading jurists to share and learn from these and other success stories from around the world. The WIPO Master Class is part of WIPO's work to support judiciaries in their vital role of ensuring that intellectual property, innovation, and creative ecosystems are balanced and effective

2.1.11 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, reaching over 2 million beneficiaries.

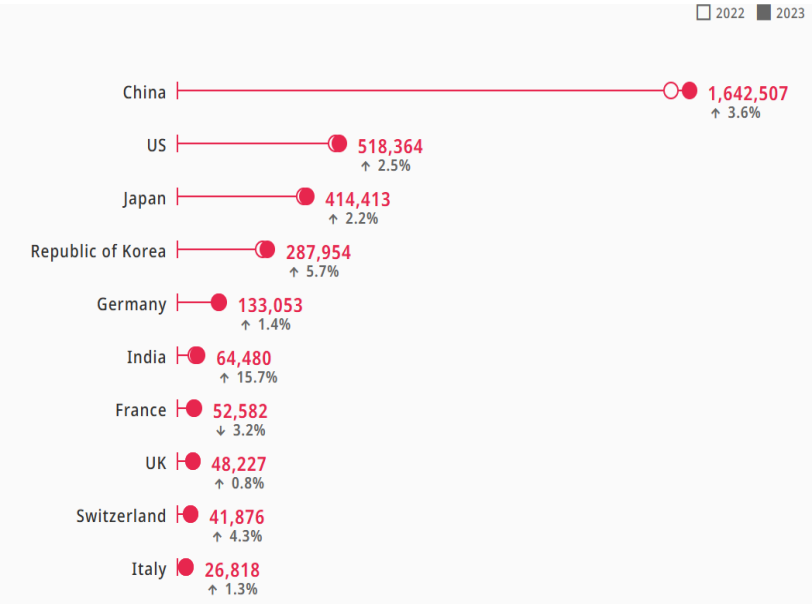
2.1.12 Further, to overcome the current limitations in innovation ecosystem, the Kalam Program for IP Literacy and Awareness (KAPILA) was launched by the Indian Government in 2020. The primary objective of KAPILA is to increase understanding of IPRs and recognizing and fostering innovation in IPR in 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. KAPILA, in collaboration with the Government of India is organizing a slew of IPR awareness programs which include addresses from experts of the Indian Patent Offices, in institutes across the country.

2.1.13 he Ministry of Human Resource Development established the Intellectual Property Education, Research, and Public Outreach (IPERPO) scheme to foster the study, research, and public awareness of intellectual property rights (IPR). The initiative aims to develop specialized courses, train enforcement personnel, organize seminars and workshops on IPR matters, and raise awareness about issues related to the World Trade Organization (WTO). As part of this effort, the Ministry has set up 18 IPR Chairs at various universities and institutes with the potential to advance IPR education, research, and training. Of these, 5 IPR Chairs are located in prominent universities, including the University of Delhi, University of Madras, and Cochin University of Science and Technology. Additionally, 5 IPR Chairs are established in National Law Universities across the country, while 5 are located in Indian Institutes of Technology. The remaining 3 IPR Chairs are situated at the Indian Institutes of Management in Ahmedabad, Bangalore, and Kolkata[12]. The aforementioned IPR Chairs are dedicated to promoting excellence in teaching and research in the field of IPR and aim to enhance public interest and engagement through a variety of educational and outreach activities.

2.1.14 The office of the Controller General of Patents, Designs, and Trademarks (CGPDTM) entered into a memorandum of understanding with the All India Council for Technical Education (AICTE) in January 2024, with the primary objective of raising awareness among students and faculty of higher education institutions about the importance of intellectual property filings, as well as the mechanisms and methodologies involved in the filing process in India. The AICTE and CGPDTM under the aforementioned memorandum of understanding, will jointly encourage students to actively participate in innovation and entrepreneurship related activities.

2.1.15 It is also pertinent to note the IPR trends in the past year. The World Intellectual Property Indicators, 2024, has found that patents filings in India saw a significant increase of 15.7% in patent applications filed worldwide, marking the fifth consecutive year of double-digit growth, primarily driven by resident filings in India in 2023[13].

[12] https://copyright.gov.in/frmlistiprchair.aspx
[13] World Intellectual Property Indicators 2024

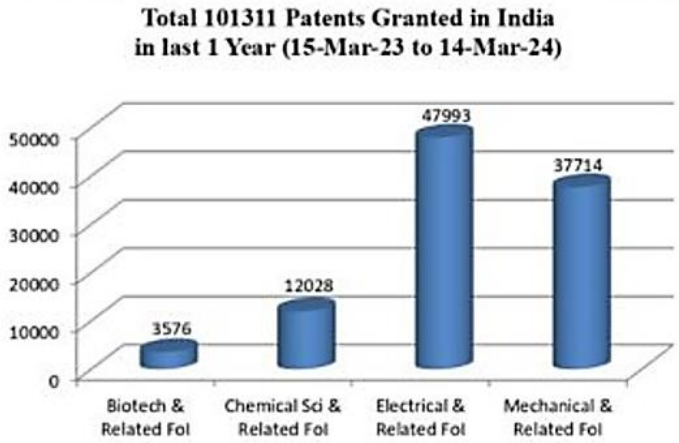


Source: WIPO Statistics Database, August 2024

India has seen the biggest change in the resident and non-resident distribution over the past 10 years, with the share of resident filings increasing from 24.8% in 2013 to 55.2% in 2023. Furthermore, India is the only origin among the top 20 countries as per WIPO, to have reported a growth in filings every year over the past decade.

2.1.16 The WIPO Indicators 2024 report states that India has secured a spot in the global top 10 for all three major IPRs, i.e., patents, trademarks, and industrial designs. ***India ranks 6th globally for patents with 64,480 applications in 2023.*** *The Indian Patent Office has granted* ***149.4%*** *more patents in 2023 compared to the previous year, underlining the fast-evolving IPR ecosystem.* The patent office is working effectively and has been clearing the pending application making it one of the fastest IP offices in the world. India ranked fourth globally in trademark filings, with a 6.1% increase in 2023. Nearly 90% of these filings were by residents, with key sectors including Health (21.9%), Agriculture (15.3%), and Clothing (12.8%) leading the way. India's trademark office holds the second-largest number of active registrations worldwide, with over 3.2 million trademarks in force, reflecting the country's strong position in global brand protection.

2.1.17 Furthermore, as per the Controller General of Patents, Designs, and Trademarks (CGPDTM), the Indian Patent Office issued over 100,000 patents between March 2023 to March 2024.



Source: Controller of Patents Designs and Trademarks.

2.1.18 The Economic Survey of 2022-23 published by the Department of Economic Affairs of the Government of India in 2024 ("Economic Survey"), demonstrated that Number of granted patents increased 17-fold from 5978 in 2015 to 103057 in 2024 The 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.

2.1.19 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.

2.1.20 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.

2.1.21 India has risen to the 39th rank in the Global Innovation Index in 2024 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 42 ranks in the last 9 years.

2.1.22 The Government of India, in its budget for the financial year 2024-25, has set aside a total of INR 3.18 billion for the intellectual property sector, of which INR 2.79 billion will go to the Office of the CGPDTM INR 208 million will go to the Management of IPR Policy, and INR 180 Million will go into the development of infrastructure in the CGPDTM offices.

2.1.23 On February 14, 2024, the CGPTDM inaugurated its Open House Helpdesk Portal, a single-window communications tool which will promptly and effectively address applicants' and stakeholders' questions and complaints in six important areas of intellectual property. It is anticipated that this effort will support India's IPR ecosystem by greatly enhancing stakeholder engagement and service delivery. Key features of the aforementioned portal include user friendly registration, real time updates regarding the status of the complaint/query, and self-paced issue resolution.

2.1.24 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[14]. 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:

2.1.24.1. 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.

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

2.1.24.2. In March 2024, India signed a trade and economic partnership agreement with European Free Trade Association (EFTA) countries comprising of Switzerland, Iceland, Norway and Lichtenstein. The agreement's main focus is market access related to goods, rule of origin, trade facilitation, trade remedies, intellectual property rights, among others.

2.1.25 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

The year 2024 has been instrumental from the standpoint of IPR in India with numerous landmark judgments on the same. The developments are laid out hereinbelow:

2.2.1. ***Saurav Chaudhary v. Union of India (2024 SCC OnLine Del 4585)***

The Hon'ble Delhi High Court underscored the need to supervise and govern patent and trademark agents, by way of the aforementioned matter, signifying the formulation of a comprehensive Code of Conduct for patent and trademark agents, detailing what constitutes professional misconduct, the process for lodging complaints, and the penalties for violations. Such a framework is essential to ensure accountability and to uphold the integrity of the intellectual property system.

2.2.2. ***EBC Publishing Pvt. Ltd. v. Parents Responsibility (2024 SCC OnLine Del 5675)***

The Hon'ble Delhi High Court, in the aforementioned matter filed by Eastern Book Company, seeking urgent interim relief against the sale of counterfeit copies of its book, restrained the defendants from manufacturing, publishing, offering for sale, or directly or indirectly selling or dealing in products under the trademark "EBC", further appointing local commissioners to enter the premises of book houses or other locations, and seize counterfeit materials.

2.2.3. ***Vifor (International) Limited & Anr. v. MSN Laboratories Pvt. Ltd. & Anr. (FAO(OS)(COMM) 159/2023)***

The Hon'ble Delhi High Court, in the aforementioned matter, held that product-by-process claims under the Patents Act, 1970, would be examined based on a new and unobvious product. The Hon'ble Court clarified the scope of products obtained by a process and those obtainable by a process, holding that the scope of a claim to a product "obtained by" a process would be only to products which had actually been made by the process.

2.2.4. ***Communication Components Antenna Inc. v. Mobi Antenna Technologies (Shenzhen) Co. Ltd. & Ors. (CS(COMM) 977/2016)***

The Hon'ble Delhi High Court, in the aforementioned matter, has set a significant precedent in the realm of patent litigation, emphasising the stringent standards of patent enforcement in India and highlighting the Hon'ble courts' commitment to upholding the rights of patent holders against infringement. The Hon'ble Delhi High Court delivered a comprehensive judgment finding the defendant guilty of infringement and ordering the defendant to pay damages amounting to USD 2,60,45,250 as compensation for the lost profits suffered by the plaintiff. This judgment is a milestone in patent enforcement in India, demonstrating a robust stance against infringement and thereby deterring future infringers.

2.2.5. ***Dr. Reddy's Laboratories Limited v. SGS Pharmaceuticals (P) Ltd. (CS (COMM) 873/2023)***

The Hon'ble Delhi High Court, in the aforementioned matter, granted relief to the plaintiff, i.e., Dr. Reddy's Laboratories, by restraining the defendant from infringing on the registered trademark, trade dress, colour scheme, and distinctive packaging of the medicine sold by the plaintiff. This decision emphasised two elements, being – as illiteracy was prevalent among probable consumers, the appearance of a product was significant; and there should be no possibility of confusion in the mind of the average consumer or purchaser of medicines. Considering that the products in the aforementioned matter are pharmaceutical products, the Hon'ble Court emphasized that a higher degree of care must be taken to avoid any possibility of identical packaging.

2.2.6. ***Seagate Technology LLC v. Daichi International (CS (COMM) 67/2024)***

In the aforementioned matter, Seagate, a leading player in the data storage industry, filed a case against the defendant, accused of importing and rebranding end-of-life hard disk drives bearing Seagate's trademark. Seagate relied on Section 30(4) of the Trade Marks Act, 1999, which empowers trademark owners to prevent further dealings of their goods if their condition has been altered or impaired after being put on the market. The Hon'ble Delhi High Court issued an ex-parte injunction, restraining the defendant from further infringing upon Seagate's trademark rights, thereby emphasising on the importance of provisions like section 30(4) of the Trade Marks Act, 1999 in brand protection and prevention of counterfeits.

2.2.7. ***GlaxoSmithKline Biologicals SA v. Human Biolife India Private Limited & Ors. (CS (COMM) 948/2023)***

The Hon'ble Delhi High Court, in the aforementioned matter, revisited the benchmarks for evaluating potential confusion among pharmaceutical products, holding that goods which are used in the pharmaceutical sector require a more stringent yardstick of measurement. The Hon'ble Court further observed that the subject matter also included a public interest perspective since the confusion among the general public could lead to fatal consequences for the recipient of the medicine.

3. PATENTS

3.1. PRE-GRANT OPPOSITIONS

3.1.1. The Special 301 Report, 2024, incorrectly reiterates previous concerns about alleged prolonged delays that patent applicants face. This issue has been addressed in all our prior submissions including those to the Special 301 Reports of 2020, 2021, 2022 and 2023[15].

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. Specifically in the field of pharmaceuticals, this provision is crucial for advancing the nation's health by ensuring access to affordable, generic medicines, which is vital for India's economic prosperity. .

3.1.4. It is crucial to emphasize that the pre-grant opposition provides a good framework to allow only quality and genuine patents to be granted. 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 behaviour of pharmaceutical innovator/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

[15] 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).

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 Hon'ble 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, 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 increase in the statutory fees as per the Patent (Amendment) Rules, 2024, 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, Egypt, and Colombia have pre-grant opposition provisions.*** The proposed changes in pharma legislation related to patents in the EU, talks of pre grant are on.

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 new Patent (Amendment) Rules, 2024, ensure that pre-grant oppositions are not abused or filed frivolously. Upon receiving a pre-grant opposition, the Controller is now required to ascertain whether a prima facie case is made out in the submissions, and only once the Controller is satisfied with the prima facie case, the opposition would be served to the patentee. Alternatively, the Controller shall now issue a notice to the opponent rejecting the opposition if it is found that a prima facie case is not made out. Further, as mentioned hereinabove, the official fees to file a pre-grant opposition has been increased, thereby deterring frivolous and serial oppositions.

3.1.10. Additionally, 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 though the patent has already been granted, even in the event of delays. 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 Hon'ble 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 and needlessly driving up the cost of the drug and making a life-saving cancer treatment financially inaccessible under a monopoly. Additionally, it's 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***.

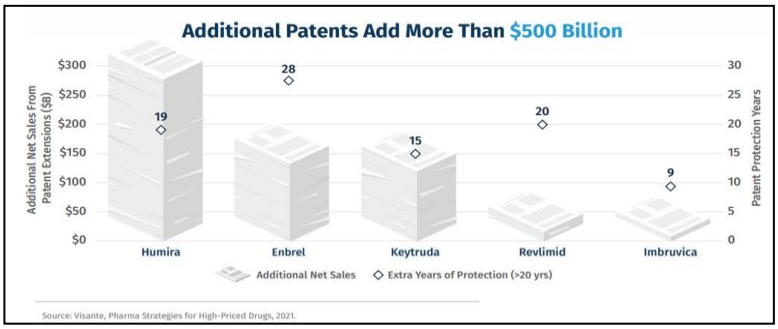
3.2.2 IPA has previously addressed this concern in its prior submissions including those to the Special 301 Reports of 2020, 2021, 2022 and 2023[16]. It is reiterated that secondary patents, involving new forms of known substances, are often strategies aimed at evergreening patents to extend their term 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

[16] 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).

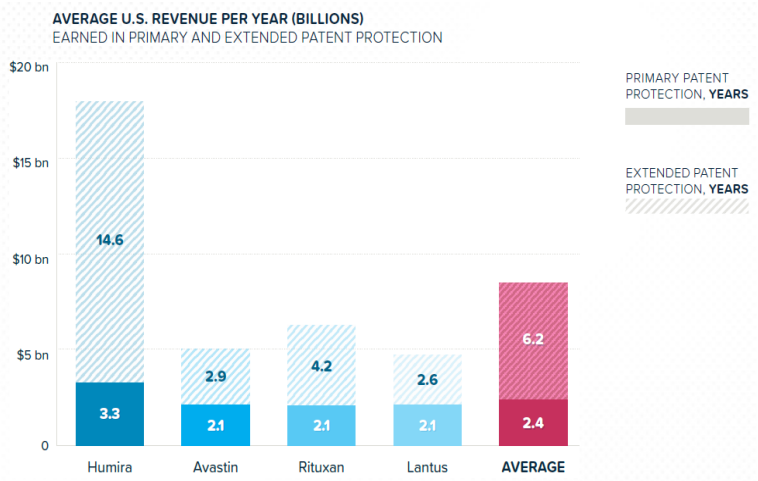
Price Competition and Innovation Act of 2009 was entered into law, establishing an abbreviated approval pathway to help provide patients with greater access to biosimilars. The U.S. has, over the years realized the necessity for quality generic medicines and biosimilars. In furtherance to the same, the United States Patent and Trademark Office (USPTO) has established an official collaboration with the U.S. Food and Drug Administration to facilitate access to affordable medicine by stopping brand companies from gaming the systems by providing selective, and sometimes incongruent data to each agency, thereby attempt to maximize brand product lifecycles to the detriment of American taxpayers and patients[17].

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. A patent 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 a recent report, 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 enhancingtheir 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 ofprotection.



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 brand 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 and the nation.

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



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 As stated above, it is evident that brand pharmaceutical companies engage in practices that disadvantage American patients by delaying their access to affordable medicines in pursuit of higher revenues and sales. Last year, the U.S. Congress spent considerable time considering legislation aimed at ending patent thickets, which will be raised again in the new Congress. ***The U.S. Congressional Budget Office (CBO) estimated that these reforms would reduce spending by $1.8 billion over 10 years***, significantly lowering the price of affected products by 20 percent on average, thereby enhancing public access to potentially life-saving medications at faster rates and reduced costs

3.2.7 Patent thickets, as detailed previously, pose significant barriers to affordable healthcare worldwide. In India, the implementation of Section 3(d) of the Indian Patents Act has been instrumental in curbing these issues. This provision uniquely prevents the evergreening of patents by ensuring that only genuine innovations, not mere modifications of existing drugs, are eligible for patent protection. Consequently, this not only avoids unnecessary patent thickets but also restricts the monopolistic practices of brand-name manufacturers, fostering a competitive market that benefits the public by making medicines more accessible and affordable.

3.2.8 India's patent laws align with TRIPS, striking a balance between encouraging innovation and safeguarding public health. As noted 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 The interpretation of Section 3(d) was further clarified in the case of Novartis AG vs. Natco Pharma Limited & Anr., where the Division Bench emphasized that enhanced bioavailability does not necessarily equate to higher therapeutic efficacy. In this case, ELT-O, a pharmaceutical salt of the known substance ELT, was found NOT to demonstrate enhanced therapeutic efficacy. Consequently, the Division Bench invalidated Novartis' suit patents and overturned the Single Bench's injunction order, reinforcing the principle that

therapeutic efficacy must be demonstrable and substantial under Section 3(d).. his decision aligns with other cases, such as FMC Corporation and Anr. vs. Best Crop Science LLP and Anr., which also underscore the necessity of demonstrating substantial therapeutic efficacy for patent eligibility under Section 3(d). The Hon'ble 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.

3.2.10 Section 3(d) therefore grants patents to incremental inventions, except those that merely make insignificant, minor modifications without significant therapeutic enhancements. This provision strategically curtails practices such as patent evergreening, the creation of patent thickets, and monopolistic control of patents, promoting substantial and authentic innovation in the process. . Some instances wherein Indian Courts have highlighted the nuances of Section 3(d) are provided hereinbelow:

3.2.10.1. In the matter of Intervet International B.V. vs. Deputy Controller of Patents and Designs, the Hon'ble Madras High Court, with respect to Section 3(d), held that "*it would suffice if the applicants are able to prove that their claimed invention has enhanced therapeutic efficacy and there is no necessity to take a specific plea in their application that the claimed invention has therapeutic efficacy"*

3.2.10.2. In the matter of Nippon Steel vs. The Controller General of Patents, Designs and Trademarks, the Hon'ble Delhi High Court adjudicated on core issues concerning the patent eligibility assessments of inventions under section 3(d) of the Act. The Hon'ble Court held that in order to reject a claim under Section 3(d), it is important for the objections raised against the patent application to identify the known substance and provide prior art documents to substantiate the same. In the absence of such identification, a refusal order is liable to be set aside.

3.2.10.3. In the matter of Galatea Ltd. vs. The Controller of Patents and Ors., the Hon'ble Madras High Court established the importance of identifying the 'known substance' and the 'known efficacy', in determining applicability of Section 3(d). It is easily deducible that 'known substance' means a substance that is 'known' or in other words published or made available to the public before the claimed invention. Merely because the claimed invention is a polymorph of a compound that is previously patented, does not automatically render the compound a 'known substance', unless the compound is published before the priority date of the claimed invention.

3.3. WORKING OF PATENT [FORM-27]

3.3.1. In India, patents are granted to foster innovation, however, their value to society hinges on their commercial utilization. A patent that remains unexploited commercially exploited fails to fulfil its intended economic and development purpose. To address this, the Indian Patents Act and Patent Rules require patentees to file Form-27, providing a statement on the commercial use of the patented invention within India.

3.3.2. The Special 301 Report, 2024, highlights concerns about excessive reporting requirements faced by patent applicants in India. The Patent (amendment) rules 2024, have amended the current Form-27 and simplify it further. As per the aforementioned patent rules, a patentee is required to file a Form-27 to show the working of a patent. The amended Form-27 would

only require the following information: Whether the patent was worked or not worked, and patentees are no longer required to disclose revenue/value from manufacturing or imports or reasons for non-working of the patent. Furthermore, the requirement to file a Form-27 under the aforementioned patent rules have been reduced to once in 3 financial years, rather than once every financial year. The concerns raised in the Special 301 Report, 2024 regarding excessive reporting requirements therefore do not arise

4. COUNTERFEIT DRUGS

4.1. The Special 301 Report for the year 2024 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 endeavour 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. By aligning with similar U.S. standards, it mandates that companies selling medicine in India must also comply with stringent track and trace protocols. This integration not only upholds the quality of pharmaceuticals within India but also ensures that products entering the U.S. and European markets meet rigorous safety and quality benchmarks.

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.[18]

4.3. PROPOSED CHANGES IN LEGISTATION:

4.3.1. The Central Government of India has published the Drugs, Medical Devices and Cosmetics Bill, 2023 (Draft Bill) which represents a transformative step in regulating the import, manufacture, distribution, and sale of drugs, medical devices, and cosmetics. It aims to replace the Drugs and Cosmetics Act of 1940, modernizing the regulatory framework to align with advancements in healthcare and technology. The definition of spurious drugs has been broadened to include drugs without an active pharmaceutical ingredient, underscoring the government’s commitment to stricter quality standards and public health safety.

4.3.2. The Draft Bill prescribes stringent penalties to deter violations. For importing or manufacturing spurious drugs that could harm public health, offenders may face imprisonment for a minimum of 10 years, extendable to life imprisonment, and a fine of ₹10 lakh or three times the value of confiscated drugs, whichever is higher. These measures are outlined in Section 104, which also specifies penalties for selling spurious allopathic drugs. Furthermore, the Bill addresses the growing presence of e-pharmacies, mandating licenses for the online sale of drugs and medical devices to curb unregulated sales. The

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

Central Government is empowered to draft detailed rules for this sector, filling a significant regulatory gap

4.3.3. Revised Schedule M, has been introduced which play a vital role in ensuring quality control and sets out Good Manufacturing Practices (GMP) for premises, plant, and equipment in pharmaceutical manufacturing. This revision ensures compliance with international quality benchmarks and enhances consumer safety.

4.3.4. The Draft Bill introduces a distinct regulatory framework for medical devices, acknowledging their unique technological and operational complexities. Key provisions include:

4.3.4.1. A broadened definition of medical devices which encompasses diagnostic equipment, implants, and life-support systems.

4.3.4.2. Creation of a Medical Devices Technical Advisory Board to oversee technical aspects and advise the government.

4.3.4.3. Establishment of Central and State Medical Device Testing Centres to ensure robust evaluation and monitoring.

4.3.5. Another notable update in the Draft Bill is the expansion of the scope of the AYUSH framework, now including Sowa-Rigpa and Homeopathy alongside traditional Ayurvedic, Siddha and Unani systems. The introduction of categories like “innovative drugs” under this framework is expected to drive research while ensuring regulation of novel formations.

4.4. The Government has also set up a portal called iVEDA which stands for the IntegratedValidation 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. As per the new directive, Pharmaceutical exporters in India will now have to implement the Track and Trace system. The Central system will be changed from DAVA to iVEDA. The iVEDA portal is envisaged to help manufacturers and merchant traders to generate and utilise tertiary and secondary level coded data in a user-friendly manner. The manufacturers and exporters are required to upload data on barcode on secondary and tertiary packaging of drugs meant for export on the portal.

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. Further, the Government of India plans to make the QR code system mandatory for vaccines, cancer drugs and antibiotics in order to prevent the supply of counterfeits.

4.6. It is pertinent to note that various pharmaceutical companies have already begun implementing QR codes in line with the DGCI’s directions. Pharmaceutical companies collectively advocate for stronger collaboration with the government to optimize the QR code system. Proposed measures include establishing a joint task force to combat counterfeiters, incentivizing enforcement efforts, and launching public awareness campaigns to educate consumers on the benefits and use of QR codes. Mankind Pharmaceuticals, which has already incorporated QR codes into 20 of its products, strongly

supports the mandatory implementation of barcodes and QR codes on medicines. In addition to QR codes, Mankind has implemented holograms for enhanced anti-counterfeiting measures. By scanning the QR code, consumers can access essential details such as the expiry date, manufacturing license number, unique product identification code, proper and generic drug names, brand name, batch number, and manufacturer details. Abbott has also integrated QR codes into its top brands, ensuring compliance with the government mandate. A spokesperson confirmed that the company recognizes the importance of authenticating medicines and protecting patients from counterfeits and has joined other industry leaders in this initiative. Similarly, Zydus Lifesciences began introducing QR codes on select products in 2021 and plans to expand their use across more products. Venus Remedies has implemented QR codes across its entire product range in India. Each unit carton now features a unique QR code for batch-level tracking and detailed product information. Bayer, incorporating QR codes in products such as Saridon and the Supradyn range, believes the initiative will not only enhance patient safety but also improve health literacy by providing access to additional product and therapy information through QR code scans.

4.7. 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 2024 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 Hon'ble 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. Further, the Hon'ble Bombay High Court, in the case of Tarun Wadhwa v. Saregama India Ltd held that when no contract exists, equitable and common law principles of breach of confidence govern disputes relating to trade secrets. The Hon'ble Court held that for such actions, the plaintiff is required to identify the information, demonstrate that it was handed in circumstances of confidence & it was to be treated as confidential, and that it was used or threatened to be used without consent. Through the aforementioned cases, 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 a significant development, the Law Commission of India released its 289th Report on "Trade Secret and Economic Espionage" on March 5, 2024 ("LC Report"), proposing a comprehensive legal framework to address claims related to trade secrets and confidential information. The LC Report emphasizes the necessity of a sui generis law, consolidating existing principles and judicial precedents while addressing the specific needs of the Indian industry and accommodating diverse stakeholder perspectives. Key recommendations of the Law Commission of India in the LC Report include defining trade secrets based on Article 39 of the TRIPS Agreement and emphasising criteria such as secrecy, commercial value and reasonable protective measures employed to protect the trade secrets. The LC Report also highlights that trade secrets lack the property-like monopoly rights seen in other intellectual property forms, as they involve no public disclosure. Misappropriation is defined narrowly to avoid overprotection, targeting only acts conducted in bad faith. Furthermore, exceptions to trade secret protection, such as those for whistleblowers, public interest, and compulsory licensing, have been proposed, citing examples like the refusal of voluntary licensing for COVID-19 vaccines as a gap in the current framework. the LC Report advises against establishing a trade secret board or registry, considering the practical challenges of maintaining sensitive information. Instead, it proposes in-built mechanisms to safeguard confidentiality during litigation. The Law Commission of India has also appended a draft bill, *The Protection of Trade Secrets Bill, 2024,* which seeks to codify the acquisition, use, and disclosure of trade secrets and associated legal proceedings. While the necessity of such codification remains a topic of debate, the LC Report underscores the growing importance of trade secrets in Industry and presents a formative attempt to balance the interests of industry, innovators, and the public.

5.5. 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. Further the aforementioned LC Report could significantly strengthen India's trade secret protection regime and address existing gaps in its legal framework

6. CUSTOMS DUTIES DIRECTED TO IP-INTENSIVE PRODUCTS

The Special 301 Report, 2024, 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, 2024 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 doesnot, from a prima facie*

reading, appear to impose data exclusivity during a certain period of time."[19]. 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 many trade experts, data exclusivity is a TRIPS plus measure[20], meaning that member states may opt to, but are not obliged to grant TRIPS-plus protection. Further, as noted above, 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"[21].

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

8. CONCLUSION

8.1. Over the years, India has demonstrated a steadfast commitment to strengthening its IPR framework through consistent policy reforms, enforcement measures, and awareness initiatives. The Special 301 Report, 2024, acknowledges India's advancements in promoting and protecting IPR, reflecting its dedication to building a robust and inclusive IPR ecosystem.

8.2. India's balanced approach to patent laws underscores its focus on fostering innovation while ensuring public access to affordable medicines. Unlike many jurisdictions where stringent patent laws limit access, India's IP regime prioritizes equity and affordability, particularly in the healthcare sector. The integration of flexibilities under the TRIPS Agreement, such as those embedded in Section 3(d) of the Patents Act, has been instrumental in preventing practices like evergreening and patent thickets, which can delay the availability of generics and affordable treatments India 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. Furthermore, India's efforts to combat counterfeit drugs through initiatives like mandatory QR codes and the Drugs, Medical Devices, and Cosmetics Bill, 2023, highlight its proactive stance in safeguarding public health. Measures such as these, coupled with extensive public awareness campaigns and industry collaborations, have reinforced trust in the Indian pharmaceutical ecosystem

8.4. 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 India's strides in expediting patent processes, enhancing enforcement mechanisms, and fostering IP awareness through programs like NIPAM and CIPAM further solidify its position as a global leader in IPR management. These achievements align with India's long-term goal of maintaining an IP-friendly environment while ensuring equitable access to knowledge and resources. We

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

contend that the concerns raised by U.S. companies regarding the long waiting periods to receive patent grants and excessive reporting requirements warrant closer examination

8.5. Section 3(d) of the Patents Act specifically targets secondary patents that lack efficacy enhancement. These patents if granted would lead to evergreening. This practice of evergreening delays the entry of generic drugs, negatively impacting global patient access to essential medications.

8.6. The present submission emphasizes India's unwavering commitment to IPR laws, demonstrated by ongoing improvements to the IPR ecosystem with a focus on enhancing the ease of doing business. This presents a compelling case for removing India from the Special 301 Report, 2024's Priority Watch List. India is fully aligned with its international IPR obligations and is proactively working towards creating a more IPR-friendly environment. We strongly urge the USTR to remove India from the Priority Watch List.

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