INNOVATION. QUALITY. GLOBAL REACH.

USTR: 2021 Special 301 Submission

(Docket No. USTR-2021-0021-0001)

Submission by

INDIAN PHARMACEUTICAL ALLIANCE

Mumbai

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INDEX

LIST OF ACRONYMS AND ABBREVIATIONS

[Listed out as below in alphabetical order]

Abbreviation/ Acronym	**Full- Form**
ANDA	Abbreviated New Drug Applications
ASCI	Advertising Standards Council of India
CGPDTM	Controller General of Patents, Designs & Trademarks
CII	Confederation of Industrial Industry
CIPAM	Cell for Intellectual Property Rights Promotion and Management
DKPTO	Danish Trademark and Patent Office
DPIIT	Department for Promotion of Industry and Internal Trade
DRPSCC	Department Related Parliamentary Standing Committee on Commerce
EO	Eltrombopag Olamine
EPO	European Patent Office
EOW	Economic Offences Wing
FICCI	Federation of Indian Chambers of Commerce & Industry
FRAND	Fair, Reasonable and Non-Discriminatory
FY	Financial Year
GeM	Government e-Marketplace
GII	Global Innovation Index
IBEF	Indian Brand Equity Foundation
INTA	International Trademark Association
IoT	Internet of Things
IP	Intellectual Property
IPA	Indian Pharmaceutical Alliance
IPAB	Intellectual Property Appellate Board
IPD	Intellectual Property Division
IPEA	International Preliminary Examining Authority
IPR	Intellectual Property Rights
ISA	International Searching Authority
JPC	Joint Parliamentary Committee

KOTRA	Korea Trade-Investment Promotion Agency
LMIC	Low and Middle Income Countries
MCDCU	Maharashtra Cyber and Digital Crime Unit
MHA	Ministry of Home Affairs
MoU	Memorandum of Understanding
MPP	Medicine Patent Pool
MSD	Merck Sharp & Dohme
MSF	Médecins Sans Frontières
MSME	Ministry of Micro, Small and Medium Enterprises
NACIN	National Academy of Customs, Indirect Taxes & Narcotics
NIXI	National Internet Exchange of India
NJA	National Judicial Academy
PDP	Personal Data Protection Bill
RFID	Radio-Frequency Identification
R&D	Research and Development
SC	Supreme Court
SEPs	Standard Essential Patents
SIPP	Start-ups Intellectual Property Protection
TPF	Trade Policy Forum
TRIPS	Trade Related Intellectual Property Rights
UK	United Kingdom
UN	United Nations
UoI	Union of India
US	United States
USA	United States of America
USD	United States Dollar
UNAIDS	United Nations Programme on HIV and AIDS
USTR	United States Trade Representative
WHO	World Health Organisation
WIPO	World Intellectual Property Rights Organisation
WTO	World Trade Organisation

1. INTRODUCTION

1.1 This submission is being made on behalf of the Indian Pharmaceutical Alliance (IPA). IPA's membership consists of twenty-four large pharmaceutical companies. IPA member companies collectively account for more than 85 percent of India's private sector investment in pharmaceutical research and development. Further, IPA member companies contribute to over 80 percent of the exports of drugs and pharmaceuticals; and service over 57 percent of the domestic market in India. IPA, therefore, has a vital interest in the protection, promotion and perseverance of innovations. The focus is not only around developing cost-effective and useful improvements to existing medicines, but also extends to the discovery of new medicines.

1.2 The IPA member companies are committed to providing safe and effective drugs to all consumers in the U.S. and across the globe in an efficient manner. The United States and India are both manufacturing hubs for our member companies. During the Covid-19 pandemic in 2020 and its spill-over to the year 2021, IPA member companies have shown commitment towards the uninterrupted supply of quality medicines. The large Indian pharmaceutical companies have been playing a critical role in U.S. healthcare. In 2020, generics accounted for 90 per cent of prescriptions filled in the U.S., yet only 18.1 per cent of prescription drug spending. In the last decade, generics contributed a significant U.S. $ 2.4 Tn to America's patients.[1]

1.3 Over the years, the trade between India and the U.S. in relation to pharmaceuticals has gained great momentum and significance. This is reflected by the fact that the Indian pharmaceutical industry is contributing to nearly 40 per cent of the generic drug production to its U.S. counterpart. Indian Pharmaceutical companies have worked to develop generic drugs to aid and cater to the demand of the U.S. Healthcare. As a result, American consumers now have a wider access to affordable medicines which has helped the U.S. Healthcare system save approximately USD 2.4 trillion over the last decade (USD 338 billion in 2020).[2]

[1]2021, Generic Drug & Biosimilars Access & Savings in the U.S. Report
[2]2021, Generic Drug & Biosimilars Access & Savings in the U.S. Report

1.4 To cater to India's domestic need as well as to aid the U.S. Healthcare, the leading Indian pharmaceutical companies have taken steps to enable the achievement of the same. Manufacturing facilities with investments of over USD 4.5 billion have been set-up across twenty states in the U.S. in the last five years and a significant employment generation (more than 5500 employees) in the U.S. has been done, which has been a remarkable feat for the member companies and this figure is only slated to grow in the coming years to aid the U.S. healthcare system. In the year 2021, Indian pharmaceutical companies have secured around 210 ANDA approvals out of a total of 635 approvals, which amounts to approximately 33% of the total approvals in favour of the Indian Pharmaceutical companies.[3]

1.5 The Special 301 reporting system was established before the adoption of the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement). At the time, the objective was to ensure that countries around the world protect intellectual property as many countries did not grant patents for pharmaceutical products. However, this objective was achieved with the adoption of multilateral trade agreement of TRIPS, which streamlined the standards for protection of pharmaceutical products and processes and established a 20-year patent term monopoly for all members of the WTO, except for the least developed nations, who enjoy a longer transition period.

1.6 Much has changed since the adoption of the IPR regime of 1995. The list of elements included in the Special 301 Report, 2021 seems to respond to the interests of a select group of originator pharmaceutical companies with regards to the Indian pharmaceutical sector. The Report disregards the fact that India provides adequate and effective protection of intellectual property rights. Furthermore, a review of the past two years clearly points that the current intellectual property system has limitations with regard to access to medicines. During the Covid-19 pandemic, the biggest humanitarian challenge of this century, vaccine and medicine inequity has become increasingly clear.

[3]2022, January 12, The Health Master 'Indian Pharma Firms get 210 out of 635 approvals from USFDA'

Today, the world needs policies that create more medicine equity while protecting IP, and do not just create more monopolies and further inequity as Covid-19 has taught us "No-one is safe until everyone is safe". The focus on growing intellectual property protections in the pharmaceutical sector has led to a significant drug inequality and inequity. Recognizing this, Australia, India, Japan and the U.S. have formed QUAD group that will help in "Creating an equitable access to an effective vaccine distribution" as is a central goal of the Quad as outlined by the leaders' joint statement entitled "The Spirit of the Quad". We urge USTR to kindly take into consideration needs of the changing world.

1.7 Nonetheless, India has been fully complying with the international obligations and is committed to the multilateral TRIPS Agreement, and that Special 301 Report should consider stopping the demand of additional monopolies in response to the pressure of select groups. The Indian pharmaceutical industry is committed and proud of its important global contribution to open up access to affordable medicines around the world in full compliance with TRIPS Agreement and Covid-19 is testimony to this.

1.8 We further like to submit that India and the U.S. are close allies in many areas, and this should be an opportunity for collaboration and partnership in relation to the pharmaceutical sector. Both the U.S. and India have an opportunity to play a greater role by developing new systems, prioritizing human life, food, health, national security and environment. A system could be created that prioritizes innovation and access to technology for the common good while boosting global cooperation. The countries should collaborate in R&D efforts in the pharmaceutical sector to ensure further developments in breakthrough treatments, at cost effective prices that are accessible and affordable to populations across the world. Together, the U.S. and India can make a huge difference in this area. The focus on growing intellectual property protections in the pharmaceutical sector has led to a significant drug inequality and inequity. It is a time for cooperation and collaboration that will help cater patients' needs and patient welfare in both the countries.

1.9 IPA has made several submissions to the United States Trade Representative (USTR) over the years and highlighted India's effective Intellectual Property Rights (IPR) ecosystem. This submission addresses the patent issues which are particularly relevant to the pharmaceutical industry and touches upon other IPRs relevant to the pharmaceutical industry, such as Trademarks. India is one among the 9 countries placed on the Priority Watch List in the Special 301 USTR 2021 Report.[4] Despite this, the Indian pharmaceutical sector supplies over 60% of the global vaccines demand, 40% of the U.S. generic demand and 25% of all UK medicines. Further, India is the second-largest contributor of the pharmaceutical and biotech workforce in the world. India ranks 3rd in terms of pharmaceutical production by volume and 14th by value.[5]

1.10 This submission puts forth and summarizes a range of key developments undertaken by the Government of India, the Indian judicial system, and other stakeholders to further strengthen and modernize India's intellectual property (IP) ecosystem. It seeks to submit information and perspectives that articulate that India provides adequate and effective protection of IPR, as also 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 of the Special 301 review process.

2. DEVELOPMENTS IN THE IPR SYSTEM IN INDIA

2.1 FACETS COMMON TO ALL FORMS OF IPR

2.1.1 The Appellate Tribunal set up to hear appeals against decisions from the Indian Intellectual Property Offices, known as the Intellectual Property Appellate Board (IPAB), has been abolished with effect from 4 April 2021, through The Tribunal Reforms (Rationalisation and Conditions of Service) Ordinance, 2021.[6]

[4]2021 Generic Drug & Biosimilars Access & Savings in the U.S. Report
[5]2021, November, Indian Brand Equity Foundation, Indian Pharmaceuticals Industry Report
[6]2021, The Tribunal Reforms (Rationalisation and Conditions of Service) Ordinance

The Statement of Objects and Reasons of the 2021 Bill states that data from the past three years shows that the presence of tribunals in certain sectors has not led to faster adjudication, and such tribunals add considerable cost to the exchequer. Therefore, with the abolishment of the Intellectual Property Appellate Board (IPAB), the jurisdiction to adjudicate upon appeals arising from orders passed in respect of Patent, Trademark, Copyright, and other IPR matters have been transferred to the High Courts. The High Court of Delhi and the High Court of Mumbai have framed some new rules and guidelines for handling the appeals. This step is expected to reduce the cost to the exchequer and increase the speed of adjudication of IP matters, in a more effective, efficient and speedy manner.

2.1.2 In July 2021, the High Court of Delhi took the initiative to set-up the Intellectual Property Division (IPD) which has been dedicated for hearing IPR matters. This move is in line with similar global practices around the world. It will help in the efficient disposal of IP matters, while bringing in consistency in terms of precedents set by the Courts. The Delhi High Court has set up a committee which is working on framing comprehensive rules for the IPD. The High Court of Mumbai, Calcutta and Chennai are also in the process of forming similar rules.

In view of the egalitarian and humanitarian approach in the wake of the Covid-19 pandemic and with a view to ease the burden on litigants, the Supreme Court of India extended the suspension of statutory deadlines applicable to various legal matters, including IP matters. This follows the principles of natural justice and prevents the loss of rights and opportunities to pursue matters, by the aggrieved parties.

2.1.3 In June 2021 the U.S.-India Trade Policy Forum's (TPF) Working Group on Intellectual Property restarted its proceedings after a gap of nearly three years. Over the years, the Government of India and the TPF continue to actively engage across various platforms, such as the U.S.-India IP Dialogue, routinely through bilateral interactions on specific IP issues.

In November 2021, United States Trade Representative met with India's Minister of Commerce and Industry and discussed various issues including those relating to IP and collaboration in this respect. In addition, the TPF has also been engaging with Indian Customs, Police and Judiciary officials and industry representatives to explore ways to strengthen India's enforcement ecosystem.

2.1.4 On 23 July 2021, India's Department Related Parliamentary Standing Committee on Commerce (DRPSCC), presented its 161st Report on "Review of the Intellectual Property Rights Regime in India". The Report is an example of vibrant democratic structure of the country wherein steps are taken in regular intervals to review the subjects of vital importance, in this case the IPRs, especially in the wake of new emerging realties and trends in spheres of innovation and research which require concrete IPR mechanisms.

2.2 INDIA FORGES INTERNATIONAL ALLIANCES

In its efforts to form new international relations and further strengthen the existing ones, India took decisive steps to work in co-operation with various countries, particularly with the U.S., Korea, Denmark and the European Union by entering into MoUs, conducting virtual conferences, awareness camps, among others to further the promotion and protection of IPRs. A few such efforts were taken through a cell called the Cell for Intellectual Property Rights Promotion and Management (CIPAM) under the Department for Promotion of Industry and Internal Trade (DPIIT) of the Indian Government.

An MoU was signed between the DPIIT and the USPTO on 19 February 2020 to increase the IP co-operation between India and the United States[7]. The signing of

[7]2020, December 03, Press Information Bureau, Government of India, Ministry of Commerce & Industry, 'India, USA sign MoU on Intellectual Property cooperation'

this MoU will further the objectives of the National IPR Policy, 2016[8] and marks India's significant presence on the global map to promote and protect innovation. In January 2021, CIPAM collaborated with the DKPTO and the Danish Embassy to conduct a workshop for capacity building between Denmark and India to share best practices on creating IPR awareness. Further, an IP Manual was launched in March 2021 and has been created to provide an easy understanding of the Indian IP Law for the benefit of international industries and start-ups that are interested in getting their IP registered in India. CIPAM also collaborated with KOTRA to conduct an awareness drive regarding counterfeit products and the rising socio-economic harms associated with the same. A 10 day Korea Fair India, 2021 was organised from 1 October, 2021 to 10 October, 2021. Apart from the above efforts, DPIIT and The European Union Commission conducted a virtual dialogue to further strengthen the relationship between India and the European Union and to facilitate their enhanced cooperation in the field of IP[9].

2.3 CREATING AWARENESS AND FOSTERING THE CULTURE OF IPR PROTECTION

DPIIT's CIPAM is entrusted with the mandate to encourage, foster, educate, train and support organizations, industries and educational institutes to understand IP better and to help create and protect one's own intellectual property rights. In this regard, CIPAM created several training materials for Schools, Universities and other Educational Institutes. CIPAM also did the same across Industries, with the Police Force and with other enforcement authorities. CIPAM also planned to conduct training programs for Judicial authorities as well. As a result, several training programs including roadshows were all conducted online in view of the Covid-19 situation prevalent in the Country and across the world. The attendance at such virtual training sessions has been phenomenal, and the outreach program is expected to continue. Over 400+ webinars were successfully organized by CIPAM for a variety of stakeholders.

[8]2018, December 27, Press Information Bureau, Government of India, Ministry of Commerce & Industry, 'National IPR Policy'
[9]2021, January 20, Indian Brand Equity Foundation (IBEF)"First India-EU IPR dialogue held to strengthen relation and facilitate enhanced cooperation in the field of Intellectual Property Rights"

2.3.1 IPR EDUCATION AND OUTREACH PROGRAMS IN ACADEMIC INSTITUTIONS BY CIPAM

2.3.1.1 Approximately 4300 academic institutions have been covered via 327 such programs/ webinars.

2.3.1.2 CIPAM, in its collaboration with FICCI hosted around 65 webinars across colleges and universities elucidating and imparting education on IPR.

2.3.1.3 The Union Education Minister along with the Tribal Affairs Minister, launched the School Innovation Ambassador Training Program for 50,000 school teachers in July 2021. In this innovative and one-of-its-kind training program, 50,000 teachers were educated and trained in areas related to IP, innovation, entrepreneurship, design thinking, product development, idea generation, etc.

2.3.2 TRAINING SESSSIONS WITH THE JUDICIARY, POLICE AND THE CUSTOMS DEPARTMENT BY CIPAM

2.3.2.1 Approximately122 programs for enforcement agencies along with the Judiciary were conducted successfully by CIPAM.

2.3.2.2 The Police and the Judiciary, being extremely important wings in safeguarding and promoting the enforcement, education and awareness around Intellectual Property were made part of CIPAM’s training and outreach programs. Police Training Programs were conducted to help in gaining familiarity with investigation trends and techniques. Over 100 such programs on IP enforcement have been conducted successfully for various law enforcement agencies, such as the Police, the Judiciary, and the Customs by CIPAM, pan India.

These programs have been conducted in association with IP experts from leading law firms and other imminent industry persons.

2.3.2.3 For the Customs officials across India, CIPAM has conducted training programmes in collaboration with the National Academy of Customs, Indirect Taxes & Narcotics (NACIN). 28 such training programmes have been successfully organised in 2021.

2.3.3 INITIATIVES TO FUEL INNOVATIONS THROUGH START-UP INDIA PROGRAM

2.3.3.1 The Start-ups Intellectual Property Protection (SIPP) scheme was launched in 2016 with the aim to protect and promote IPR amongst start-ups. The Scheme, which was first introduced on pilot basis till 31 March, 2020, has now been extended to 31 March, 2023. Start-ups only bear the cost of the statutory fees payable on the filing of their applications. The Central Government bears the entire fees of the facilitators for any number of patents, trademarks or designs. A list of such facilitators, being IP experts in IP are readily available online for the start-ups to utilize them. Start-up entities also enjoy the privilege of fast-tracking their patent applications.

2.3.3.2 Some key trends on start-up filings and registrations are reflected as below:

- As of December 2021, a total of 6771 start-ups have filed patent applications.
- For start-ups, CGPDTM has empanelled 510 facilitators for patents and designs and 392 facilitators for trademarks.

- As of 31 December 2021, 1716 start-ups had requested for an expedited examination of their patent applications, out of which 1620 applications have already been examined, and 784 patents already granted.

2.3.3.3 CIPAM has conducted 382 programs for MSMEs and Start-ups. Intensive IPR training has been given to MSME Officers and further, MSME clusters have also organised 195 awareness programmes. Approximately 104 IPR webinars were conducted in 2021 to educate and incentivize start-ups, young entrepreneurs and innovators. Further, on the occasion of India's 75th Independence Day, the CGPDTM started a programme to impart awareness to one million students on IPR from 15 August 2021 to continue through to 15 August, 2022.

2.3.4 AWARDS, REWARDS AND RECOGNITIONS TO ENCOURAGE IP SEEKERS

2.3.4.1 THE NATIONAL START-UP AWARDS 2021

The National Start-up Awards 2021 seeks to recognize and reward outstanding start-ups and ecosystem enablers that are contributing to economic dynamism by spurring innovation and injecting competition. Start-ups that are building innovative products/solutions, scalable enterprises, with high potential of employment generation or wealth creation, demonstrating measurable social impact are being lauded. The measure of success will not only be the financial gains for the investors but also the contribution to the social good.

2.3.4.2 NATIONAL INTELLECTUAL PROPERTY AWARDS 2021

National Intellectual Property Awards are conferred every year to recognize and reward the top achievers comprising individuals, institutions and organizations for IP creation and commercialization since 2009. This initiative was undertaken to create a reward and recognition system at the national level, to boost the IP filing rates to motivate industry and entrepreneurs in a sustained model. The award is provided in collaboration with Confederation of Industrial Industry (CII) mostly on the World IP Day. This year also the award was provided. The award contains a cash prize of approximately USD 1500, a trophy and citation. CII in association with DPIIT had conferred the National IP Awards for the year 2020, in August 2021 virtually. Based on an impartial jury, comprising IP professionals, industry associations, academia, R&D professionals, representatives of the DPIIT and co-opted personnel and special invitees, the jury evaluated the applications and determined the awardees, and the awardees were duly facilitated.

3. INDIA MOVES FURTHER UP IN GLOBAL INNOVATION INDEX 2021

The 14th edition of the Global Innovation Index (GII), (released on 20 September 2021) considered and ranked more than 131 economies. India has been ranked at the 46th place in the Global Innovation Index 2021[10] released by World Intellectual Property Organization (WIPO). It has jumped 35 spots in last 6 years (81 in the year 2015), which shows the consistent policy making and strengthening of a conducive eco-system of IPR in India. India has now entered the league of top 50 economies amongst a total of 131 economies of the world.

[10] 2021, Global Innovation Index 'Global Innovation Index (GII) 2021, Tracking Innovation through the COVID-19 Crisis'

4. PATENTS

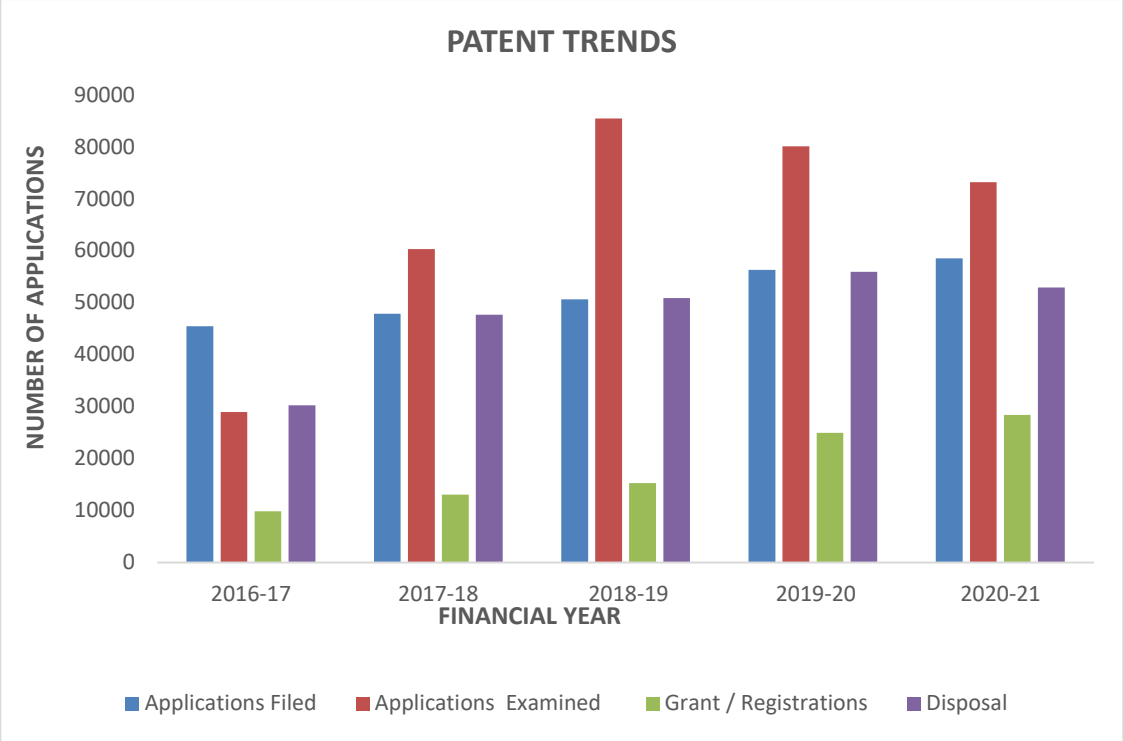
Patent Trends	Financial Year (FY)					% Change FY 2020-21 vs. 2016-2017
	2016-2017	2017-2018	2018-2019	2019-2020	2020-2021	
Applications Filed	45444	47854	50659	56284	58502	29
Applications Examined	28967	60330	85426	80088	73170	152
Grant/ Registrations	9847	13045	15283	24936	28391	188
Disposal	30271	47695	50884	55945	52943	75

4.1 THE GROWTH OF PATENTS IN INDIA

Over the years, the trends have shown an increase in the number of patent filings in India and a positive trend is visible in this respect. From the Table below, it can be clearly seen that numbers pertaining to patent filings is on the increase. Year-on- year, India is seeing an increasing number of patents being filed in the country. Despite the unprecedented Covid-19 pandemic, entities and individuals in India, owing to increasing education, awareness, government schemes and efforts, are filing patents to protect their innovations. If one looks at the trend of grant of patents, that too has been increasing year-on-year. From a mere 9847 in 2016-2017, the number of patents granted in 2020-2021 has increased to a whopping 28,391. This is a massive feat for the Indian IP landscape and the number is only set to increase in the coming years.

Table No. 1: Patent Trends in India from 2016-17 to 2020-21

The trend in Patent applications from 2016 to 2021 can be seen in the graphical representation given below.



Source: CIPAM

The Patent Office working effectively online, in the year of 2021, has substantially cleared the backlog of the pending applications and the pendency, which existed for several years. This has enabled the Indian Patent Office to be one of the fastest IP offices across the globe to examine the applications.

4.2 CHANGES EFFECTED IN LAW IN 2021

Patent (Amendment) Rules, 2021

The Patents (Amendment) Rules, 2020 were notified on 20 October 2020 which streamlined the rules to promote ease of doing business primarily revolving around the submission of the Priority Documents and the Form-27, which relates to the Statement of Working for a granted patent. In 2021, the Patent Rules were once again amended.

The Patent Amendment Rules, 2021 came into force on the date of the official publication in the Official Gazette being 9 February 2021. The major amendment in these rules is in respect of fee reduction for eligible educational institutions.

This is yet another step towards the encouragement of the Indian educational institutions to become IP savvy. By this amendment, the Rule 24(c) has been amended by adding the sub section (k) which includes the eligible educational institutions.

Many educational institutes have benefitted from this scheme and the Indian Patent office expects a quantum leap in the number of filings by the Indian educational institutes for which institutes, the cost was a restriction earlier.

The 80 per cent fee reduction offered for filing of patents to all Recognized Educational Institutions, be it government, aides or private, irrespective of whether such institute is in India or outside India, provides an immense financial benefit to these educational institutes, by decreasing the fee to one-fifth of the earlier value.

Further, Expedited Examination is permitted for start-ups, SMEs, Female applicants, Government Departments, institutions established by a Central, Provincial or State Act, which is owned or controlled by the Government, Government Company, an institution wholly or substantially financed by the Government and applicants under the PPH and the applicant who has chosen India as an International Searching Authority (ISA) or as an International Preliminary Examining Authority (IPEA) in a corresponding PCT application.

4.3 PROPOSED CHANGES IN LAW UNDER CONSIDERATION FOR 2021-2022

Review of the Intellectual Property Rights Regime in India

The Department Related Parliamentary Standing Committee on Commerce undertook the exercise of reviewing the IPR regime of India and presented a Report 'Review of the Intellectual Property Rights Regime in India'. The Report reinforced the importance of Intellectual Property Rights (IPR) and aims to promote and develop IP environment in India. The Report reinforces the below:

> *"..imperative for India to maintain a fine balance between private rights through IPRs on one hand and rights of the society as public interest on the other hand. This could only be achieved by establishing an IPR ecosystem that facilitates an environment of research and innovation that is consistent with larger public interest while ensuring a fair competition in industrial, economic, social, scientific and technological spheres."*

The Committee reviewed the IPR regime vis-à-vis the current and emerging trend in innovation space. It suggests the need to continuously encourage and incentivise patent/IP filings and make the system more user friendly. In particular, the Committee is considering amendments with respect to:

- Section 3 of the Patents Act, which specifies as to "what are not inventions" with regard to the specific sub-sections,
- Amend other pertinent sections to render them clear,
- Amend the existing Manual of Patent Office and Procedure (2019) specifically, with regard to the sub-sections of Section 3 of the Patents Act. The intention of these amendments is to minimize the arbitrariness with which the sub-sections of Section 3 are presently being exercised,
- Provide the structure of a "Board of Appeals" (as a substitute to the abolished IPAB) within the Patent Office, so as to provide a cost and time effective mechanism, before necessitating the need to appeal before the Commercial Courts on matters related to the orders of Controllers, etc. This could generally be along the lines of the Board of Appeals in the EPO.

This is under consultation with stakeholders at this time and basis the suggestions of stakeholder the actions will be taken.

Pre-grant opposition

The 2021 Report voices concern that 'patent applicants continue to confront costly and time consuming pre- and post-grant oppositions, long waiting periods to receive patent approval, and excessive reporting requirements. This issue has been addressed in all our previous submissions including that in 2020 and 2021.[11] We would like to reiterate that India's Patents Act has been amended several times over the years in order to be WTO and TRIPS compliant. The Supreme Court of India has upheld the Act as being compliant with the provisions of TRIPS.

We have categorically cited provision in the legislation to this effect. Even if the pre-grant opposition adds time to the patent prosecution time, it is less time consuming and less costly than defending the post-grant opposition proceedings. Pre-grant opposition provides opportunity of quick assessment for patentability for the patent application. The Patents Act of India has provisions where a professed infringer will be accountable for the damages from the date of publication of the patent application. Whereas, in the U.S., the right to sue for infringement commences only on grant of the patent.

4.4 ENFORCEMENT OF PATENTS

The earlier USTR Reports highlighted the lack of presumption of patent validity, and the narrow patentability criteria under the India Patents Act to be a burden for companies across different sectors, especially pharmaceutical companies. The recent progress by way of case laws pave way to remove the ambiguities associated with the interpretation of Patent law and enable enforcement.

The current Patents Act, which is TRIPS compliant, was brought into force in 2005. It takes time for applications to be prosecuted under this Section, to be litigated and then to be opined by the judiciary of India.

[11] 2020, IPA Submission to USTR Report 301

Some of the relevant highlights are as below:

- **Admissibility of Evidence**

  The Court upheld the legal interpretation of the scope of the claim over mere technical conclusions provided by the Expert. Further, it showed that the Court will apply its judicial mind, without being bound by the Independent Expert's opinion.[12]

- **Presumption of Validity**

  In a judgement this year, the Hon'ble High Court of Delhi[13], concluded that a credible challenge must be posed against a patent by defendant, while leaving open the determination of "credibility" by individual courts

  "*10.4 Thus, the challenge, posed by the Defendant to the validity of the Plaintiff's patent need not be such as to demonstrate, conclusively, the invalidity thereof. It is sufficient if the Defendant is able to make out a case of the suit patent being vulnerable to revocation under the Patents Act. This vulnerability has, however, to be demonstrated by way of a credible challenge. The onus would be on the Defendant, therefore, to establish the credibility of the challenge raised by it. The challenge cannot be incredible, fanciful, or moonshine. It must not strain the sinews of acceptability. There can, however, needless to say, be no fixed standard on the basis of which the credibility of the challenge can be assessed. It would be for the Court, in each case, therefore, to ascertain, for itself, whether the challenge raised by the Defendant, to the validity of the suit patent, is, or is not, credible*".

  The issue of the credible challenge was also discussed by the Hon'ble Delhi Court in another matter.[14] Dealing with the facts of the matter of this patent, the Hon'ble Delhi Court stated that one ought to "clear the way" before launch either at pre-grant or post-grant stage before exploiting a patent.

[12] CS (COMM) 62/ 2019, High Court of Delhi
[13] CS(COMM) 69/ 2021, High Court of Delhi
[14] CS(COMM) 256/ 2021, High Court of Delhi

The Court also submitted that revocation is a drastic act, and a patent, once granted, cannot be treated as easily vulnerable to revocation. The Court stated in this matter that even if a *prima facie* ground is made for revocation of a patent, this is not automatic but remains to be a matter of discretion of the patent authority.

- **Cost of Patent Litigation**

  Against the popular belief that litigation in Indian High Courts is costly, the Court refunded the court fee, when the parties amicably settled the matter. This matter was settled before the initiation of the suit, even before notice was served. The parties filed an application asking the Court to decree the suit as per the terms of the settlement agreement, which request was granted by the Court and the fee was duly refunded.[15]

- **Patentability Exceptions: Section 3(d) of the Indian Patents Act**

  Section 3(d) enables the grant of patents to new forms of known substances that demonstrate enhanced efficacy. Examples of new forms include salts, esters, ethers, polymorphs, metabolites, pure forms, isomers and new particle sizes. Also, new forms are eligible for patents for the process of their preparation and composition comprising them.

  We have made extensive submissions in the past that secondary patents seek to 'evergreen' patents by extending their term and delay the entry of affordable generics.[16] Such evergreening has been the cause of considerable concern globally, including in the U.S. and there has been extensive discussion on this subject area. Most recently, letter dated 10 September, 2021, by the US FDA Commissioner and Letter of U.S. Members of Congress (dated 16 September, 2021) to USPTO, concerns regarding evergreening and patent thicket have been raised as to how the lack of competition in the pharmaceutical sector resulting in higher drug prices in the U.S. and means to contain the consequent injury to public health.

[15] CS(COMM) 103/ 2021, High Court of Delhi
[16] 2019, IPA Submission to USTR Report 301; 2020, IPA Submission to USTR Report 301

Also, other countries have also been taking measures through their patent system to stop the process of evergreening which seriously hampers access to affordable medicines.[17]

The Government of India believes that India's patent law is TRIPS-compliant and represents a balance between the incentive to innovate and public health. Section 3(d) only prohibits the grant of patents for new forms of known substances that do not have enhanced efficacy. In other words, India deems it fair and equitable to reward innovation with the grant of a patent for a new and useful invention, conferring a commercially valuable monopoly to a patentee for twenty years. India also seeks to safeguard public health by prohibiting the grant of secondary patents (and extension of monopoly) for a known substance without evidence of therapeutic benefit.

The contention earlier was the interpretation of the term 'Enhanced Efficacy' by earlier case laws. Now the Hon'ble Delhi High Court has furthered the understanding regarding the interpretation of Section 3(d) of the Patents Act by analysing the decision of Novartis v. UOI by Supreme Court of India. The relevant excerpt is as below:

"14.1. 1 The Supreme Court held that a product, in order to be entitled to grant of a patent, was required, in addition to being an "invention" within the meaning of Section 2(1)(j), not to fall foul of the exceptions from patentability engrafted in Section 3. Sub-section (d) of Section 3, it was observed, delineated the circumstances in which, despite being an "invention", the product was not entitled to a patent. The 2005 amendment of Section 3(d), it was held, was aimed at dealing with pharmaceutical products. [last few lines]"

[17] 2020, IPA Submission to USTR Report 301

"*14.2.11 "Therapeutic efficacy" refers to efficacy as therapy, i.e. efficacy as a mode of treatment of the malaise sought to be remedied. Seen thus, bioavailability cannot be said to be altogether irrelevant, while assessing therapeutic efficacy. The underscored words in the passage from Novartis[9](SIC), extracted hereinabove, also observe as much. If, when administered in a particular modified form, or formulation, hitherto unknown, the availability of the active pharmaceutical ingredient, for treatment of the disease, is increased, the modified form, or formulation, would certainly have greater therapeutic efficacy than the active pharmaceutical ingredient when administered in free base or free acid form. Of course, it would be for the seeker of the patent for such modified form or formulation to provide material, with its application, vouchsafing such enhanced efficacy. Once material in that regard is produced, and patent granted, it would be for the person challenging the validity of the patent to demonstrate, with positive evidence, that the patented form, or formulation, does not possess additional efficacy. It is such a form, or formulation, which is referred to, often, as an "incremental innovation*".

"Whether increased bioavailability would or would not, result in enhanced therapeutic efficacy had to be decided on the basis of research data, and had to be specifically claimed. [para 30]"

From the excerpt, the decision, provides allowances for considering on a case-to-case basis as to whether increased bioavailability would result in enhanced therapeutic efficacy.

In an another matter adjudicated by the Hon'ble Delhi High Court, while permitting and accepting the data under Section 3(d) of the Patents Act, the Court referred to the Supreme Court decision of Novartis Vs. UOI at para 191 to conclude that Section 3(d) does not prohibit the grant of patents for incremental inventions so long as enhanced efficacy is established.[18] The relevant extract reads:

[18] CS(COMM) 1225/ 2018, High Court of Delhi

"191. We have held that the subject product, the beta crystalline form of Imatinib Mesylate, does not qualify the test of Section 3(d) of the Act but that is not to say that Section 3(d) bars patent protection for all incremental inventions of chemical and pharmaceutical substances. It will be a grave mistake to read this judgment to mean that section 3(d) was amended with the intent to undo the fundamental change brought in the patent regime by deletion of section 5 from the Patent Act. That is not said in this judgment."

Therefore, Section 3(d) is an enabling provision while barring evergreening.

- **Court upholds patent owners right of enforcement by passing anti-anti suit injunction**

In a first case of its kind in India, an anti-anti suit injunction[19] was passed by the Delhi High Court wherein the Court protected the right of a patent owner to pursue an infringement suit and claim of damages against a foreign entity in India. By way of background, the patent owner, a U.S.-headquartered technology company, had filed a suit in India against a Chinese multinational company, claiming injunction and damages for infringement of its registered patents. The Chinese company had in turn approached a Court in Wuhan, China and obtained an anti-suit injunction whereby the U.S. company was injuncted from pursuing the infringement suit in India. In May 2021, the Delhi High Court confirmed a decision passed in favour of the U.S. company, granting an anti-anti suit injunction against the Chinese company. As per the decision, the Chinese company was directed not to pursue or enforce in India the anti-suit injunction it had secured from the Court in Wuhan. Further, the Delhi High Court also directed the Chinese company to undertake to indemnify the U.S. company against any future penalties imposed by the Chinese Court for pursuing the suit filed by it in India. In passing the order, the Delhi High Court reviewed precedents from around the world and concluded that the Delhi High Court had personal jurisdiction against the Chinese company, owing to the facts of the matter.

[19] CS(COMM) 295/2020, High Court of Delhi

With this decision, the Delhi High Court has upheld the rights of a patentee against an infringer which attempted to obtain a repressive order in a different jurisdiction to obstruct patent enforcement proceedings initiated in India.

Indian judiciary is known for its fairness, and hence, above instances sufficiently demonstrate the protection of patents. One of the important cases to show the fairness is the example, in the Vodafone taxation case, the court in its 2012 judgement ruled that Vodafone Group's interpretation of the Income Tax Act of 1961 was correct and that it did not have to pay any taxes for the stake purchase. It thus interpreted government action to be illegal despite the case having substantial financial stake.

4.5 A FEW HIGHLIGHTS IN THE SPHERE OF PATENTS

Compulsory Licensing

India has time and again proven that a compulsory license is only granted for the rarest of rare applications. India has always encouraged beneficial partnership between the members of the pharmaceutical arena, while balancing the equity between all stake holders.

Baricitinib is a drug approved in the U.S. and European Union, for the treatment of rheumatoid arthritis, under certain regulated conditions. Baricitinib has been shown to prevent oxygen breathlessness in patients and has been approved for emergency use, in many countries including India. Currently, the drug Baricitinib is licensed to U.S. pharma giant Eli Lilly & Company, by its originator company INCYTE, providing them the rights for marketing it across the globe.

The drug is covered by the Indian Patent 270765 granted on 18January, 2016. An Indian pharma Company filed a compulsory license application against this patent, but on receiving confirmation from Eli Lilly to a voluntary licensing deal, withdrew the Compulsory license application.

Thus, the enabled private entities, through the use of Voluntary license, ensured access of the medicine in this pandemic situation to safeguard the public health at large, which has always been the intent of Indian Government.

Voluntary Licensing in Covid-19 Pandemic

During the pandemic countries are discussing various measures including TRIPS Waiver and beyond. The mechanism of voluntary license by various organizations has proven to be beneficial in creating far reaching patient access along with production of quality products which is equivalent to what the originator companies provide and that too at a fraction of the cost to such originator companies. India, has in this regard showed its commitment of being a dependable partner. For example - Gilead is the patents right holder for Remdesivir, a drug considered useful in Covid-19. In a win-win situation for the stake holders, and the public, Gilead signed non-exclusive voluntary-royalty-free- licensing agreements with Indian generic pharmaceutical manufacturers, which was to be valid till declaration of end of pandemic by WHO or approval of any other drug for treatment or prevention of Covid-19. The licenses were granted to generic pharmaceutical manufacturers based in Egypt, India and Pakistan to further expand the supply of remdesivir.[20] In an additional support, the companies were offered a right to receive a technology transfer of the Gilead manufacturing process for remdesivir to enable them to scale up production. This created a much wider access not only for India but also 126 other countries which are part of the agreement and face significant obstacles to healthcare access.

In another example, MSD tied up with UN-backed organisation for Molnupiravir. Medicine Patent pool (MPP), that negotiates public-health driven licences with patent holders, and sub-licenses to generic manufacturers encourages the sale of lower-cost generic versions of medicines, took the lead for this drug.

[20] 2021, November 2, ET Healthword.com, 'HC restrains generic pharma firms from making, selling patent drug of Novartis'**;** Gilead.com, 'Voluntary Licensing Agreements for Remdesivir

Merck signed deals with several Indian Pharma companies to enable the production of this drug at a large scale. These generic makers hold World Health Organization or WHO Pre-Qualified Manufacturing facilities and have experience as major suppliers to global and key LMIC procurers. These agreements are expected to accelerate availability of Molnupiravir in India and in other countries following approvals or emergency authorization by local regulatory agencies and will enable accelerating and expanding Global Access to Molnupiravir. This again proves, in another instance that India is the pharmacy of the world.

5. TRADEMARKS

5.1 THE GROWTH OF TRADEMARKS IN INDIA

The year 2021 was the second consecutive year when most parts of India were under lockdown and restrictions had been imposed due to the havoc caused by the Covid-19 pandemic. Having been through 2020, this year saw businesses and government authorities better prepared for hybrid work environments and handling matters through digital media.

This year, the Indian Trademark Office has maintained its efficiency as new trademarks applications continue to get examined in a span of less than 30 days. Often, in several cases where Examination did not result in any objections, marks get registered within 6 months. Even in cases where objections are raised, all proceedings are time bound and managed digitally, reducing delay.

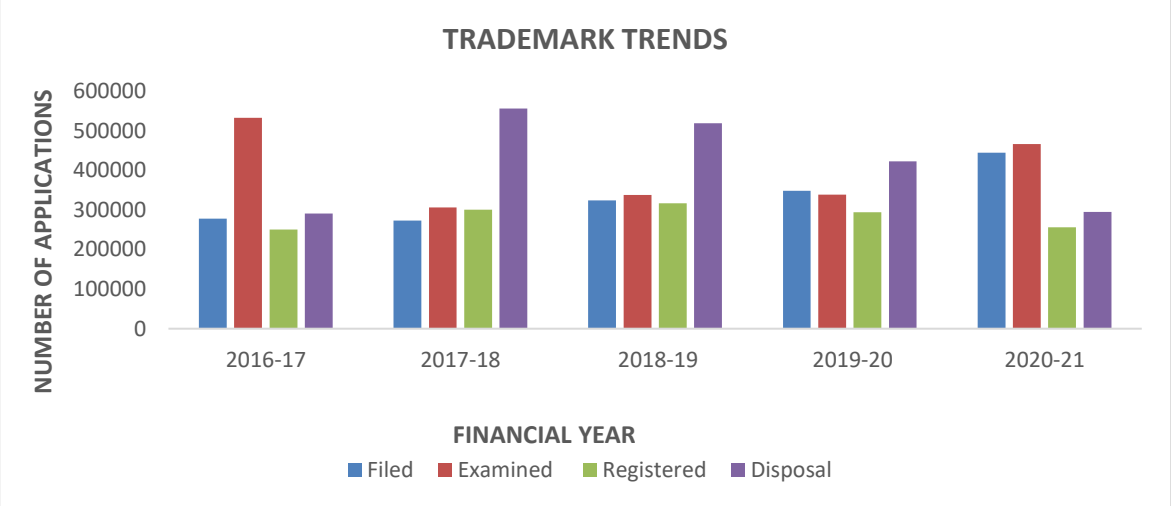
Cumulative statistics along with year wise comparison (FY 2016-17 to FY 2020-21) is given in the Table below:

Table No. 2: Trademark Trends in India

	Financial Year (FY)					
Trademark Trends	**2016-2017**	**2017-2018**	**2018-2019**	**2019-2020**	**2020-2021**	**% Change FY 2020-21 vs. 2016-17**
Applications Filed	278170	272974	323798	348247	444126	60
Applications Examined	532230	306259	337541	338551	465915	-12
Grant/ Registrations	250070	300913	316798	294172	255993	2
Disposal	290444	555777	519185	422566	294961	2

A comparative analysis of the trademark trends across FY 2016-17 to FY 2020-21 as given in the figures, illustrate a significant increase in the number of trademark filings.

The trend in trademark applications from 2016 to 2021 can be seen in the graphical representation given below.



Source: CIPAM

For FY 2020-21, 444126 trademark applications were filed, 465915 were examined and 255993 trademark applications were provided grants as of 31 December, 2021.

5.2 ENFORCEMENT OF TRADEMARKS

The enforcement of Trademarks in India has shown a massive upward trend over the last few years. Start-ups, business entities, industrious organisations and companies from virtually all sectors are now gravitating towards getting their trademarks registered. As of 10 June, 2021, the trademark application number marked a historic 5,000,000, as such a record of 5 million trademark applications were filed before the Indian trademark Registry on the said date and the number is only going to grow leaps and bounds.

Owing to the increasing awareness campaigns and schemes being rolled out by the Indian Government, businesses are becoming increasingly aware of the benefits of safeguarding their trademarks and are now realizing the downfalls of not having done so earlier.

Some relevant decisions of the Courts in respect of the same are as below:

- **Court ruled in favour of arbitration to resolve IP disputes**

  The Court clarified the position that IPR issues arising from contractual obligations can be referred for arbitration. These findings are beneficial for IP owners as they recognize the importance of alternate dispute resolution mechanisms such as arbitration and mediation for determining IP matters and encourage parties to explore outside court settlements, which prove to be less time consuming and more cost effective for parties.[21]

- **Stricter Test to evaluate deceptive similarity in Pharmaceutical Sector**
  Specifically for the pharmaceutical sector, considering the adverse effects that confusion among consumers can cause, the Courts in India continue to adopt a stricter test while evaluating deceptive similarity between two trademarks.[22]

[21] CS(COMM) 98/ 2020, High Court of Delhi ; CS(COMM)178/2021, High Court of Delhi
[22] CS 176/ 2021, High Court of Delhi; CS(COMM) 237/ 2021, High Court of Delhi; CS 687/ 2014, High Court of Delhi; COMIPL 12337/ 2021, High Court of Mumbai

The Indian Courts, at all levels have played an important role in tipping the scales in favour of protecting one's IP via trademarks. Decisions by the Courts of India in 2021, in trademark disputes have further strengthened, deepened and popularised the concept and enforcement of trademarks.

6. MISCELLANEOUS

6.1 EFFORTS TO TACKLE COUNTERFEITING IN THE PHARMACEUTICAL SECTOR IN INDIA

Amidst the Covid-19 pandemic, India has played a vital role in meeting the increasing demand for vaccines and other medicines around the world. Indeed, it has been admired and hailed as the pharmacy to the world. With the increasing production of medicines, the country also faced challenges related to manufacture and sale of spurious drugs. While the pharmaceutical industry in India is one of the highly regulated industries in the country, the menace of spurious and sub-standard medicines has been an area of concern for the Government and the industry, alike. It is, however, important to acknowledge that counterfeiting is not an issue limited to India but is a global phenomenon and no country in the world is unaffected by it.

With a view to curb counterfeit and spurious drugs, several measures are being taken at different levels. At the Government level, a Parliamentary panel has recommended implementation of track & trace mechanisms for pharmaceutical products in India. In a report submitted by the Department Related Parliamentary Standing Committee on Commerce, concerns have been raised regarding manufacture and sale of spurious and adulterated drugs in India. The Committee has recommended implementation of a track and trace mechanism at the earliest for the detection of authenticity and genuineness of medicines and medical devices.[23]

[23] 2021, August 12, 'Parliamentary panel recommends implementation of track & trace mechanism for pharmaceutical products'

Even at the industry level, the Confederation of Indian Industries (CII) organized the Smart Packaging Summit, which was held on 15 December 2021. During the summit several next levels of tracking solutions were discussed, such as, blockchain, IoT, RFID, geospatial mapping etc., to enable consumers to verify the authenticity of any product.

Drug procurement via blockchain at government hospitals is being explored to ensure authenticity and quality of medicines procured in bulk using the Government e-Marketplace (GeM). The GeM portal aims to employ blockchain technology to facilitate traceability of medicines from the point of supply to their final destination.[24]

On the enforcement level, several police raids were conducted over the year where counterfeit medicines have been seized and criminal proceedings initiated against the wrongdoers.[25]

In another operation carried out in coordination with Interpol, code named Operation Pangea XIV, more than 1.10 lakh web links, including websites and online marketplaces engaged in the sale of fake and illicit medicines and medical products, were taken down. The operation involved the police, customs and health regulatory authorities of 92 countries, including those from India. Indian agencies also participated in the operation that led to the arrest of 277 suspects and seizure of spurious pharmaceuticals worth over $23 million.[26]

[24] 2021, March 12, IndianExpress.com 'Drug procurement via blockchain at govt hospitals in one year'
[25] 2021, September 10, Times of India, Indiatimes.com 'Delhi: Fake medicines for cancer patients seized, 3 arrested'; 2021, May 14, Times of India, Indiatimes.com 'Mumbai: Cipla files complaint against e-sale of fake Covid medicines'
[26] 2021, June 8, The Hindu, 'Over 1 lakh web links removed in global crackdown on illegal medical trade'

Initiatives taken by CIPAM in spreading awareness against spurious and counterfeit drugs

CIPAM conducted several trainings and outreach programs for the Judiciary, Police and the Customs Officials. Some such initiatives that have been taken by CIPAM to further the cause of IPR and spread the awareness of IPR are listed out below:

- National IP Enforcement workshops were conducted by the DPIIT to spread awareness for various enforcement agencies, being the Police and the Customs. Such workshops were organised with the aim to sensitize these enforcement agencies on their role as IPR enforcement officers. At these workshops, Police and Customs personnel, alike were invited and encouraged to share their experiences and exchange views on best practices, to strengthen and forge efficient and effective coordination mechanisms.
- A total of 122 programs on IP Enforcement have been conducted by CIPAM, pan India for the Judiciary, Police and Customs in 2021.
- DPIIT-CIPAM in association with Federation of Indian Chambers of Commerce & Industry (FICCI) devised an intensive IPR Enforcement Toolkit for the Police. This Toolkit provides a roadmap to aid the Police officials in dealing with IP Crimes, in the domain of Trademark counterfeiting and Copyright piracy.
- In addition to the above, the Police Departments across various states set-up IPR Cells in their jurisdictions to specially tend to the IPR issues.
- The Ministry of Home Affairs (MHA) issued an advisory to all the State Police Departments and the Union Territories to include IPR awareness and enforcement in their existing training curriculum.
- DPIIT and CIPAM, in association with leading IP law firms and imminent industry persons, conducted several training programs with various stakeholders.

- Organised by CIPAM also organised training sessions for judges to sensitize them on IP enforcement and adjudication in collaboration with the National Judicial Academy (NJA), Bhopal, the National Judicial Academy (NJA), Delhi and the State Judicial Academies of Meghalaya, Uttarakhand, and Kerala.
- In a collaboration between CIPAM and INTA, a three-phase training session was organised on the 3rd, 10th and the 17th of March, 2021, focussing on Anti-Counterfeiting and Brand Protection for Custom Officials across India.

6.2 CUSTOMS DUTIES DIRECTED TO IP- INTENSIVE PRODUCTS

The 2021 Special 301 Report raised concerns relating to high custom duties on IP intensive products. We would like to humbly submit that the custom duties have been the same from last few years. Further, it has been same for the patented, as well as the generic drugs.

7. CONCLUSION

7.1 India is committed to a strong IP ecosystem and over the years it has taken steps towards strengthening it. The 2021 Report has recognised and acknowledged the progress made by India in its commitment to promote IPR and enhance enforcement. The same is reflective from the below:

- India has consistently been modernizing its IP ecosystem, legislation and has revised the patent rules. The Patents (Amendment) Rules, 2020 were notified, which streamlined the rules to promote ease of doing business primarily revolving around the submission of the Priority Documents and the Form-27, which relates to the Statement of Working for a granted patent.

- In 2021, the Patent Rules were once again amended and came into force in February 2021. The major amendment in these rules is in respect of fee reduction for eligible educational institutions. This is yet another step towards the encouragement of the Indian educational institutions to become IP savvy.

7.2 Even during the unprecedented time of pandemic in 2021, extensive initiatives have been undertaken by the Government of India to strengthen the significance of IPR in the country through various knowledge sharing platforms, awareness programmes. India has taken active steps in strengthening its existing international relations, especially in the field of IP with various countries across the globe and has taken further initiatives with the U.S., Denmark and Korea as well as the European Union over the last two years.

7.3 India has moved significantly on the the Global Innovation Index in the last six years (Rank 81 in 2015) to 46th in 2021 amongst 131 economies and has now entered the league of top 50 economies of the world.

7.4 India is fully compliant with the multilateral TRIPS agreement and continues to take steps in accordance with international trends and progress.

- *Compulsory Licensing*: There has been no grant of a compulsory license in the last eight years in India even during the COVID 19 pandemic. Our submission above, clearly suggests that access of the medicine in this pandemic situation to safeguard the public health at large, has always been the intent of Indian Government. A judicious approach has been maintained by the IP machinery in this regard.Furthermore, granting of compulsory licenses is in line with the provisions of the TRIPS Agreement.

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

7.5 India has made progress in the procedural aspects by abolishing the IPAB with a view to resolve IP disputes efficiently and creating specialized courts and rules for handling IP matters across India. The High Courts in the States are now taking up the matters related to IP. For example, High Court of Delhi has set-up the Intellectual Property Division (IPD) which is dedicated to hear IPR matters.

The High Court of Mumbai, Calcutta and Chennai are also following similar route and are in the process of forming the rules. The creation of IPD at the High Court of Delhi is a historic development which is in line with similar global practices in this regard and will help in the efficient disposal of IP matters, as well as in bringing consistency in precedents set by the Courts in the area of IP law.

7.6 The Indian Government, through CIPAM created under DPIIT, has conducted several educational, training, awareness camps, etc. to strengthen IP knowledge amongst students, teachers, police customs and judicial officers, etc. These efforts are spreading knowledge and awareness around IP protection and enforcement across the country.

7.7 India's judicial system has taken major strides in providing fair and quick justice in IPR Cases. The enforcement of Patents and Trademarks in India is further gaining strength and momentum as clarity is being provided by the Courts on interpretations of various facets of IP law in India. Our submission in 4.4 above is testimony to the efficient and just enforcement of IPs.

We submit that India has demonstrated strong commitment to IP laws and has been consistently up-grading IPA ecosystem keeping ease of doing business in perspective. Therefore, a compelling case already exists for the removal of India from the Special 301 Report's Priority Watch List, as India is compliant with all international obligations related to intellectual property rights and is taking massive steps to make the Indian ecosystem an IP friendly one. We urge the USTR to consider the removal of India from the Priority Watch List.

We thank you for the opportunity to make this submission.

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