



**FICCI SUBMISSION
FOR
SPECIAL 301 REVIEW, 2016**

FEDERATION OF INDIAN CHAMBERS OF COMMERCE AND INDUSTRY (FICCI)

Established in 1927, FICCI is the largest and oldest apex business organisation in India. Its history is closely interwoven with India's struggle for independence, its industrialization, and its emergence as one of the most rapidly growing global economies.

A non-government, not-for-profit organisation, FICCI is the voice of India's business and industry. From influencing policy to encouraging debate, engaging with policy makers and civil society, FICCI articulates the views and concerns of industry. It serves its members from the Indian private and public corporate sectors and multinational companies, drawing its strength from diverse regional chambers of commerce and industry across states, reaching out to over 2,50,000 companies.

FICCI provides a platform for networking and consensus building within and across sectors, and is the first port of call for Indian industry, policy makers and the international business community.

INTRODUCTION

FICCI's submissions are in response to the Federal Register Notice by the Office of the United States Trade Representative (USTR) requesting written submissions from the public for the Special 301 Review of 2016.¹

In light of the commendable proactive vision which the Government of India is presenting worldwide by synergising Intellectual Property with India's various policy initiatives, USTR's Special 301 review process is hardly called for; undermining the spirit of the bilateral dialogue between India and US.

FICCI intends to address several unfounded assertions of USTR which have been levied against India's IP Regime and endeavours to put forth an objective picture in lieu of the progress which India has been making in the past two years to further strengthen its IP Regime in India.

FICCI is of view that India should no longer be placed under the Special 301 review process. In support of this view, FICCI through its submissions brings forth an array of key developments which the Government of Indian and the Industry has been undertaking to further strengthen the IP ecosystem in India.

¹USTR Requests Comments for the 2016 Special 301 Report, January 12, 2016. Available at: <http://infojustice.org/archives/35600>

NATIONAL IPR POLICY

FICCI has been intensively involved in building a strong IP ecosystem in India and has been instrumental in offering substantive and comprehensive inputs to the IPR Think Tank on the National IPR Policy. Notably, FICCI's suggestions have been well reflected in the first draft of the Policy Document. The policy draft serves a very positive message by stating that "The Policy will aim to foster predictability, clarity and transparency in the entire IP regime in order to provide a secure and stable climate for stimulating inventions and creations, and augmenting research, trade, technology transfer and investment."²

As per the latest update on the National IPR Policy, the final draft of the National IPR Policy after being circulated for inter-ministerial consultation has now been placed before the Union Cabinet for approval. It is pertinent to mention here that Ms. Nirmala Sitharaman while inaugurating a seminar on 'Protecting Brands Abroad with the Madrid System' organized by FICCI, in association with World Intellectual Property Organization (WIPO) and Department of Industrial Policy and Promotion (DIPP) sought to allay apprehensions in the minds of foreign investors about the strength of the Indian IPR regime, stating that final draft of the National IPR Policy has been arrived at through a transparent process with inputs from all stakeholders.³

While the National IPR Policy is in the offing, FICCI in its endeavour to serve India's businesses and Industry will continue to strive and assist the Indian Government in delivering an all-encompassing IP Policy, which will promote a holistic and conducive ecosystem to catalyze the full potential of intellectual property for India's economic growth and socio-cultural development.⁴

FICCI commends the Indian Government for being pro-active in integrating and synergising Intellectual Property with India's overall development policy through initiatives such as Make In India⁵, Digital India⁶, Start Up India and Imprint India⁷. These policy initiatives are highly

²National IPR Policy (First Draft), December 19, 2014. Available at:

http://dipp.nic.in/English/Schemes/Intellectual_Property_Rights/IPR_Policy_24December2014.pdf

³ Minister felicitates Mircomax for acquiring 1.25th Million International Trademark, Jul 20, 2015. Available at:

<http://ficci.in/past-Events-page.asp?evid=22461>

⁴ National IPR Policy (First Draft), December 19, 2014. Available at:

http://dipp.nic.in/English/Schemes/Intellectual_Property_Rights/IPR_Policy_24December2014.pdf

⁵ Make in India. Available at <http://www.makeinindia.com/home>

⁶ Digital India: Power to Empower. Available at: <http://www.digitalindia.gov.in/>

encouraging and are paving the way for Intellectual Property to be recognised and appreciated as a strategic tool for India's economic development.

COPYRIGHT PROTECTION AND ENFORCEMENT

In India, the laws relating to copyright are mainly governed by the Copyright Act, 1957⁸ and the Copyright Rules, 2013, which came into effect from January 1958. This Act has been amended five times since then, i.e. in 1983, 1984, 1992, 1994, 1999 and 2012. The Copyright (Amendment) Act, 2012 is the most substantial. The main reasons for amendments to the Copyright Act, 1957 include bringing the Act in conformity with WCT and WPPT; to protect the Music and Film Industry and address its concerns; to address the concerns of the physically disabled and to protect the interests of the author of any work; Incidental changes; to remove operational facilities; and enforcement of rights.

Some of the important amendments to the Copyright Act in 2012⁹ are extension of copyright protection in the digital environment such as penalties for circumvention of technological protection measures and rights management information, and liability of internet service provider and introduction of statutory licences for cover versions and broadcasting organizations; ensuring right to receive royalties for authors, and music composers, exclusive economic and moral rights to performers, equal membership rights in copyright societies for authors and other right owners and exception of copyrights for physically disabled to access any works.

The Copyright Act provides the owners of copyright with dual legal machinery for enforcement of their rights in the form of both civil and criminal remedies. Civil remedies available to owners of copyright are provided for in Chapter XII of the Copyright Act. These, are in the nature of grant of injunctions, damages, declaration of authorship etc.

S. No	Provisions on Civil Remedies in the Copyright Act, 1957
1.	Section 55- Provides for the civil remedies by way of injunction, damages, rendition of accounts etc. Further, sub-section (3) extends discretion to the Courts with respect to costs of the legal proceedings.

⁷ IMPRINT INDIA: Impacting Research Innovation and Technology. Available at: <http://imprint-india.org/>

⁸ The Copyright Act, 1957 Available at: <http://copyright.gov.in/Documents/CopyrightRules1957.pdf>

⁹ The Copyright(Amendment)Act,2012 Available at: http://mhrd.gov.in/sites/upload_files/mhrd/files/upload_document/CRACT_AMNDMNT_2012.pdf

2.	Section 58 Provides for additional safeguards for owners of copyrights by creating a deeming fiction in their favour. According to the provision, all infringing copies of any work in which copyright subsists, and all plates used or intended to be used for production of such infringing copies, shall be deemed to be the property of the owner of the copyright.
3.	Section 66- Empowers the Court trying an offence of copyright infringement to order delivery up of all copies of the work or all plates in the possession of the alleged offender, which appear to it to be infringing copies, or plates for the purpose of making infringing copies, to the owner of the copyright.

India is sensitive towards IP infringement and the Copyrights Act prescribes criminal sanctions of imprisonment and fine for infringement of Copyrights. Criminal remedies available to owners of copyright are provided for in Chapter XIII of the Copyright Act. Legal remedies include imprisonment and/or monetary fines depending upon the gravity of the crime.

S. No	Provision on Criminal Remedies in the Copyright Act, 1957
1.	Section 63- Any person who knowingly infringes or abets the infringement of copyright is considered as an offender and is punishable with a minimum of six months imprisonment which may extend to three years and a fine between fifty thousand and two lakh rupees.
2.	Section 63A- Provides for an enhanced penalty in case of second and subsequent convictions. On conviction, a subsequent offender is punishable with a minimum of one year imprisonment which may extend to three years and a fine between one to two lakh rupees
3.	Section 63B- Any person who knowingly uses an infringing copy of a computer programme an offence which is punishable with a minimum of seven days imprisonment which may extend to three years and a fine between fifty thousand and two lakh rupees.
4.	Section 65- Any person who knowingly makes, or has in possession, any plate for the purpose of making infringing copies of any work in which copyright subsists shall be punishable with imprisonment which may extend to two years and shall also be liable to fine.
5.	Section 65A- Any person who circumvents an effective technological measure

	applied for the protecting the owner's rights, with the intention of infringing such rights, shall be punishable with imprisonment which may extend to two years and shall also be liable to fine.
6.	Section 65B- It makes the removal/alteration of rights management information and distribution/selling of copies of works with such altered RMI an offence punishable with imprisonment which may extend to two years along with fine.
7.	Section 67- Any person makes or causes to be made a false entry in the Register of Copyrights or makes or causes to be made a writing falsely purporting to be a copy of any entry in such register, or produces or tenders or causes to be produced or tendered as evidence any such entry or writing, knowing the same to be false, he shall be punishable with imprisonment which may extend to one year, or with fine, or both.
8.	Section 68- Any person makes a false statement or representation knowing the same to be false, with a view to deceive any authority and/or influence any person to do or omit to do anything, he shall be punishable with imprisonment which may extend to one year, or with fine, or with both.
9.	Section 68A- Any person who publishes a sound recording or video film in contravention of Section 52A of the Copyright Act, which mandates the display of particulars of the author, owner and the censor certificate (if required) on them shall be punishable with imprisonment which may extend to three years and also be liable to fine.
10.	Section 69- In case an offence under the Copyright Act is committed by a company or a partnership firm, all directors, partners, managers, secretaries etc. who are responsible for the conduct of the business of the said company/partnership firm shall be guilty of such offence along with the company/partnership firm as the case may be. However, such persons shall not be liable if they prove that they exercised all due diligence to prevent the commission of such offence or it was committed without their knowledge.

In addition to the offence of copyright infringement under Section 63 of the Copyright Act, the following offences/provisions under the Indian Penal Code, 1860 are also relevant for effective protection of copyright.

S. No	Provisions under the Indian Penal Code, 1860 for effective protection of
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	copyright
1.	Section 107- Abetment of a thing Whether Cognizable/ Bailable - Depends as per the offence of which there was a abetment - Triable by Court by which offence abetted is triable - Non - compoundable
2.	Section 120B- Punishment of Whether Cognizable/Bailable - Depends as per the offence criminal conspiracy of which there was a criminal conspiracy - Triable by Court by which abetment of the offence which is the object of conspiracy is triable - Non – compoundable.
3.	Section 174- Non-attendance in Non-Cognizable - Bailable - Triable by any Magistrate – Nonobedience to an order from public Compoundableservant
4.	Section 177- Furnishing false Non-Cognizable - Bailable - Traible by any Magistrate -information Non- Compoundable
5.	Section 179- Refusing to answer Non-Cognizable - Bailable- Triable by any Court - Triable by public servant authorized to any Magistrate - Non-Compoundable question
6.	Section 204- Destruction of Non-Cognizable - Bailable- Triable by Magistrate of the first document to prevent its class - Non-Compoundable production as evidence
7.	Section 206- Fraudulent Non-Cognizable - Bailable- Triable by any Magistrate- Non removal or concealment of Compoundable property to prevent its seizure as forfeited or in execution
8.	Section 217- Public servant Non-Cognizable - Bailable- Triable by any Magistrate-Non disobeying direction of law with Compoundable intent to save person from punishment or property from forfeiture
9.	Section 417- Punishment for Non-Cognizable - Bailable - Triable by any Magistrate -cheating Compoundable by the person cheated with the permission of the court
10.	Section 420- Cheating and Cognizable - Non-bailable-Triable by Magistrate of the first dishonestly inducing delivery class - Compoundable by the person cheated with the of property permission of the court.
11.	Section 465- Punishment Non-Cognizable - Bailable -Triable by Magistrate of the first for forgery class - Non-Compoundable

12.	Section 466 -Forgery of record Non-Cognizable - Non-bailable - Triable by Magistrate of the of court or of public register, etc. first class - Non-compoundable
13.	Section 468 -Forgery for purpose Cognizable - Non-bailable - Triable by Magistrate of the first of cheating class - Non-Compoundable
14.	Section 471 -Using as genuine Cognizable - Bailable - Triable by Magistrate of the first class a forged document - Non-compoundable
15.	Section 481 - Using a false Non-Cognizable - Bailable - Triable by any magistrate - property mark Compoundable by the person to whom loss or injury is caused by such use with the permission of the Court
16.	Section 486 -Selling goods Non-cognizable - Bailable- Triable by any Magistrate

The Copyright Rules, 2013¹⁰ was notified on 14 March, 2013 replacing the old Copyright Rules, 1958. The Rules provide for procedure for relinquishment of Copyright; grant of compulsory licences in the matter of work withheld from public; to publish or republish works (in certain circumstances); to produce and publish a translation of a literary or dramatic work in any language; licence for benefit of disabled; grant statutory licence for cover versions; grant of statutory licence for broadcasting literary and musical works and sound recordings; registration of copyright societies and copyright registration.

These legislative and statutory measures are supplemented by appropriate administrative measures by the Governments and the Industry both at the Centre and in the States for enforcement of IPRs:

- An Inter-Ministerial Committee on Enforcement of IPR laws under the chair of the Department of Industrial Policy & Promotion has been set up to deliberate on the IPR enforcement issues.
- A Copyright Enforcement Advisory Council (CEAC)¹¹ has been set up by the Ministry of Human Resources Development (MHRD) for advising Government on measures to improve the enforcement of the Copyright Act and for reviewing the progress of enforcement periodically. The CEAC was set up by the Government of India on November 6, 1991 to periodically review progress of copyright enforcement in the country and to advise the government regarding measures for improvement in the enforcement mechanism.

¹⁰The Copyright Rules, 2013 Available at: <http://copyright.gov.in/Documents/Copy-Right-Rules-2013.pdf>

¹¹ Report Of The Sub-Committee On Issues Pertaining To Enforcement Of Copyrights In India; October 7, 2013

- Enforcement Cells have been set up in the police headquarters and nodal officers have been appointed by the State Governments to handle copyright related offences. Assam, Goa, Gujarat, Haryana, Jammu & Kashmir, Karnataka, Kerala, Madhya Pradesh, Maharashtra, Meghalaya, Orissa, Rajasthan, Sikkim, Tamil Nadu, West Bengal, Andaman & Nicobar Islands, Chandigarh, Dadra & Nagar Haveli and Daman & Diu have either set up copyright enforcement cells or special cells in the Crime Branch to look after copyright offence cases
- To expedite the resolution of IP disputes, the Intellectual Property Appellate Board (IPAB) was also established for hearing appeals arising from the decisions, orders or directions of the Registrar of Trade Marks and Geographical Indications and the Controller of Patents.
- FICCI has been engaging with the Ministry of Information & Broadcasting and stakeholders from the M&E Industry, both nationally and internationally to draft and provide a real time amending document to tackle piracy in the digital age. It is understood that the new Cinematograph Bill, which would suggest legal remedies and penal provisions in the Cinematograph Act, particularly with reference to making unlawful copies, camcording in cinemas, among other issues, will be tabled before the Parliament in the next six months.
- Enforcement measures taken w.r.t. curbing film piracy in the last one year:
 - The anti-piracy wing of Kerala police, investigating the piracy of Malayalam blockbuster "Premam"¹²;
 - formation country's first anti-piracy unit - the Telangana Intellectual Property Crime Unit (TIPCU)¹³;
 - Comprehensive 'Film Policy' in the offing by the Telangana government¹⁴.
- In order to facilitate proper co-ordination between the stakeholders and the enforcement agencies in the matter of enforcement of copyright laws, the Ministry of Human Resource Development requested the State Governments to designate Nodal Officer to deal with enforcement issues.¹⁵
- The CBEC has set up the Automated Recording and Targeting System (ARTS) portal for effective and speedy identification and redressal of counterfeited and de-merit goods. ARTS

¹² 'Premam' row: Kerala Anti-Piracy Cell intensifies probe, July 6, 2015, The Indian Express, Available at:

<http://indianexpress.com/article/entertainment/regional/premam-row-kerala-anti-piracy-cell-intensifies-probe/>

¹³ Baahubali theft inspires country's first anti-piracy police unit, December 9, 2015, Business Standard, Available at:

http://www.business-standard.com/article/current-affairs/baahubali-theft-inspires-country-s-first-anti-piracy-police-unit-115120900046_1.html

¹⁴ Telangana Film Policy soon, Jan 26, 2016, The Hans India, Available at:

<http://www.thehansindia.com/posts/index/Business/2016-01-26/Telangana-Film-Policy-soon/202696>

¹⁵ Updated List of Nodal Officers, January, 1, 2015, Available at: <http://copyright.gov.in/Documents/Appointment-of-Nodal-Officers.pdf>

provides for a single centralized bond and surety/security account that can be used at all ports in India, so that the IPR holders do not have to rush to different customs formations to execute consignment specific bonds and sureties/ securities upon receipt of information about an interdiction of allegedly infringing consignment. ARTS have provision for recording and targeting of Trade Marks, Copyright, Patents, Designs and Geographical Indications. It is pertinent to mention herein that Indian government officials have become increasingly savvy on IP and TRIPS issues and the need to abide by them. The Indian economy and society too now appreciate the need to assimilate with the international IP regime.

- In order to limit the adverse effects of counterfeit and unauthorized imports, the *Intellectual Property Rights (Imported Goods) Enforcement Rules, 2007*¹⁶ was issued by the Government of India, which provides mechanism for registration of Intellectual Property Assets with the Central Board of Excise and Customs (CBEC). This registration (with CBEC) along with the conventional registration of IP assets provides a holistic approach to protect and enforce the IP Rights in India. Registration with CBEC empowers the Customs Authority to intercept, seize, and confiscate goods found to be or suspected to be infringing IPR registered and in-force in India by any person other than the IPR holder or without permission/authorization of the IPR holder. Further, by making one application, the applicant can cover all the Customs Air Cargo Complexes, Seaports and Land Customs Stations through which importation or exportation of pirated article is suspected in India. The registration is usually obtained within a month and is valid for five years. Once registered, the Customs Authority store the IPR in their electronic database which is flashed across all entry points in India.
- An instance of Enforcement Authorities effectively curbing infringement practices in India is when the Crime Branch of the Delhi Police raided Akasaki, a trusted name in mobile phones and accessories at Lotus Plaza in Karol Bagh, and found counterfeit iPhones and all kinds of assembling material for other smartphones. The shop was seized and a huge scam unearthed.¹⁷

The Indian Copyright Act today is compliant with most international conventions and treaties in the field of copyrights. India is a member of the Berne Convention of 1886 (as modified at Paris in 1971), the Universal Copyright Convention of 1951 and the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement of 1995. The two Internet Treaties were negotiated

¹⁶ *Intellectual Property Rights (Imported Goods) Enforcement Rules, 2007* Available at: <http://www.cbec.gov.in/htdocs-cbec/customs/cs-act/formatted-htmls/ipr-enforcementrules>

¹⁷ **Fake iPhones being sold in popular Delhi markets**, Available at: <http://indiatoday.intoday.in/story/fake-iphones-smartphone-delhi-markets/1/450893.html>

in 1996 under the auspices of the World Intellectual Property Organization (WIPO). These treaties are called the 'WIPO Copyrights Treaty (WCT)' and the 'WIPO Performances and Phonograms Treaty (WPPT)'.

These treaties were negotiated essentially to provide for protection of the rights of copyright holders, performers and producers of phonograms in the Internet and digital era. India is not a member of these treaties; amendments are being mooted to make Act in compliant with the above treaties in order to provide protection to copyright in the digital era. Though India is not a member of the WCT and the WPPT, the Copyright Act, 1957 is fully compliant with the Rome Convention provisions. The provisions of the Act is also in harmony with two other new WIPO treaties namely, the Beijing Audiovisual Performers treaty, 2012 and the Marrakesh Treaty to Facilitate Access to Published Works by Visually Impaired or Otherwise Print Disabled Persons, 2013.

FICCI and FICCI's Committee Against Smuggling and Counterfeiting Activities Destroying the Economy (CASCADE) are already working with International organizations such as ICC-BASCAP for fact finding studies and working on further tightening up enforcement. However, the primary responsibility of enforcement remains that of right holders since IPRs are private rights. India has made piracy and counterfeiting criminal offences being subjected to the judiciary awarding imprisonment and fines for violators widespread, besides compensatory damages to plaintiffs. Aggrieved companies are also being encouraged to file more cases against infringers.

Indian Patent System

It is pertinent to mention at the onset that the Indian Policy framework is driven by public policy and needs of its people. The Constitution of India mandates that India become a Welfare State and hence all its policy decisions are driven by the same ideology. It shall be wrong to infer that Indian IP policies will be emulated by other developing countries. Indian law and policies are made keeping in view Indian needs, priorities and international obligations and available policy space. All its policies are framed within the framework of International treaties and agreements. In that context, each country is sovereign and may adopt or reflect or emulate as per its tailor made needs.

There has been only one instance of issue of a Compulsory Licence (CL) and another instance of denial of a patent in nine years, which should not warrant a discussion on unilateral trade sanctions especially as the actions are TRIPS compliant. The provision of 3(d) in the Indian Patents Act and CL have worried international pharmaceutical companies since the amendment to the Indian Patent Act in 2005, these instances may encourage other developing and even some developed countries to introduce similar provisions in their

laws. Where by their profits and their current ability to extend patents beyond 20 years through minor tweaking of drugs as their 20-year patent expires would be considerably restricted. However, such bilateral pressures are now seen globally as pressure tactics on developing countries into serving as profit ground for the ‘big’ international pharma companies.

FICCI reiterates that **India favour’s “Strong Patents”**, which is evidenced by the strict scrutiny and procedure of granting patents by the Indian IP Office. In India, there has been only one instance where the Indian Patent Office has granted a CL to Nacto Pharma Ltd. for producing the generic version of Bayer Corporation’s patented drug Nexavar and the decision was backed by public policy, i.e., the multinational innovator could not make its invention available in India on affordable pricing and commercial scale.¹⁸In addition to this, as a mark of its careful scrutiny, the Indian patent office has recently rejected two applications on compulsorily licenses, namely Saxagliptin¹⁹ and Dasatinib²⁰. The Patent application process in India follows the due process strictly. The Indian Patent authorities have constantly endeavoured to assert a strong patent regime in India and the following is the factual testimony to it:

S.No.	Particulars	Details
1.	SAXAGLIPTIN(AstraZeneca) ²¹ - Diabetes drug	In an order dated January, 19, 2016, the Controller General of Patents and Trademarks (CGPTM) rejected the application for Compulsory License (CL), filed by Lee Pharma Limited (Lee Pharma), for the patent covering AstraZeneca's diabetes management drug Saxagliptin. In this CL application, CGPTM has not only passed an order refusing to grant CL but has now laid down parameters for CL applicants to establish a "reasonable requirement" especially where there are other drugs in the market which treat the same ailment / condition.
2.	NEXAVAR (BAYER) ²² Kidney/liver cancer drug	NATCO was granted a CL on Bayer patented drug Nexavar on the ground of public policy as the German Innovator was unable to provide the lifesaving drug at affordable prices in the domestic market
3.	DASTINIB(BMS)-immunologic and oncologic disorders	The CL application for the Bristol-Myers Squibb(BMS) drug by BDR pharmaceutical Int. Ltd. was rejected by the patent office. Injunction was awarded by Indian court in infringement proceedings brought by BMS against Natco, Hetero Pharma and BDR pharmaceutical Int. Ltd.
4.	PYRROLE (SUGEN INC)- cancer drug	Post Grant opposition was filed by M/s Cipla Ltd. India. The Patent was revoked under section 2(1)(j) of Patent

¹⁸ Natco Pharma Ltd. V. Bayer Corporation; Order No. 45/2013 (Intellectual Property Appellate Board, Chennai)

¹⁹ http://www.ipindia.nic.in/iponew/compulsoryLicense_Application_20January2016.pdf

²⁰ http://articles.economictimes.indiatimes.com/2013-10-31/news/43561264_1_voluntary-licence-compulsory-licence-dasatinib

²¹ http://www.ipindia.nic.in/iponew/compulsoryLicense_Application_20January2016.pdf

²² Natco Pharma Ltd. V. Bayer Corporation; Order No. 45/2013 (Intellectual Property Appellate Board, Chennai)

		Act on grounds of obviousness. On appeal, the HC directed Cipla to not market its product.
5.	Erlotinib Hydrochloride (Pfizer, OSI) - Epidermal Growth Factor Receptor	Patent was granted disposing pre patent opposition by Natco Ltd.
6.	Pegasys (Hoffman La Roche)- Hepatitis- C drug	Patent was granted on 21 st Feb, 2006. In Mar, 2009, Patent office rejected the post grant patent by Sankal Rehabilitation Trust. IPAB on appeal reversed the decision of Patent Office and rejected the Patent for Pegasys for lack of inventive step and section 3(d).
7.	Gifitinib (AstraZeneca)- lung cancer drug	Patent was refused due to pre grant opposition by Natco pharma Ltd. and G.M. Pharmaceuticals. Appeal is pending before the High Court
8.	Asthma Combination Product(M/s Merck Sharp & Dohme Corp.)	Patent granted and then was subsequently revoked on 10 th Dec, 2012 based on the post grant opposition by Cipla Ltd.
9.	DP-IV Inhibitors (M/s Merck Sharp & Dohme Corp)	MSD has filed infringement suit against Glenmark and Aprica Pharmaceuticals. MSD won the infringement suit against generic diabetes drug.
10.	Gliver (Novartis)- Cancer drug	Supreme Court of India denied the grant of patent for Gleevec on ground of failure in the test of invention and patentability under Section 2(1) (j) and (ja) and Section 3(d).
11.	Praxada (Boehringer)- anti-coagulant	Patent granted in 2013 after the matter was remanded back by IPAB.
12.	Herceptin (Genentech Inc.)	Patent was granted on 6 th April, 2007 and in 2008 Glenmark Pharma filed a post grant opposition, which is still pending.
13.	Combigan (Allergan Inc.)	Patent was granted on 7 th May, 2008 and revocation application was filed by Ajanta Pharma Ltd. The patent stands revoked by IPAB.
14.	Ganfort (Allergan Inc.)	Patent was granted on 20 th Oct 2013 but was later revoked under Section 64 read with section 117 D of Patent Act on the basis of application filed by Ajanta Pharma.

India's Patent Regime is robust, effective and TRIPS compliant. In essence, section 3(d) aims to check ever-greening by providing that only those pharmaceutical derivatives that demonstrate significantly enhanced "efficacy" are patentable. The real function of section of 3(d) is not against innovation rather it is supportive of innovations which result in the enhancement of the known efficacy of the substance. Section 3(d) draws a line between ever-greening and incremental innovation.

TRIPS allows the member countries to use certain flexibilities in the context of public health to interpret the terms ‘novelty’, ‘inventive step’ and ‘industrial application’. This has also been mandated in the Doha Declaration. Accordingly, the Indian Patent Act prescribes a higher threshold on inventive step with regard to inventions related to medicines, which is in keeping with the TRIPS Agreement, Paris Convention and the Doha Declaration.

Section 3(d) only tries to filter out any frivolous inventions made in an attempt to ever-green patent incorporating trivial changes unless such changes result in significant improvement in the efficacy. It is also worth mentioning that Section 3(d) was enacted by the legislature only with the intent of discouraging the abysmal practice of the pharmaceutical companies from ever greening of patents. The Supreme Court in the Novartis Judgment affirmed that India has adopted a standard of pharmaceutical patenting that is stricter than that followed by the US or the EU. For India, a patent application must not only show that a new form of known compound is different than an old form, but the modification will result in an improvement in the treatment of the patient. Efficacy means “the ability to produce a desired or intended result”. Hence, the test of efficacy in the context of section 3(d) would be different, depending upon the result the product under consideration is desired or intended to produce. In other words, the test of efficacy would depend upon the function, utility or the purpose of the product under consideration.

Therefore, in the case of a medicine that claims to cure a disease, the test of efficacy can only be “therapeutic efficacy”. Section 3(d) is fully in conformity with the TRIPS agreement. It does not lay down a fourth requirement of patentability; rather it is a second tier requirement in cases of new uses of a known substance covered by the section. *Hence, the Indian Stance on the Section 3 (d) is sound in terms of TRIPS, Public policy and Health policy. The Novartis Judgment is well reasoned, reasonable and TRIPS permissible*

The Draft National IPR Policy further reiterates FICCI’s Stand on Section 3(d), “India’s statutory framework is robust, effective and balanced. It is in consonance with national development priorities while being in conformity with international treaties, conventions and agreements to which India is a party. India’s laws are notable for their far-sightedness and have also anticipated international developments.” The Draft Policy further states that “India is a party to a number of international treaties and conventions including the TRIPS Agreement. India is fully conscious of its international obligations and has always abided by them. At the same time, it has protected the national interest and balanced the rights of IP owners with their obligations to society. In future negotiations in

international forums and with other countries, India shall continue to give precedence to its national development priorities whilst adhering to its international commitments and avoiding TRIPS plus provisions.”

In India, some recent decisions demonstrate efforts by the Indian judiciary in protecting the rights of IP owners. The Indian judiciary have made significant progress in interpreting some complex but important statutory provisions of IP legislation, which would have far-reaching implications on the nature and extent of IP protection and enforcement in India. Some of these decisions are as follows:

Public interest as a defence in patent infringement suits: In *Novartis v Cipla*, January 2015 the Delhi High Court granted an interim injunction and restrained Cipla from manufacturing the generic version of Indacaterol. The court observed that a defendant cannot escape from the liability of infringement by merely citing public as a defence argument.

Markush Claims ought to be held valid: In *Merck v Glenmark*, October 2015 the Delhi High court observed that Markush claims of the patent to be valid and on this basis the court held the defendants product to be infringing.

Section 3(d): There was a series of cases filed by Novartis against multiple defendants for infringement on its patent on anti-diabetic drug Vildagliptin. Defendants challenged the validity of the patent under section 3(d), but different courts in India have granted injunctions in favour of Novartis and thereby protected the rights of patentee, Novartis.

Compulsory Licences have been used as a Tool against anticompetitive activities and enforcement of affordable commodities all over the World. The benefit of CL has been used by Canada, United States and Germany in the recent past. On February 2006, Canadian generic firm Biolyse requested the ministers of health and industry to add Osteltamivir to the list of pharmaceutical products eligible for CL for export. On July 2006, the Canadian government announced granting this license. In US, the anthrax scare in the fall of 2001 compelled the government to build a large enough stockpile of ciprofloxacin (Cipro) to treat 10 million people. This quantity was far greater than the supply and the manufacturer of the patented product Bayer lacked the capacity to produce it in a timely manner. The US granted compulsory licenses to generic manufacturers. In Germany, a licensing agreement was reached between pharma companies Roche and Chiron. Roche had been attempting to get the German government to issue a compulsory license

for patents on "Blood screening HIV probe" held by Chiron. Also countries like Egypt (for CL for Viagra in 2002) and Brazil (for HIV-Aids in 2007) have used CL in the past to their advantage.²³

Compulsory Licenses have also been invoked in the US through use of executive powers of President, to ensure availability of certain products. The US Government has wide powers under several legislations to exercise Compulsory License for reasons such as government use, public purpose or anti-competitive remedies. Besides this, CL provisions exist under the **Clean Energy Act, Atomic Energy Act and the Federal Insecticide, Fungicide and Rodenticide Act**. The US through Executive orders in the last 2 years has taken decisions in the apparent best interest of US consumers. The US Government allowed the import of 'Lipodox', a replacement drug for 'Doxil' from India (M/s Sun Pharmaceuticals). Thereafter, in February, 2013 the USFDA approved the first generic version of the cancer drug 'DOXIL' from Sun Pharmaceuticals. Similarly, the USTR decided in favour of Apple Incorporation in the **Apple Vs. Samsung**²⁴ case where infringement action had been initiated by Samsung Electronics for infringement of their US patent by Apple. This decision now allows the company to continue selling cheaper versions of iPhone4 and iPad2 in US.

In 2006, the US Supreme Court ruled that notwithstanding the exclusive rights associated with a patent, a patent holder was not automatically entitled to obtain an injunction to prevent future infringements. In the eBay case it was opined by the SC that to grant an injunction is a question of equity, and the court must consider a four part test, and require the plaintiff to demonstrate:

- (1) that the plaintiff has suffered an irreparable injury;
- (2) that remedies available at law are inadequate to compensate for that injury;
- (3) that considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and
- (4) that the public interest would not be disserved by a permanent injunction.

The practical impact of *eBay v. MercExchange* was to transform many infringement and injunction proceedings into compulsory licensing cases, and to include a public interest test. *The US has constantly set precedence of using CL as a tool to curb anti-competitive activities and for providing*

²³ Examples of Health-Related Compulsory Licenses, Available at:

<http://www.cptech.org/ip/health/cl/recent-examples.html>

²⁴ Apple, Inc., V. Samsung Electronics Co., Ltd., Samsung Electronics America, Inc., And Samsung Telecommunications America, LLC, US Federal Court Ruling 2012-1105. Decided on May 14, 2012, Available at:

<http://www.finnegan.com/files/Publication/9906806d-8e8b-46fa-aef5-c52fc0b68f13/Presentation/PublicationAttachment/74314560-f745-498c-b6d2-c5eb84404c45/12-1105%205-14-12.pdf>

to its citizen availability of commodities at a affordable price thereby signalling that it would not enforce exclusive rights in patents at the cost of public interest or other domestic concerns. Hence, India cannot be held deficient in terms of TRIPS Agreement, when India has issued just one CL under the Indian Patent Act, based on the rational of public policy and access to affordable lifesaving drug to the citizens; especially there is precedence in International Patent jurisprudence to support such actions.

DATA PROTECTION AND TRADE SECRET

TRIPS Agreement doesn't mandate data exclusivity. As of now, the issue of data protection is generally governed by the contractual relationship between the parties. However, the relevant laws in India dealing with data protection are the Information Technology Act, 2000 and the (Indian) Contract Act, 1872. A codified law on the subject of data protection is likely to be introduced in India in the near future.

TRIPS agreement does not refer to data exclusivity, nor does it refer to any period of data protection. The introduction of data exclusivity depends on the interpretation of Article 39(3) of the TRIPS Agreement because data protection regimes vary considerably among WTO members. The most difficult issue is whether government use of data submitted by innovator companies to determine bioequivalence of generic drugs is a commercial use or not. A basic premise for the application of Article 39.3 is that test data must only be protected if national authorities require their submission for obtaining marketing approval of pharmaceuticals or agrochemical products.

Given the territoriality of the intellectual property system - a feature that the TRIPS Agreement has not altered - the obligation to protect test data only arises in the Member countries where national regulations require the submission of such data. If a member country opts not to require those data, Article 39.3 will not apply. In addition, the submission of data must be necessary to obtain approval. Data voluntarily submitted by an applicant, or in excess of what is required for approval, are not subject to protection under Article 39.3. In March 2003, the Indian government took an in principle decision to provide data exclusivity for up to four years for toxicology, pharmacology, pharmacokinetic, and clinical trial data submitted by innovator companies. *India continues to discuss the introduction of data exclusivity as data exclusivity is not mandated by the TRIPS Agreement. It is to be understood*

that India's decision of not allowing data exclusivity is an effort to not venture into the area of TRIPS Plus and remain TRIPS compliant keeping in view India's socio-economic setup.

Trade Secret, at present, is protected through the contract law in India and is part of the concept of protection against unfair competition. Section 27 of the Contract Act, provides the remedy and it restricts a person from disclosing any information which he acquires at the time of employment or through a contract. Trade Secret is an important form of intellectual property and most innovative companies rely upon this confidential/proprietary information to gain business advantage. A predictable and recognizable trade secret regime will improve investor confidence and create a facilitative environment for flow of information.

Modernization and Strengthening of IP Offices

Recognizing the importance of the modernization of IPOs, the Government has implemented projects for modernization of Patent Offices, Trade Marks Registry (TMR) and Geographical Indications Registry (GIR) in the 9th and 10th Five Year Plans at a cost of Rs.1495.8 million. The focus of these projects was commissioning of four state-of-the-art offices in Delhi, Kolkata, Chennai and Mumbai, creation of additional posts in the Patent Office and TMR, providing initial level of computerization and Internet facilities, launching of electronic filing (e-filing) of patent and trade mark applications, establishment of online search facilities, establishment of Intellectual Property Training Institute (IPTI) to provide training and develop strategies for awareness creation. As a result of these initiatives, timelines for patent and trade mark processing have come down considerably and backlog of over 44,000 patent applications and 3,75,000 trade mark applications was liquidated in the last three years. The initiatives for creation of awareness have triggered IP activity in the country in terms of increased filing of the applications for grant of intellectual property rights. The impact of these initiatives is as under:

1. The filing of patent applications increased six-times from 4,824 in 1999-2000 to 28,882 in 2006-07. The number of patents granted increased four-fold from 1881 to 7359 during the same period.
2. Trademarks filings increased 1.5 times from 66,378 in 1999-2000 to 103,419 in 2006-07. Registration of trademarks increased more than ten-fold from 8010 to 109,361 during the same period.

3. Average time taken for grant of patents reduced from about 6-10 years earlier to about 2-3 years. In case of trademarks, the average time for registration reduced from 7-10 years to 2 years.
4. e-filing system for patent and trade mark applications, which is user-friendly, speedy and transparent, has been launched.
5. Provided for an institute with facilities for training of fresh examiners as well as Controllers and Registrars in the IPOs.

Some recent developments on this front are:-

1. *State of the Art International Searching Authority and an International Preliminary Examining Authority (ISA/IPEA) building:* Indian Patent Office was recognized as an ISA/IPEA under the Patent Cooperation Treaty (PCT) of World Intellectual Property Organization (WIPO), which is a specialized agency of the United Nations in the field of IPRs, in October, 2007, joining an exclusive group of 15 countries/organizations. The operational requirements for an ISA/IPEA was an establishment of digital database of patent records, access to major patent databases and modern search engines, and a minimum of 100 Examiners in the Patent Office. In this regard, the new ISA/IPEA building was inaugurated on 8th September 2014. The infrastructure includes Public Facilitation Centre, Space for examiners, libraries for Patents & Trademarks with public search facility, training halls, meeting spaces, discussion rooms and conference rooms for pan India Connectivity.

2. *Comprehensive payment gateway for Patents & Trademarks:* The e-filing facility for Trademarks and Patents was launched in 2007 for initial filling and was enhanced to comprehensive e-filing in the year 2012. The web-based facility with digital signature based authentication and payment through internet banking attained wide acceptance from the stakeholders. Further, by the Amendment in the Patent Rules in February 2014, a differential fee of 10% less by e-filing was introduced.

To meet the need for flexible payment options for e-filing, the IPO on 8th September, 2014 also unveiled the comprehensive payment gateway for e-filing whereby IPO became the first Government organization to enable internet, credit card and debit card payment facilities.

3. Stock & Flow of Patents: To enhance transparency, the IPO has introduced the unique feature of Stock & Flow of Patents. IPO is the first IP Office in the world to provide this facility. The Stock & Flow is the real time reflection of the entire patent process that presents a snapshot of current pendency, processing and disposal of the entire patent office at a glance. This facility was also launched on 8th September 2014.

Other recent developments:

- Proposed Amendment in Patent Rules, 2003 were published on 26th October, 2015. These amendments propose new provisions such as like Expedited Examination of Patent Applications.
- Proposed Amendment in Trade Marks Rules, published on 17th of November, 2015. These amendments propose new provisions such as Expedited Examination of TM application and Registration of Sound Mark.

IP Trends in India

Patents In India- The table below displays the patent filing trend in India for the last eight years. There has been significant annual growth in terms of the number of patents filed at the Indian Patent Office. Maintaining strictest quality measures, the increase in number of patents granted was in tune with the number of patents filed only until 2010 after which the proportion of number of patents granted reduced substantially. It is evident from the figures that the Indian industry, academia and government are very much aware about the importance of intellectual capital for an inclusive growth of a country. The increase in the number of patents filed shows the faith of people in the IPR and with government support, the time required to examine and grant a patent will definitely decrease.

Year	Filed	Examined	Granted	Disposal (Granted+ Abandoned+ Withdrawn + Refused)
2007-08	35218	11751	15261	15795
2008-09	36812	10296	16061	17136
2009-10	34287	6069	6168	11339
2010-11	39400	11208	7509	12851
2011-12	43197	11031	4381	8488
2012-13	43674	12268	4126	9027

2013-14	42950	18306	4225	11672
2014-15	42774	22631	5978	14532

Key observations

- There has been a substantial increase in the number of patents examined, granted and disposed during 2014-2015.
- There has been a marginal decrease in the patent filing trend in comparison to the previous year.

The e-filing trend too has been on the rise since the inception of the e-filing facility in 2007. With the new comprehensive e-filing system and payment gateway this trend shall see an upward surge in the coming years.

Trademarks in India - The table below depicts the trend in Trade Marks applications for the last eight years. To further speedup the process and increase the response time, an electronic system was developed at the Trade Mark Registry for printing and dispatching Trade Mark certificates. To enhance transparency, the registry was directed to share all the essential process documents with the public via the official portal. As a new feature, a comprehensive filling system and payment gateway has been launched to make the registration process hassle free and flexible from 8th September 2014.

Year	Filed	Examined	Registered	Disposal (Registered+ Abandoned+ Refused+ Withdrawn +)
2007-08	123414	63605	100857	NA
2008-09	130172	105219	102257	126540
2009-10	141943	25875	54814	76310
2010-11	179317	205065	115472	132507
2011-12	183588	116263	51735	57867
2012-13	194216	202385	44361	69736
2013-14	200005	203086	67873	104753
2014-15	210501	168026	41583	83652

Industrial Designs in India- The table below shows the trend with regard to designs for the last eight years. The number of designs granted in year 2010-15 increased significantly as compared to

previous years, the primary reason being the digitization of various processes at the Designs Wing, Patent Office at Kolkata. The Designs Wing has also published a manual consisting of all the design registration practices to increase transparency.

Year	Filed	Examined	Registered
2007-08	6402	6183	4928
2008-09	6557	6446	4772
2009-10	6092	6266	6025
2010-11	7589	6277	9206
2011-12	8373	6511	6590
2012-13	8337	6776	7252
2013-14	8533	7281	7178
2014-15	9382	7459	7171

Geographical Indications in India:-There has been substantial increase in the number of applications filed in 2011-15 due to increased awareness among all the stakeholders of the intellectual capital generators of our country.

Year	Filed	Examined	Registered
2007-08	37	48	31
2008-09	44	21	45
2009-10	40	46	14
2010-11	27	32	29
2011-12	148	37	23
2012-13	24	30	21
2013-14	75	42	22
2014-15	47	66	20

Conclusion

The Indian IP Landscape in the last decade has witnessed a paradigm shift. With each passing year, the foundations of the Indian IP System are gaining more ground and strengthening itself for an effective and sustainable future. In this context, Prime Minister Modi's statement made during his

September 2015 visit to New York finds much relevance, particularly in context of the thriving Indo-US economic ties:

“India is committed to protecting IP rights—a subject on which the US and India differ. This is a technology-driven era. We are a technology-driven society. We are committed to protecting IP rights, which is essential to fostering creativity.”

An assessment by FICCI of the Indian legal framework and practices for IP enforcement vis-a-vis “25 Best IPR Enforcement Practices”²⁵ reveals that India is primarily in compliance with international standards provided under the TRIPS agreement. However, there is significant scope for developing a more conducive IP enforcement environment in the country.

Recent government initiatives have set the metaphorical stage. India is ready to see how these initiatives are implemented and what their effect on its socio-economy will be. In any event, any initiative of the government in relation to IP must go hand in hand with the corresponding statutory/administrative changes in the regime. It is not enough for policies to be in place for strengthening IP laws without any efficient systems to enforce them. India has all necessary legislative laws and policies in place today. The emphasis needed is on enforcing these effectively to boost Indian innovators and industry.

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²⁵ 25 Best IPR Enforcement Practices (a format developed by BASCAP - Business Action to Stop Counterfeiting and Piracy)