Response to Hearing Testimony of India

India has a well-established legislative, administrative and judicial framework to safeguard IPRs which meets its obligations under TRIPS, and has withheld the test of severe international scrutiny. The two Trade Policy Reviews conducted by WTO in respect of India in 2007 and 2011 have found the Indian IPR regime to be adequate and there has been no mention to the contrary.

India has an independent authority and appellate board and courts to decide on due processes. The fact that a number of cases are being appealed or being invalidated by the Indian courts only show the robustness of the Indian IP eco-system. There has been no concerted effort by the Indian system discriminating foreign companies and there have been a number of Indian patents also being invalidated. Similarly there is increasing number of cases being decided by the US Supreme Court relating to patents and infringements, revocation and other disputes relating to IPRs and the US Federal courts have upheld only 39 patents in 283 cases between 2007 and 2011.

India is a party to and is compliant of the following International IPR Treaties:

- Berne Convention (copyright) – since 1928
- Madrid Protocol (trade marks) –since 2013
- Paris Convention (priority rights) – since 1998
- Patent Cooperation Treaty (patents) – since 1998
- World Trade Organization (WTO) /Trade Related Aspects of Intellectual Property Rights (TRIPS) – since 1995
- Nairobi Treaty (Protection of the Olympic Symbol)- since 1983
- Budapest Treaty (the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure) –since 2001

Indian policies are directed to promote accelerated development and growth of the country. The Indian policy is not protective towards its domestic industry, but is protective of the interests and welfare of its citizens. The Govt. of India policy on public health and affordable healthcare works with in the international framework and in genuine interest of Indian public.

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 despite the actions being 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. Such bilateral pressures and threat of trade sanctions are seen as pressure tactics on developing countries into serving as profit ground for the 'big' international pharma companies.

During the United States Trade Representative (USTR) and the United States International Trade Commission (USITC) hearing under Section 332 the Indian IP regime has been question on its commitment towards establishing an effective and balanced IP system keeping in view of its national priorities and needs. The main allegations have been leveled under the following heads:

1. Indian IP laws are not TRIPS Compliant
2. Copyright infringement is rampant in India
3. The Indian Patent system is protective of domestic Industry and discriminates against the foreign participants.
4. The provisions under CL are not TRIPS compliant and are deterrent to FDI and R&D investment in India
5. The provisions under Section 3(d) enforces a fourth condition for grant of Patent which is in contravention of TRIPS.

6. Data Protection and data exclusivity law in India is non compliant with the TRIPS provisions.

"INDIA IS TRIPS COMPLIANT"

Indian IP law is TRIPS Compliant and more. While TRIPS requires member states to protect products and processes, it does not specifically refer to the protection of new uses, thus leaving member countries free to choose whether or not to protect them. In principle, a country that broadly excludes methods of medical treatment could also broadly exclude new therapeutic uses for old products. [1] Hence the Novartis judgment denying patent on the ground of lack of enhancement of "therapeutic efficacy" is well within the interpretation of TRIPS.

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. The Supreme Court judgment has also put finality on the implication of the term therapeutic efficacy in Section 3(d) in the Novartis Judgment[2].

The TRIPS Agreement also provides certain flexibilities as to the method of implementing TRIPS obligations. These result from **Article 1.1** of the agreement, as per which, WTO members can exploit creative solutions to transpose into their national law and practice those concepts of TRIPS Agreement which have been mentioned but not defined. Thus, herein lies the genesis of Section 3(d) of Patents Act, 1970 which is nothing but an exercise of liberty given to all member states under TRIPS. **Article 27.1** of the TRIPS Agreement obliges WTO Members to make available patent protection to all inventions, in all fields of technology. The said article apart from spelling out the criterion of patent eligibility also offers some flexibility as it does not define the parameters of novelty, inventiveness and industrial applicability, thus giving WTO members the scope to determine the criteria of how these should be interpreted and applied.

[1] Correa, Carlos M., Public Health and Patent Legislation in Developing Countries, 3 TUL. J. TECJ & INTELL, p 1.49 (2001)

The TRIPS agreement itself does not prevent countries from denying the patentability of new uses for lack of novelty, inventive step or industrial applicability.[3]

Article 8 of TRIPS Agreement aims at cautioning member states, that while they formulate or amend their laws, adequate measures must be adopted necessary to protect public health and nutrition besides ensuring that the intellectual property rights are not abused by the right holders. **Article 7** of the TRIPS agreement obliges member states to provide Intellectual Property protection in such a manner that it gives mutual advantage to the producers and users of the technological knowledge which is conducive to the social and economic welfare. Hence ***the implementation and interpretation of the TRIPS must be in a manner supportive of public health, by promoting both the access to existing medicines and research and development into new medicines***.[4]

"INDIAN COPYRIGHT LAW IS THE MOST EXTENSIVE LEGISLATION ON THE SUBJECT"

Copyright is a right given by the law to creators of literary, dramatic, musical and artistic works and producers of cinematograph films and sound recordings. It is a bundle of rights including, inter alia, rights of reproduction, communication to the public, adaptation and translation of the work. **Indian copyright law is one of the strongest and best in the world**. India has protected computer programs by copyright much earlier than the US. Indian Copyright Act 2012, as mentioned above also brings Indian law fully in conformity with international treaties of WIPO.

Copyright ensures certain minimum safeguards of the rights of authors over their creations, thereby protecting and rewarding creativity. **Creativity being the keystone of progress**, no civilized society can afford to ignore the basic requirement of encouraging the same. Economic and social development of a society is dependent on creativity. The protection provided by copyright to the efforts of writers, artists, designers, dramatists, musicians, architects and producers of sound recordings, cinematograph films and computer software, creates an atmosphere conducive to creativity, which induces them to create more and motivates others to create.

[3] Id citing The National Institute of Health Care Management Research and Educational Foundation (NIHCM) showed that the 12 year period of 1988-2000, only 35% of the 1035 drugs approved by the FDA contained a new active ingredient (NIHCM 2002). Highly innovative drugs are increasingly rare.

[4] WTO, Ministerial Declaration, Fourth Ministerial Conference in Doha, Quatar, ¶ 17 (adopted Nov 14 2001)

The Copyright Act, 1957 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 to bring 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 2012 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 Rules, 2013 was notified on 14 March, 2013 replacing the old Copyright Rules, 1958. The Rules, inter alia, 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.

The abovementioned legislative and statutory measures are supplemented by appropriate administrative measures by the Governments 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)**[5] has been set up by the Ministry of Human Resources Development (MHRD) for advising Government on measures to

[5] Report Of The Sub-Committee On Issues Pertaining To Enforcement Of Copyrights In India; October 7, 2013; **ANNEXURE 1**

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.

- ✓ **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.
- ✓ 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.
- ✓ The **CBEC** has set up the ARTS portal for effective and speedy identification and redressal of counterfeited and de-merit goods.

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 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.

To strengthen enforcement of IP laws in India various measures have been taken undertaken by the Ministerial and Industry Level, like:

- ***Automated Recording and Targeting System (ARTS)***[6] ***portal of*** **Central Board of Excise and Customs (CBEC) for cross-border protection of IPR-** is a part of the proposed Reforms and Measures Undertaken by Central Board of Excise and Customs (CBEC) to Facilitate Trade. ARTS intends to provides protection of Intellectual Property Rights by creating a database of Trademarks, Copyrights and other IP rights whereby identification of counterfeits and de-merit goods are effectively identified and stopped from flowing into the main stream market place. ARTS 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 very sophisticated about IP and TRIPS issues and one cannot fool them anymore. The Indian economy and society has embraced and has been capacity building to take the international IP regime head strong.
- ***National IP Strategy***[7]- India has always given utmost importance of IPR Portfolios and several organizations have incorporated business intelligence tools and IP management to avoid infringement. This decade has been called the **Innovation decade** and efforts have been made for Promoting respect for IP and stimulating creation of Intellectual Property Rights. In the knowledge economy, creation of IP and its incorporation in designs, products and production techniques are increasingly becoming important for commercial competitiveness and economic growth. With the intent of promoting innovation the there's a need to encourage the **MSMEs** to protect their IP through formal methods and incentives are needed to encourage MSMEs to create new IP. Synergizing the services of the IP facilitation centers to improve their impact. This requires considerable intervention by the Government. Access to Database on patent and non patent literature to enable prior art search should be provided to premier institutions like IIT's and NIT's. Favorable tax treatment for R& D Expenditures incurred could play a positive role in incentivizing innovation and IP creation.

[6] http://pib.nic.in/newsite/efeatures.aspx?relid=101785

[7] http://dipp.nic.in/English/Discuss_paper/draftNational_IPR_Strategy_26Sep2012.pdf

Most of the studies on piracy done are normally perception based and not objective. IPR Division of FICCI is intensively involved in issues pertaining to protection of IPR and copyrights and its effective enforcement. FICCI has engaged in capacity building and training in industry and enforcement agencies, including the police and customs departments. In addition, FICCI sensitizes judiciary on the quality and speedy adjudication of Intellectual Property and copyright related matters.

India is sensitive towards IP infringement and the Copyrights Act prescribes criminal[8] sanctions of imprisonment and fine for infringement of Copyrights. It is pertinent to mention herein that Police personnel of crime branch raided four different outlets selling computer peripherals after complaints of copyright violation from an agency involved in protection of intellectual property rights. Four persons were arrested in the raids. The raids were conducted by crime branch officials along with representatives of EIPR (India) Ltd in Alkapuri, Productivity Road and Sayajigunj areas of the city. The agency had complained that products violating the copyright of Hewlett-Packard were being sold at shops and showrooms located in these areas. Crime branch officials checked the shops and found laptop batteries, adaptors and speakers that were violating the intellectual property rights of the company. Material amounting to Rs 5.97 lakh was seized during the raids by the crime branch and an offence was registered at the Gotri police station[9]. Hence it is evidenced that not only are the e**nforcement authorities sensitive and active in curbing infringement practices in India**.

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

FICCI CASCADE Objectives:

- Generating awareness on the hazardous impact of smuggled, contraband and counterfeit products amongst consumers and citizens
- Capacity building of law enforcement agencies including Judges, Police and Customs Officers
- Research and proposing law reforms

[8] **Chapter 13**, The Copyrights Act, 1957
[9] http://timesofindia.indiatimes.com/raids-conducted-for-copyright-violation/articleshow/19300365.cms

- Interactions with the law enforcement authorities to emphasize on the importance of continued awareness and seriousness of the impact of counterfeit goods
- Enforcement of IP related laws
- Systematic dissemination of enforcement techniques, procedure and strategy through regular workshops for the guidance of its members
- Sharing the best practices followed globally for combating contraband, smuggled and counterfeit product
- Provide knowledge support to the industry members

Activities of CASCADE include

- **Joint Publicity Campaign** with Ministry of Consumer Affairs under their "Jago Grahak Jago" umbrella to create awareness amongst the consumer.
- "Hum Kishore Festival 2012" on theme "Fight Smuggling and Counterfeiting" amongst youth of NCR , Delhi (30th April- 4th May, 2012)
- **World Anti-Counterfeiting Day** on 13th June, 2012 on "Building a Pro-Active Strategy to Curb Counterfeiting"
- Training workshop with Custom officers at Delhi, Mumbai, Chennai and Bangalore
- Sensitization and Awareness Seminar at Lucknow, Jaipur, Srinagar, Ahmedabad, Bhopal Patna and many other parts of the country to provide knowledge support to all the stakeholders about the menace of counterfeiting and smuggling
- **National Consumers Rights Week**, 2012 celebrated in collaboration with Ministry of Consumer Affairs to advocate socially responsible behaviour among the consumers

CASCASDE has undertaken in-depth research to gather reliable information on the impact of illicit trade in counterfeit goods in core sectors of industry on subject. To further gather information on the mode and magnitude of this threat on the economy. Interactions with Industry facilitating sharing of information, training sessions and best practices. Interactions with media and journalist emphasizing on the seriousness of the issue. Further motivating and encouraging members of the media to give serious and extensive coverage through media. Awareness campaign in 100+ schools in New Delhi, though interactions, creative competitions and rewards. International Conference on Trade in Counterfeit, Pirated and Smuggled Goods -A Threat to National Security and Economy, New Delhi.

FICCI IPR Division has been working on policy, enforcement and awareness level and has undertaken the following activities to strengthen the IP Regime in India:

- Industry and Cluster specific Sensitisation Programs

- Capacity Building and Training Programs with Police and Customs
- IP tool Kits and Copyright tool kits are being distributed at National Level to Police and Customs officials to increase awareness and sensitivity towards IP Crimes.

Hence the Indian Industry and industry organisations have been effectively involved in **building Brand Awareness** to tackle the problem of counterfeiting at the grass root level.

THE INDIAN PATENT ACT, 1970- "Strong Patent" Advocacy

The patent law in India has its origin in the 19th century, during the British rule of the country. Justice N. Rajagopala Ayyangar submitted a comprehensive Report on Patent Law Revision in September 1959 and the new law of patent, namely, the Patents Act, 1970, came to be enacted mainly based on the recommendations of the report, and came into force on April 20, 1972. . The second amendment to the 1970 Act was made through the Patents (Amendment) Act, 2002 (Act 38 0f 2002). This Act came into force on 20th May 2003 with the introduction of the new Patent Rules, 2003 by replacing the earlier Patents Rules, 1972. The third amendment to the Patents Act 1970 was introduced through the Patents (Amendment) Ordinance, 2004 w.e.f. 1st January, 2005. This Ordinance was later replaced by the Patents (Amendment) Act 2005 (Act 15 of 2005) on 4th April, 2005 which was brought into force from 1st January, 2005.

Since the amendment of the Patents Act 1993 in 2005, India has been the subject of centre stage debate on Compulsory Licensing (CL), provision against ever-greening under Section 3(d), pre and post grant patent objections, due process, etc. The stance on these allegations is manifold and well rooted:

1. **Indian policy is driven by Public Interest and Health Care:**

   The factual scenario in India remains that only 25% of the population is covered under public or private insurance, and about 71% of all health-care expenditure continue to be out-of-pocket expenses. Health Sector in India is the responsibility of central, state and local government. In terms of service delivery it is more concerned with State government. In 2011, The World Bank reported that 32.7% of the population in India fall below the international poverty line of USD 1.25 per day (PPP) while 68.7% live on less than USD 2 per day. Hence health care remains out of

reach for a larger chunk of the general population in India. Hence affordable and accessible health care is a driving force in Indian Policy.

WHO says the pharmaceuticals cost about 60% of the total cost of health care in India. India's healthcare initiatives should consider the interests of the 40% of the people who live below poverty line. The crux of the matter is that monopolies should not be extended to inventions which are not 'genuinely innovative enough' which otherwise if granted protection would hamper or prove to be highly deterrent to the social and economic welfare.

To elucidate the need for Indian mandate on CL it must be noted that the price for Nexavar, in India, was $5,626 (US dollars) per month, in a county where the per capita income was $132 per month. Hence, if Bayer was charging a price for Nexavar equal to 42 times average incomes in the United States, as it was in India, the price in 2012 would have been $183,190, per month, or $2.2 million per year. Private and Public spending in Indian health care sector would touch USD 14.2 billion in 2013, at an annual growth rate of 5.8% from 2009. India has more than 1.237 billion residents and one third of the world's poor live in India. In light of the same the Novartis plea that it provides its drug to 42 million persons seems meagre.

The WTO states that the TRIPS Agreement **should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.**

Furthermore Part VI of the Constitution of India lays down provision for raising the health and standard of living of the general population. These principles serve as guidelines for the State and Central governments in policymaking and to achieve the objectives of a Welfare State. In light of immense poverty and inaccessible health care in India, the CL and Section 3(d) of the Patent Act must be viewed as protective and not restrictive. An anti-competitive and closed patent protected pharma industry may not be collusive with the ideology of a welfare state.

It is true although that the US cannot ignore the Indian Pharma Market. **India is the most feasible market for generic drugs and primary source of affordable generic medicines to the developing countries.** But the Policy drive to affordable drug is not a move to exclude foreign players from participating in the Indian Pharma Market or to create hostile

market barrier. The Policy is directed towards one goal towards attaining better standards of health and making life saving drugs affordable and accessible in domestic and international markets.

2. **<u>The provisions of Compulsory License[10][11] is within the paradigm of TRIPS :</u>**

The basic approach of patent law is to strike a balance between the interest of the inventor and that of consumers and to ensure that the benefits of the new technologies reach the people, and not exploited by the inventor for establishing monopolistic control. **Compulsory licensing (CL)** is when a government allows someone else to produce the patented product or process without the consent of the patent owner. It is one of the flexibilities on patent protection included in the WTO's agreement on intellectual property- the **TRIPS**[12] (Trade-Related Aspects of Intellectual Property Rights) Agreement. The TRIPS Agreement does not specifically list the reasons that might be used to justify compulsory licensing. However, the **Doha Declaration on TRIPS and Public Health**[13] confirms that countries are free to determine the grounds for granting compulsory licenses. Governments can refuse to grant patents for three reasons that may relate to public health:

- inventions whose commercial exploitation needs to be prevented to protect human, animal or plant life or health. [14]
- diagnostic, therapeutic and surgical methods for treating humans or animals.[15]
- certain plant and animal inventions.[16]

Under the TRIPS Agreement, governments can make limited exceptions to patent rights, provided certain conditions are met.[17]

With respect to Compulsory Licensing, it is stated that the provisions under the Indian Patents Act (Section 84, 92, 92A, 100) are strictly in compliance with **Article 31** of TRIPS Agreement which relates to "other use without authorization of the right holder". **Section**

[10] Section 84, Indian Patent Act, 1970
[11] Article 31(f), TRIPS
[12] Uruguay Round of the General Agreement on Tariffs and Trade (GATT); 1994
[13] DOHA WTO MINISTERIAL 2001: TRIPS, WT/MIN(01)/DEC/2, ***Declaration on the TRIPS agreement and public health*;** Adopted on 14 November 2001
[14] Article 27.2, TRIPS
[15] Article 27.3a, TRIPS
[16] Article 27.3b, TRIPS
[17] Article 30, TRIPS

84 of the Patents Act enables interested persons to apply for grant of compulsory license on the grounds that reasonable requirements of the public with respect to the patented invention have not been satisfied; that the patented invention is not available to the public at reasonably affordable price or that the patented invention is not worked in the territory of India.

There are no WTO rules which limit compulsory licencing to pandemics, or such emergencies and no rules prevent India from issuing CLs to address high prices. Moreover TRIPS states that individual members retain the right to adjust laws to serve local needs. The preamble of TRIPS recognizes an '**underlying public policy objective'** of national systems for protection of IP, including developmental and technological objectives.

India favour's "Strong Patents", the same is evidenced by the strict scrutiny and procedure of granting patents as is adopted by the Indian IP Office. In India, the Bayer's cancer drug Nexavar is the only drug that has been granted CL 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.

In addition as a mark of its careful scrutiny, the Indian patent office rejected an application to compulsorily license Dasatinib[18]. The Patent application process in India follows the due process strictly. The Indian Patent authorities has constantly endeavoured to assert a strong patent regime in India and the following is the factual testimony to the same:

S.No.	Particulars	Details
1.	NEXAVAR (BAYER)[19]- Kidney/liver cancer drug	NATCO was granted a CL on Bayer patented drug Nexavar was granted on ground of public policy as the German Innovator was unable to provide the life saving drug at affordable prices in the domestic market
2.	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**

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

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

		pharmaceutical Int. Ltd.
3.	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 Act on grounds of obviousness. **On appeal the HC directed Cipla to not market its product**.
4.	Erlotinib Hydrochloride (Pfizer, OSI) - Epidermal Growth Factor Receptor	Patent was granted disposing pre patent opposition by M/s Natco Ltd.
5.	Pegasys (Hoffman La Roche)- Hepatitis- C drug	Patent was granted on 21st 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).
6.	Gifitinib (AstraZeneeca)- 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
7.	Asthma Combination Product(M/s Merck Sharp & Dohme Corp.)	Patent granted and then was subsequently revoked on 10th Dec, 2012 based on the post grant opposition by Cipla Ltd.
8.	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.
9.	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).
10.	Praxada (Boehringer)- anti-coagulant	Patent granted in 2013 after the matter was remanded back by IPAB.
11.	Herceptin (Genentech Inc.)	Patent was granted on 6th April, 2007 and in 2008 Glenmark Pharma filed a post grant opposition, which is still pending.
12.	Combigan (Allergan Inc.)	Patent was granted on 7th May, 2008 and revocation application was filed by Ajanta Pharma Ltd. The patent stands revoked by IPAB.
13.	Ganfort (Allergan Inc.)	Patent was granted on 20th 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.

The above table exemplifies how the Indian Patent authorities have followed the due process under Section 8 of the Patents Act, which in turn is in consonance with the TRIPS Agreement, *hence the allegation of discriminative policy against foreign companies is unfounded.*

3. <u>Compulsory Licences have been used as a Tool against anticompetitive activities and enforcement of affordable commodities all over the World:</u>

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 ciprofioxacin (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.[20]

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[21], 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

[20] http://www.cptech.org/ip/health/cl/recent-examples.html
[21] USC 28§1498

the **Apple Vs. Samsung**[22] 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.[23] 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 to its citizen availability of commodities at a affordable price. Whereby 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 life saving drug to the citizens; especially there is precedence in International Patent jurisprudence to support such actions.

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

[23] eBay Inc. v. MercExchange, L.L.C; 547 U.S. 388 (2006),

4. **Indian Patent regime is R&D conducive and is not affected by CL:**

The US assertion that the Indian IP policy subverts the investment in R&D is also unfounded. Firstly, there have been examples of increase in the FDI in pharmaceutical R&D in a environment where CL's are rampant. In 1977, F.M. Scherer conducted an investigation that focused on seven hundred companies, 44% of which were subject to CL. The research states that companies subjected to CL invest more in R&D than companies that were not the object of similar measure. Hence it is concluded that CL does not cause a reduction in investments in R&D in the long run.[24] Secondly, Gleevec[25] was funded by the **US government, academic institutions and philanthropic organizations**; the total out of the pocket expense to Novartis was $15 million, whereas on the other hand the sales of Gleevec in 2013 were estimated at $12.9 million per day[26]. In case of Nexavar the total R&D cost was $134.8 million[27] and the trial was subsidised under the US Orphan Drug Tax Credit[28]. Hence it seems infructuous to have hosted a centre stage debate over the extensive profits derived from low R&D costs.

5. **Section 3(d)[29] against Ever-Greening of Patents is TRIPS compliant:**

Section 3(d) to the Patents Act, 1970, provides that mere discovery of a new form of a known substance which does not result in enhancement of the known efficacy of that substance or mere discovery of new property or new use for a known substance or of the mere use of a known process, etc., are not patentable.

Section 3(d) does not hamper the growth of the pharmaceutical industry. The statistics reveal that the total number of pharma patents granted in 2004-05 was 765 and in 2008-09 it was 2373. Since the implementation of the new patent Act in 2005 a total of 3500 "product patents" were filed. The growth in terms of applications filed and grant of patents the foreign

[24] Alberto do Amaral Junior, Compulsory Licensing and Access to Medicine in Developing Countries, SELA 2005 Panel 5: Poverty and the International Order
[25] R&D costs for Gleevec, April 3, 2013. http://keionline.org/node/1697
[26] The NDA filing was February 27, 2001. The FDA approval as May 10, 2001;
[27] Onyx Pharmaceuticals, Inc. Annual Report Pursuant To Section 13 Or 15(d) Of The Securities Exchange Act Of 1934 For The Fiscal Year Ended December 31, 2005. Page 3536. Research and Development Expenses.
[28] IPAB hearing on the Nexavar compulsory license, part 1, R&D costs, January 19, 2013. http://keionline.org/node/1640.
[29] http://ipindia.nic.in/ipr/patent/eVersion_ActRules/sections/ps3.html

applicants has been appreciable. The statistics revealed that in 2004 -05, 20% of the patent applications were filed by residents and 80% by non-residents. . In 2007-08 residents were granted 21% of the patents and 79% to non residents. In 2007-08 alone 12088 patents were granted to foreign applicants amounting to 79% as against 3173 patents granted to residents amounting to 21%. In 2008-09, 17% of the applications were filed by residents and 83% by non-residents. In the matter of grants, 40% of the patents were granted to residents and 60% to non-residents.

Recently, the Indian Patent Office (IPO) published comprehensive list of pharmaceutical patents granted on its website. It is interesting to note that more than **two thirds of pharmaceutical patents were granted to foreign multinational companies** and foreign drug makers by the Indian Patent Office (IPO). On the basis of patent data published on Indian Patent Office (IPO), it was noticed that 1,001 pharmaceutical patents had been granted between April 2010 and March 2013 to various pharmaceutical companies. The patent data also revealed that out of the granted pharmaceutical patents in India, 771 patents were issued to foreign pharmaceutical companies and drug makers such as Pfizer Inc., Novartis AG and F Hoffmann La Roche Ltd.[30]

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. The mere reading of the said section clearly recites as to what is not patentable. In other words if the „prospective patent" substance results in the enhancement of the known efficacy of the substance then it is patentable. The section 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 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.

[30] Pharma Patents Granted During 2010-11 To 2013-14 (UP TO 31-7-2013) ; http://www.ipindia.nic.in/patent_Applications_Filed/patentGranted_Pharma_2010-11_Jul2013.pdf

Section 3(d) of the Patents Act is similar to US Patent Act of **"Threshold Limit**" which sets up standards in order to leave door open for genuine inventions but at the same time checks any attempt at repetitive patenting and extension of a patent term on frivolous grounds. According to this section, the discovery of a new form of a known substance which does not result in the enhancement of a known efficacy of that substance or if it is a mere discovery of a new property or new use of a known substance or of the mere use of a known process machine or apparatus unless such process results in a new product or employs at least one new reactant is not patentable.

The **Novartis Judgment**[31] is well reasoned, reasonable and TRIPs permissible. In the Novartis case the Supreme Court of India denied the patent application for the Gleevec- on the ground of modifications of known drug. This criterion is viewed as a "Second Tier" condition for granting of patents and is applicable only on pharma patents. Under the Section 3(d) of the Indian Patent Act 1970, patent can only be granted in such cases if the drug differs significantly in properties with regard of efficacy. The Supreme Court denied the patent application observing that there was no increase in the therapeutic efficacy of the drug, thereby quashing all attempts of ever greening the drug. This led to the international contention that lack of patent protection curbs investment in R&D. The Supreme Court affirmed that India has adopted a standard of pharmaceutical patenting that is stricter that 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.

[31] Novartis A.G. vs. UOI, (2007)4 MLJ 1153, Date of Judgment: 6th August 2007

Also to cite the example of the ruling by the US Federal Court of Appeals in Pfizer vs Apotex in 2007, the court agreed with Apotex that Pfizer's Pfizer's patent on the compound besylate (a salt form of amlodipine) was invalid because the besylate form lacked the "unexpected superior results" from the base compound (amlodipine) in order for it to be patented. This judgment is similar to India's Supreme Court's decision rejecting patent for Glivec for not demonstrating enhanced efficacy under Section 3 (d) of India's Patents Act. Moreover Glivec being accepted in 40 different patent jurisdictions does not take away the right of the Indian system to review and decide on it.

6. Local content and CL requirement in Solar, Telecom sector has seen precedence all over the world:

Solar: Indian policies are being not developed as a counter to any policy of another country but develop the Indian market. The use of local content provisions in the Solar sector are restricted to projects under **National Solar Mission,** a Federal initiative to meet India's global commitment on climate change. States and local bodies do not have any local content provided they are not supported by Solar mission.

Presently, vast majority of clean energy technology patents are held by developed countries. India is pushing for a global climate agreement to include provisions to ensure that essential patented clean tech innovations to be available at affordable prices to be able to meet both international obligations and targets set by it to achieve reduction in greenhouse gases. FICCI is working with all stakeholders to promote policies in India that will accelerate the transfer and diffusion of clean technologies and help the Indian low carbon growth trajectory.

The federal government in India brought out Local Content Regulations (LCR) to support a manufacturing base in the country to create a market. This support is given through a subsidy to enable investments in solar manufacturing to happen across the country. Unlike in the US where the market is so mature that even at sub-federal levels there is competition. And despite the maturity of the market, there is government support through tax credits and export financing. States within the US are competing with each other in manufacturing with LCR imposition. In India the market will take some time to mature. India has set out its own policy to give an impetus to solar energy in the country including creating a manufacturing base and this is independent of policies in other countries. India has set out its own policy to give an impetus to solar energy in the country including creating a manufacturing base. There is a strong need to

incentivize investments in creating the domestic supply chain with help from both domestic and global players, and to facilitate collaborative arrangements towards enhancing research and development efforts.

Firstly, state policies in the US encourage local content requirement (LCR). The US promotes renewable energy in Michigan, California, and Texas through LCR.

Secondly, the US has imposed anti-dumping duty on Chinese solar equipment that they believe is hurting the interests of the US manufacturing industry. Thirdly, US government provides tax credit upto 30% to encourage domestic production and this applies to solar manufacturing sector as well. Solar farms in the US that are using locally made equipment get 30% tax credit. Lastly, financing is made easy through Exim Bank finance to support exporters of US solar equipment. Financing in the US is available at a 85:15 debt-equity ratio while in India it is only 60:40. This is enabling US solar equipment manufacturers to penetrate the Indian solar energy market easily and putting Indian companies at a disadvantage. US companies have been part of India's solar programme. The state policies in India do not have LCR and therefore US companies have had their share in such projects. Even projects under phase I of National Solar Mission where thin film modules are being used, have US companies participating. Therefore it is unfair for the US to make allegations against India on LCR.

Telecom Sector: Despite significant growth of the Indian telecom network and the subscriber base over the last decade, the telecom manufacturing sector has not shown corresponding increase. The telecom ecosystem has not been able to adequately spur the manufacturing segment and as a result, the domestic telecom equipment manufacturing segment has not been able to meet the demand forcing the telecom operators to import most of the equipment required for their network.

The Preferential Market Access (PMA)[32] policy of the Indian government had stipulated that the government would have to procure a certain percentage of its requirements from domestic manufacturers based on a timetable. Similarly, domestic manufacturers have to value-add to production otherwise they would be considered imported products.

The Preferential Market Access (PMA) policy is not country specific and preference is for all domestic manufacturers, not only national (i.e. Indian) manufacturers but even foreign

[32] Section 4.1 of National Manufacturing Policy, 2011-

manufacturers as long as they are able to comply with minimum value addition norms. India is not the only country with concerns regarding critical components in electronics and IT products and similar concerns have been voiced in the US. The PMA policies have been developed after extensive year-long stakeholder consultations, which also included US companies.

At present India imports more than $30 billion of electronic goods with very little value addition in the country taking place. Such critical infrastructure cannot be built with continuous reliance on imports. One of the mandates at FICCI and Government of India has been to create more jobs in the manufacturing. **PMA is a legitimate tool for enhancing domestic manufacturing capacity and is well within the purview TRIPS Agreement and Indian Patent Act. It is being used by different countries across the world to promote domestic manufacturing, create jobs, due to security consideration etc.**

Moreover the United States have enacted the CL statute for patents on energy storage, which include local working obligations. The provisions are part of the United States Energy Storage Competitive Act 2007, which have been designed to support the ability of the United States to remain competitive globally in energy storage systems for application in electric drive vehicles, stationary applications etc.

Clean Technology: Under TRIPS, all members of the World Trade Organization (WTO) must provide a minimum level of patent protection, which includes the right to exclude others from making, using, selling, or importing patented inventions for the term of the patent. The intellectual property rights set forth in TRIPS are enforceable through the WTO's highly effective system of dispute resolution. However, those rights are not absolute. While the TRIPS agreement does not use the term "compulsory licensing," Article 31 clearly pertains to compulsory licensing and could be used to argue for such licensing of green technology. Article 31 sets forth a procedural prior negotiation requirement between users and patent owners that must be met before the patents can be used without authorization. However, this requirement may be waived in the case of "national emergency, other circumstances of extreme urgency, and in cases of public non-commercial use." Under such a scenario, a state may allow its citizens to produce the patented invention without giving notice to, or receiving authorization from the owner of the patent. The 2001 Doha Declaration on TRIPS further encouraged states to take advantage of compulsory licensing by stating that "each Member has the right to grant

compulsory licenses and the freedom to determine the grounds upon which compulsory licenses are granted."

Section 4.4 of the National Manufacturing Policy, 2011 talks of Compulsory licensing of **Green Technology** and arrays as follows:

> "*4.4.1 On occasion, a company may be unable to access the latest patented green technology, which can substantially reduce its carbon footprint, because of its inability to obtain a voluntary license from the patent holder. This could arise for two reasons. First, the cost of obtaining such voluntary license could be a barrier for the company. Second, the patent holder could be unwilling to part with the license, or it is not available at reasonable rates or it is not being worked in India.*
>
> *4.4.2 To address the first issue, the Technology Acquisition and Development Fund will also function as an autonomous patent pool and licensing agency. It will purchase Intellectual Property (IP) rights to inventions from patent holders. Any company that wants to use the IP to produce or develop products can seek a license from the pool against the payment of royalties. This company may then produce the product for use in specified geographical areas subject to meeting agreed quality standards. The TADF would reserve the right to license more than one company for a particular patent.*
>
> *4.4.3 To address the second issue, the Fund will have the option to approach the Government for issue of a Compulsory License for the technology which is not being provided by the patent holder at reasonable rates or is not being worked in India to meet the domestic demand in a satisfactory manner. Such compulsory licenses will be issued only within the provisions of TRIPS. Reasonable royalty will be paid to the patent holder."*

It is note-worthy that the above provision is not a legislation and is targeted to facilitate the SME sector of the Industry. Furthermore it is assert able that the **Section 4.4 of the National Manufacturing Policy, 2011 is compliant with Article 31 of the TRIPS,** hence the Indian policy is within the Paradigm of international mandate.

DATA PROTECTION AND TRADE SECRETS- TRIPS doesn't mandate data exclusivity

Data Protection refers to the set of privacy laws, policies and procedures that aim to minimize intrusion into one's privacy caused by the collection, storage and dissemination of personal data. Personal data generally refers to the information or data which relate to a person who can be identified from that information or data whether collected by any Government or any private organization or an agency.

As of now, the **issue of data protection is generally governed by the contractual relationship between the parties**, and the parties are free to enter into contracts to determine their relationship defining the terms personal data, personal sensitive data, data which may not be transferred out of or to India and mode of handling of the same. 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.

The **(Indian) Information Technology Act, 2000** deals with the issues relating to payment of compensation (Civil) and punishment (Criminal) in case of wrongful disclosure and misuse of personal data and violation of contractual terms in respect of personal data.

Under **Section 43A** of the (Indian) Information Technology Act, 2000, a body corporate who is possessing, dealing or handling any sensitive personal data or information, and is negligent in implementing and maintaining reasonable security practices resulting in wrongful loss or wrongful gain to any person, then such body corporate may be held liable to pay damages to the person so affected. It is important to note that there is no upper limit specified for the compensation that can be claimed by the affected party in such circumstances.

Under **Section 72A** of the (Indian) Information Technology Act, 2000, disclosure of information, knowingly and intentionally, without the consent of the person concerned and in breach of the lawful contract has been also made punishable with imprisonment for a term extending to three years and fine extending to INR 5,00,000 (Approx. US$ 10750)

It is to be noted that **Section 69** of the Act, which is an exception to the general rule of maintenance of privacy and secrecy of the information, provides that where the Government is satisfied that it is necessary in the interest of the :

- sovereignty or integrity of India

- defence of India
- security of the State
- friendly relations with foreign States or
- public order or
- for preventing incitement to the commission of any cognizable offence relating to above
- or investigation of any offence,

it may by order, direct any agency of the appropriate Government to intercept, monitor or decrypt or cause to be intercepted or monitored or decrypted any information generated, transmitted, received or stored in any computer resource. This section empowers the Government to intercept, monitor or decrypt any information including information of personal nature in any computer resource.

Where the information is such that it ought to be divulged in public interest, the Government may require disclosure of such information. Information relating to anti -national activities which are against national security, breaches of the law or statutory duty or fraud may come under this category.

At present trade secret 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.

DATA PROTECTION OF CLINICAL TRIALS- Test Data Must Only Be Protected If National Authorities Require Their Submission For Obtaining Marketing Approval Of Pharmaceuticals Or Agrochemical Products.

Article 39.3 of the TRIPS Agreement provides-

"*Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use."*

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**.

India is an active advocate of the policies and strategies of UNFCCC, WTO and WIPO

The allegation levelled tagging India as a" bad actor" in UNFCCC, WTO and WIPO; is incorrect and mischevious. On the contrary, India always tries to engage constructively in these

organizations, exploring solutions to intricate problems and trying to build a consensus. India plays a major positive role in cooperating with these organizations in development of international norms and legal instruments and capacity building. India also is party to many FTAs as well as ongoing discussions on new ones. India has been an active participant in bilateral or multilateral participant in trade and policy negotiations and has acceded to treaties and abided by them too. **The Indian Policy framework has always worked within the paradigm of International mandates.**

List of Reliance's

1.	**Natco Pharma Ltd. V. Bayer Corporation**; Order No. 45/2013 (Intellectual Property Appellate Board, Chennai) available at http://www.ipindia.nic.in/iponew/compulsory_license_12032012.pdf
2.	**Pharma Patents Granted During** 2010-11 To 2013-14 (UP TO 31-7-2013) available at http://www.ipindia.nic.in/patent_Applications_Filed/patentGranted_Pharma_2010-11_Jul2013.pdf
3.	**Novartis A.G. vs. UOI**, (2007)4 MLJ 1153, Date of Judgment: 6th August 2007

ANNEXURE

1.	**ANNEXURE 1**	Report Of The Sub-Committee On Issues Pertaining To Enforcement Of Copyrights In India; October 7, 2013;