Confederation of Indian Industry

Submissions to United States Trade Representative (USTR) by the Confederation of Indian Industry (CII)

Introduction

USTR has been reviewing IPR systems in other countries to examine and analyse them from the points of view of the US companies, think tanks and research groups. Based on the reviews, the US government may be designing country specific trade policies. The Confederation of Indian Industry is thankful to USTR for giving it an opportunity to share its experience and views on the Indian IPR system.

Confederation of Indian Industry

The Confederation of Indian Industry (CII) works to create and sustain an environment conducive to the development of India, partnering industry, Government, and civil society, through advisory and consultative processes. CII is a non-government, not-for-profit, industry-led and industry-managed organization, playing a proactive role in India's development process. Founded in 1895, India's premier business association has around 8000 members, from the private as well as public sectors, including SMEs and MNCs, and an indirect membership of over 200,000 enterprises from around 240 national and regional sectoral industry bodies. CII charts change by working closely with Government on policy issues, interfacing with thought leaders, and enhancing efficiency, competitiveness and business opportunities for industry through a range of specialized services and strategic global linkages. It also provides a platform for consensus-building and networking on key issues. Extending its agenda beyond business, CII assists industry to identify and execute corporate citizenship programmes. Partnerships with civil society organizations carry forward corporate initiatives for integrated and inclusive development across diverse domains including affirmative action, healthcare, education, livelihood, diversity management, skill development, empowerment of women, and water, to name a few. In its 120th year of service to the nation, the CII theme of Build India - Invest in Development: A Shared Responsibility, reiterates Industry's role and responsibility as a partner in national development. The focus is on four key enablers: Facilitating Growth and Competitiveness, Promoting Infrastructure Investments, Developing Human Capital, and Encouraging Social Development. With 66 offices, including 9 Centres of Excellence, in India, and 8 overseas offices in Australia, Bahrain, China, Egypt, France, Singapore, UK, and USA, as well as institutional partnerships with 312 counterpart organizations in 106 countries, CII serves as a reference point for Indian industry and the international business community.

CII represents all types of companies covering practically all areas of technologies. Multinational companies having their registered office in India are also served by CII by advancing their viewpoints to the government. CII has been studying and engaging itself directly in the IPR eco-system in India and elsewhere, critically analyzing global developments, participating in the innovation processes in India along with the government and industries and, undertaking frequent consultations with foreign governments, their agencies, industry associations, academicians, lawyers and law firms.

CII has a unique stature in the country and elsewhere in respect of its efforts in developing and enhancing the IPR eco system in the country. It has been active in awareness creation about various dimensions of IPR with the local resources and with the help of other countries such as USA, European Union and Japan through their official agencies.

CII through its National IPR Committee has addressed many copyright issues. It set up many sector specific working groups to identify issues concerning the Indian industries. The working groups have given their recommendations which have been shared with the Government of India. These recommendations include addressing online piracy, anti-cam cording measures and circumvention of technological protection. It is expected that these issues will be taken care of in the final version of the National IPR Policy.

CII has prepared a study on piracy in the publishing sector in India which was finalized in close consultation with the publishers of all kinds. The level of piracy is noticeable but not alarming. This report has been shared with the Ministry of Human Resource Development and it is hoped that the government would consider the recommendations and take suitable actions.

In regard to India's Copyright legislation, CII is of the opinion that the provisions of the Act are sufficient to take care of infringements and provide adequate protection to creators of copyright work. It is felt that greater emphasis would need to be placed on awareness creation among all the players. For example, theatre owners may be educated on some of the issues especially how advancing technology can help violation of copyrights. The Indian industry also suffers a great deal on this account and the dimension of this malice includes loss in revenue and jobs. Online piracy is an international concern and not limited to India. CII feels that technologies encouraging online piracy are generally developed in advanced countries and their use is encouraged by the industries concerned. The malice is global and can be addresses through international efforts only through multilateral engagements.

CII has frequent meetings and discussions with representatives of foreign governments, trade and business associations, law firms and IPR researchers on common topics of interest including some global issues. These discussions help CII to have a better understanding of other countries in the realm of IPR and create opportunities for sharing various good practices. CII in its various deliberations, seminars and IPR summits have experts from foreign countries sharing their knowledge and experience.

CII introduced a national Industry Intellectual Property Award for companies registered in India to recognize their achievements in the area of IPR through an extensive evaluation process including their IPR portfolios. It is heartening to note that some industries have enhanced their patent portfolio by many times both through domestic and foreign filings, some have added many countries in the portfolios and continued to maintain the granted patents effectively. At the same time, many companies are enhancing their brand value by increasing the trademark portfolio; a better understanding is emerging towards Use of IPR for brand building.

CII has been conducting a series of workshop and training programmes to sensitize officials of police and customs in all enforcement issues in association with many partner agencies. It also organizes seminars and workshop for sharing best practices of industries and governments in handling counterfeiting matters. These have resulted in better understanding

of legal provisions and importance anti-counterfeiting measures in the interest of economy and employment.

Compliance with TRIPS

It has been iterated time and again that India is fully compliant to TRIPS. It is unfortunate that we need to state it again and again. The recent Trade Policy Review of India by WTO did not find anything in India's legal system which could be considered as violation of TRIPS provisions. That is a very positive development in maintaining and strengthening multilateral system. We strongly feel that the multilateral approach adopted in WTO should be encouraged rather than derailing it by pluri-lateral and bilateral mechanisms.

India is concerned about the recent push towards harmonization of patent rules and practices through agreements such as IP 5, ACTA and TPP which tend to go beyond TRIPS and influence the legal system of a nation. One of the points of concern is that such agreements outside the provision of TRIPS may render dispute settlement mechanism under WTO meaningless.

We would like to submit that the criticism against India by companies, government and some research groups is illogical and tend to create a negative environment.

Patentability

The standard for inventiveness has been raised by various countries ever since inventiveness became one of the recognized criteria for determining patentability. The advances made by one invention become part of our shared knowledge which becomes a threshold for determining inventiveness of the next invention. It is befitting for nations to ensure that inventions should satisfy the new threshold set up by each preceding invention or knowledge base to ensure a reasonable balance between social aspirations and monopolistic rights is maintained. If the threshold is not maintained patents will slowly start losing their impact as an important parameter for economic and industrial growth and may not remain an effective vehicle for new inventions.

Section 3(d) of the Patent Act is in consonance with the above principle and thus prohibits patenting of new forms of a known substance such as polymorphs, isomers, esters, particle size etc. if the new form does not yield improved/ higher efficacy than the known substance. It may be noted that TRIPS only states that an invention has to be inventive and it does not lay down any specific criterion for establishing inventiveness. CII feels that India's patent laws are fully TRIPS compatible. In fact it has been observed that India, perhaps the only country, has explicitly defined exclusions based on inventiveness. In many other countries interpretations on inventiveness are provided by courts which often lead to avoidable expenses on litigation. It is also wrong to say that the Indian patent laws do not allow patents

on incremental inventions. The law is uniform in assessing incremental inventions and other inventions in terms of novelty and inventiveness.

There are some studies which have found that polymorphs and isomers of known substances don't necessarily lead to improved therapeutic effects. Patents related to new forms often called secondary patents have been found to be tactics adopted by drug companies to extend life of the primary drug. The resulting drugs from such secondary patents are also called follow on drugs. The above inferences are based on the following research publications:

a) Nathalic Vernaz et al., Patented drug extension strategies on healthcare spending: A cost evaluation analysis; PLOS Medicine, June 2013, Vol. 10, Issue 6
b) Somogyi A, Bochner F, Foster D (2004); Inside the issues of chiral switches, Australian Prescriber, 27,47-49
c) Hughes DA, Ferner RE (2010): New drugs for old:BMJ, 340, c572
d) Hitchings AW, Baker EH, Khong TK (2012) Making medicines evergreen, BMJ 345, e7941
e) Amin T, Kesselheim AS (2012) Secondary patenting of branded pharmaceuticals: A case study of how patents on two HIV drugs could be extended for decades, Health Aff. (Millwood) 31,2286-2294
f) Landefeld CS, Steinman MA(2009): The Neurontin legacy-marketing through misinformation and manipulation, N England J Med, 360, 103-106
g) Ame Kapczynski et al.; Polymorphs and prodrug and salts: An empirical analysis of secondary patents, PLOS ONE December 2012, Vol. 7, Issue 12.

The Swiss study as listed at a) above is based on hospital data over a nine year period from 2000 to 2008. The study observes that drug manufacturers have developed strategies to compete with generic medicines after patent termination through introduction of follow on drugs. It concludes that the follow on drugs have been successful in offsetting the competition from generic drugs and hospitals have added to the healthcare cost by prescribing follow on drugs. While the world is looking for cheaper drugs, the secondary patents on existing drugs act as a barrier for wider utilization of generic drugs which were initially allowed exemption from full scale safety studies to keep the prices low.

Therefore, it can be seen that the Indian position on inventiveness of polymorphs, isomers etc. would lead to cheaper health care by only allowing patents on new drugs which satisfy the inventiveness criterion and encouraging the use of generic drugs. Taking a clue from India, several countries are contemplating introducing similar provisions in their laws.

Recently the Max Planck Institute for Innovation and Competition, Germany has issued a declaration on Patent Protection: Regulatory Sovereignty under TRIPS prepared in consultation with scholars from 25 countries. The declaration was issued on April 15, 2014. It says that States have latitude to define what constitutes patentable inventions to determine how the patentability requirements are interpreted and applied. In particular Article 27 of the TRIPS Agreement does not prevent states from denying patent protection for new uses of known products and substances, derivatives of known products and substances and selection inventions otherwise lacking novelty and/ or inventive step.

The Federal Circuit of US Appeal Court quite recently, invalidated reissue patent on "Celebrex", a medicine for arthritis and declared it a case of **obvious-type double patenting.**

We would like to draw attention of USTR to the KSR v Teleflex case in which the Supreme Court of USA raised the standard of patentability (specifically inventiveness). It was surprising to learn that the teaching on the inventiveness had to come from the Supreme Court. It is thus obvious that at least the concerned industries did not quite understand and apply the criterion of inventiveness. A comparison of this case with the cases decided under Section 3(d) shows that the Indian Patent Act provides more clarity on the inventiveness to the patent applicants and can lead to overall economy of the patent system.

Thus, the Indian position is endorsed by intellectuals, researchers and some nations. CII feels that Section 3(d) of the Indian Patent Act is in total consonance with TRIPS. On the contrary, countries not following similar provisions should fall in the category of TRIPS minus.

We take serious objection to the conclusions drawn by some agencies declaring the Indian patentability criterion inferior to those of many other countries.

Membership to international treaties

It has been held that India is not member of many international treaties and hence its IPR system is not strong and supportive of international trade. India has recently become a member of Madrid Protocol. India thus is a member of member of all important treaties such as TRIPS, Paris Convention, Berne Convention, PCT and Budapest Treaty. India honours and practises the philosophy of National Treatment and provides a level playing field to all nationalities for obtaining IP rights in India.

Impact of India implementing Madrid Protocol

Until December 31st, 2015 The WIPO has notified to Indian Office 20094 international registrations seeking protection of trademarks in India. Out of that 7820 such international registrations were notified only during the period from April 1st to December 31st 2015. The Government of India has received appreciable amount of foreign currency as fee for international registrations designating India.
India has been recognised by international entrepreneurs not only an important market but also an investment destination. This is evident from the increasing number of international registrations of the trademarks wherein protection of the mark is sought in India.

After accession to the Madrid Protocol, the Indian Intellectual Property law and system, particularly relating to registration and protection of trademarks in India, have become more widely known to the foreign entrepreneurs/traders and IP experts.

Compulsory licensing

India came into focus because it granted one compulsory license (CL) a few years back for the first time since its independence. We maintain that the provision of CL in the Indian laws is TRIPS compatible and CL is granted after a good amount of due diligence. It is wrong to assume that all requests for CL end up in grant of CL.

On 19th January 2016, the Controller General rejected the Compulsory Licence Application filed by Lee Pharma for Patent No 206543 granted on 30th April 2007 to Bristol Myers Squibb which was later assigned to Astra Zeneca. LeePharma claimed that the Patent for Saxagliptin a drug prescribed for Type II Diabetes Mellitus is not available to public at reasonable prices and has not been worked in India. The Application was rejected on the grounds that the Applicant had failed to provide prima facie evidence that the drug was too expensive or that there was shortage of drug due to importation only. Similarly, a request by BDR Pharmaceutical was also rejected.

We would like draw attention to the study of the Max Planck Institute mentioned above which also studied the issue of CL. It concluded that Article 31 of the TRIPS Agreement does not limit the grounds on which CL can be granted. The non-discrimination principle in Article 27 of the TRIPS Agreement does not apply to CL otherwise permissible under Article 31.

Licensing of standards essential patents

A leading development in the Indian IPR eco-system took place recently when an Indian high court handled a few standard essential patent infringement cases in respect of smart phones. The court while the final arguments are awaited, gave interim relief to the patent holder in terms royalties on the concerned patents on a basis similar to what is being followed in developed countries. This certainly opens up a new culture in the country. CII is promoting discussions on the issue in many different forums.

Trade secrets

Many developed countries have expressed that India should have a separate and an independent law on trade secret. CII had a meeting with a USTR representative in a round table on this issue. Based on the discussions, CII has undertaken a study of trade secrets in India which should be ready in few weeks. The study is based on a survey of many companies including large, medium and small. CII also conducted a half a day seminar in December 2015 on the subject which had speakers from CII, law firms, business associations, Indian industry and USPTO. It was observed that many participants had little understanding of trade secret as an important form of IPR.

It would be pertinent to mention at this point that India's IPR regime is completely TRIPS compliant which includes protection of undisclosed information which in turn embodies trade secrets. We have many different laws which can be deployed to protect trade secrets and know how. India would like to look at the larger picture which has under its ambit not only trade secrets but also confidential information in research programmes including collaborative research programmes with other countries. The general argument that there is a multiplicity of laws in India to take care of protection of trade secret is not considered very sound as there are many examples of multiple laws utilized for protecting geographical indications. We do feel that USTR should look at convenience of protecting GI in different countries. India would like to evaluate various alternatives available presently in this regard and would come to a final position after extensive consultations among various stakeholders including the political leaderships.

Some recent court decisions

Indian courts have been handling IPR cases effectively, competently and timely which is a very good omen for the IP driven industries in India. It is also a signal to ever improving enforcement system being developed. CII is confident this development would pave a way for ease of doing business in the country. Some examples of recent court judgments are given below:

Merck Sharp Dohme vs. Glenmark Pharmaceuticals Ltd for Merck's Patent No 209816 for Sitagliptin

Delhi High Court held that Glenmark's Sitagliptin phosphate monohydrate infringed Merck's patent for the anti diabetic drug Sitagliptin. To arrive at its opinion, the Hon'ble High Court relied on the facts that the free base Sitagliptin was the active biological ingredient having therapeutic efficacy as DPP-IV inhibitor and, that the monohydrate phosphate salt of Sitagliptin only had improved chemical and physical properties for delivering Sitagliptin to the body, wherein its therapeutic efficacy was due to the free base Sitagliptin whereas phosphate had no role to play in the therapeutic efficacy. The Hon'ble court held that use of Sitagliptin free base by Glenmark in its product Sitagliptin Phosphate Monohydrate amounts to infringement of Merck's patent IN'816.

Ericsson vs. Xiaomi over Ericsson's 8 Standard Essential Patents:

In December 2014, Ericsson had filed a suit against Xiaomi in India for the alleged infringement of the 8 *standard-essential patents*. The Delhi High Court granted an ex-parte injunction on the sale, manufacture, advertisement, and import of Xiaomi's devices.

Xiaomi challenged the injunction before a Division Bench of the Delhi High Court, on the grounds that the handsets sold in India i.e. Mi3, Redmi1S and Redmi Note 4G, contained Qualcomm chipsets which was licenced by Ericsson. The Division Bench issued temporary orders to allow Xiaomi to resume the sale, import, manufacture, and advertisement of its mobile devices subject to the following conditions namely, Xiaomi would only sell devices having Qualcomm chips and that Xiaomi would deposit Rs. 100 towards royalty for every device it imported to India from the date of the launch of the device in India toJanuary 5, 2015. This amount was to be kept in a fixed deposit for three months during the proceeding of the case.

The HC has also asked Xiaomi to maintain a proper inventory of unsold phones in India.

Novartis vs. Cipla for Novartis' patents on ONBREZ

In January 2015, the Delhi High court injuncted Cipla from making or selling generic copy of Novartis's "Onbrez" used for treatment of COPD. Cipla had launched its generic version Indacarterol in October 2014. The court observed that Cipla did not provide any figures about the "inadequacy or shortfall in the supply of the drug."

In an unprecedented move, Cipla had approached the Department of Industrial Policy and Promotion (DIPP) to exercise its statutory powers under Section 66 and Section 92(3) to revoke Novartis' Indian Patents IN222346, IN230049, IN210047, IN230312 and IN214320 on the grounds that the disease is "epidemic" creating "public health crisis", high cost of drug and failure to manufacture the same in India by the Patentee.

In December 2014, the Ministry of Health issued a statement that Cipla's petition dies not make a prima facie case for the revocation of Novartis' patents. Novartis then sued Cipla. Presently injuncted, Cipla offered to pay royalty to Novartis which Novartis has rejected. Matter is pending final adjudication.

SYMED Labs vs. Glenmark Pharmaceuticals

Symed Labs Ltd. sued Glenmark Pharmaceuticals Laboratories before the Delhi High Court for allegedly infringing two of its process patents: IN213062 & 213063. On 9th Jan 2015, the Court granted an *ad interim* injunction restraining Glenmark from manufacturing, selling, offering for sale, advertising or directly or indirectly dealing in the production of Linezolid manufactured in a manner so as to result in infringement of Symed's Patents. Glenmark appealed the injunction before the Division Bench of the Delhi High Court which held that the Glenmark process does not infirnge the Symed Patents and accordingly vacated the injunction (vide Order of July 2015).

Maj. (Retd.) Sukesh Behl & Anr. vs Koninklijke Phillips

Sukesh Behl made a counter claim for revocation of the suit Patent No. 218255 under Section 64(1)(m) of the Patents Act, 1970 for non-compliance of the provisions of Section 8 in a suit where Koninklijke Phillips sought for permanent injunction restraining Sukesh Behl from infringing its patent and for other incidental reliefs. Section 8 requires details of cooresponding foreign applications to be provided to the patent office during prosecution. Citing *Chemtura* case, the judge held that the power to revoke a patent under Section 64(1) is discretionary and consequently it is necessary for the Court to consider the question as to whether the omission on the part of the plaintiff was intentional or whether it was a mere clerical and bonafide error. Court dismissed Sukesh Behl counter-claim for revocation of said patent under section 64(1)(m).

Roche v. Cipla on Roche's Patent No 196774 fro TARCEVA

On 27th November 2015, the Division Bench of Delhi High Court held that the Erlocip of Cipla infringed the Roche's Patent No 196774 for erlotinib hydrochloride granted on February 23, 2007. The Division Bench also imposed cost of of INR 5 lakh on Cipla. It held that the single judge "erroneously compared the products of Roche and Cipla when he ought to have mapped the claims of the suit patent against Cipla's product".

On 29th January 2016, the Supreme Court admitted two Special Leave Petitions [SLP (C) No. 1677-78 of 2016] by Cipla against the Delhi High Court's ruling.

Incentives to SME and Start ups

The Government of India has reduced the patent filing fees for SME by half to promote innovations by SME. It has also provided special incentive for start- ups, by adopting a definition of start- ups, in respect of patent filing. Going by the principle of National Treatment, the reduced fees structure will be applicable to SME and start-ups from other countries if they satisfy the criteria stipulated in the Patent Rules. It is also hoped that these initiatives would also encourage international collaborative research and development.

Setting up of Commercial Courts

Govt. of India has enacted "The Commercial Courts, Commercial Division and Commercial Appellate Division of High Courts Act, 2015" to speed up "commercial disputes" including the disputes related to intellectual property rights. These commercial courts are expected to provide the necessary impetus to IPR enforcement in India.

National IPR Policy

Govt. of India has drafted the National IPR policy with an objective to strengthen IP laws, administration, enforcement and adjudication. The policy intends to:

a. create public awareness on benefits of IPR,

b. encourage IP generation,

c. have strong and effective laws with regard to IP rights that are consistent with national priorities and international obligations and which balance the interests of rights owners with public interest,

d. modernize and strengthen IP administration for efficient, expeditious and cost effective grant and management of IP rights and user oriented services,

e. strengthen the enforcement and adjudicatory mechanisms for combating IP violations, piracy and counterfeiting; to facilitate effective and speedy adjudication of IP disputes; to promote awareness and respect for IP rights among all sections of society.

f. strengthen and expand human resources, institutions and capacities for teaching, training, research and skill building in IP.

An IPR think-tank was formed that went into designing and formulating India's IPR policy. In this connection all stakeholders including domestic and foreign companies, industry associations, NGOs and R&D institutions were consulted and each stakeholder was given a chance to present its viewpoint to the think-tank. The final policy would be in public domain after clearance by the Union Cabinet.

Patents grant to inventions based on bio-resources

There has been a concern about grant of patents to inventions based on bio-resources from India. It may be appreciated that India has been very serious about preserving its bio-diversity and traditional knowledge. In this connection India's successful efforts in

contesting patents based on its bio- both at pre or post grant stages resources are well known. This philosophy is reflected in the Indian Patent Act and the National Biodiversity Act.

Section 6(1) of Biodiversity Act 2002 provides that prior approval of NBA is necessary before applying for any kind of IPRs in India and outside based on any research or information on a biological resource obtained from India. However, in case of patents, permission of the NBA may be obtained after application is made but before grant of the patent.

According to this provision, the Patents Act stipulates that, if the invention as disclosed in the specification uses the biological material from India, the applicant shall submit to the Patent Office necessary permission from the National Biodiversity Authority before grant of patent.

Requirement of such permission in the relevant cases is raised in the First Examination Report and maintained as objection till such permission is submitted by the applicant. Pending submission of NBA permission, a patent cannot be granted even if there are no other objections to the grant of patent by Patent Office.

It is observed that, foreign applicants can easily escape the condition of submission of NBA permission by replying to the Patent Office against such objection in FER that the invention as disclosed in the specification does not use the biological material from India; consequent to which the objection is waived.

Thus, it may be noted that only Indian applicants affected due to the delay occurring for grant of patents due to delay in submitting NBA permission. As per the Patent Office there are about 80 applications pending for want of clearance from the NBA. All the applicants in these cases are of Indian origin.

Appointment of new patent examiners

459 new patent examiners have been selected and they will soon be joining the Patent Office after undergoing and completing their training. In addition, 263 posts of Contract Examiners have also been approved and they would soon be helping the Patent Office. Once we have adequate number of examiners, the backlog in examining patents will be eliminated and the time for grant of patents would be drastically reduced.

Guidelines for patent examiners

The Patent Office has brought out guidelines for examining patent applications on varied subject areas. The guidelines on computer related inventions will soon be released. It may be stated that these guidelines have been finalized in consultation with many stakeholders.

Some experiences of Indian industry

Even though all activities in relation to agreements need to be performed by the Indian Company / Agency in India, US based companies often insist that for the purpose of adjudication, US laws will apply and sometimes even laws of a particular state (e.g.

California, Denver etc.). Most of the Indian companies are unaware of the intricacies of US National or State laws. This can create immense difference for Indian Companies / Agencies in the event of a dispute.

In case of US companies where transfer of technology takes place from a US company to an Indian company, US entities insist on tie-in clauses and also insist that all improvement or additions to the core technology and all IPR relating thereof will be a property of the US entity. Indian companies and entities on the other hand, often need to improve the technology received from the US in the process of indigenization. This may often generate an IP of its own, in which case the Indian entity loses out on the ownership and development of such IP rights. This appears to be against the principle of contractual licensing of IPR enumerated in TRIPS.

The concept of trans-border reputation in trademarks registered in India is not appreciated in USA. It may be noted that Indian courts now recognize the trans-border reputation of foreign companies, including the US companies, even if the international trademarks are not used in India. For the purpose of registration they insist that it must be used in commerce in the US and unless the mark is used in commerce in the US, it will not be registered. Although India recognizes all trans-border reputation of American Trademark, US does not recognize the reputation of Indian Trademark.
A similar situation exists in respect of Domain Name disputes. It is reported that a significant number of squatters of Indian brands are based in the US.