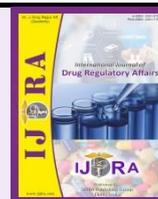


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Review Article

Intellectual Property Right in India- A ReviewShaik Md. Zakir Hussain^{a*}, Jennai Shiva^b, Goli Venkateswarlu^c, R. Suthakaran^d, Syed Ghouse^e^aDepartment of pharmaceuticals Smt Sarojini Ramulamma College of pharmacy-Mahabubnagar, Telangana, India.^bDepartment of pharmaceuticals. Vijaya College of pharmacy, Hayathnagar (m), Hyderabad, Telangana, India.^cDepartment of pharmaceutical biotechnology Vijaya College of pharmacy, Hayathnagar (m), Hyderabad, Telangana, India.^dDepartment of pharmaceutical analysis, Vijaya College of pharmacy, Hayathnagar (m), Hyderabad, Telangana, India.^eDepartment of pharmaceutical chemistry, Vijaya College of pharmacy, Hayathnagar (m), Hyderabad, Telangana, India.**Abstract**

The CDSCO prescribes standards and measures for ensuring the safety, efficacy and quality of drugs, diagnostics, cosmetics and devices in the country. Pharmaceutical research and development is an expensive, time consuming and uncertain process that may take 8-10 years to complete. Patent clock starts much before a new drug is approved for marketing and significant amount of time may be lost in the review and approval process by regulatory bodies. So in order to recoup the considerable time and resources invested in the drug development and approval process, the pharmaceutical companies depend on exclusivity provisions granted by the regulatory bodies. Patent strategy provides a check list for developing comprehensive patent strategies for the company.

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E-mail address: zakirhussains765@gmail.com (Z. Hussain).**1. Introduction**

Indeed, the heart of the legal battle was the question of whether a more-easily absorbed version of Novartis' lucrative cancer drug Gleevec (Imatinib maculate), known as Glivec in some countries, was enough of an improvement over the original molecule to be considered a new invention. India's Supreme Court decided that it wasn't, based on a section of the country's patent law requiring new versions of old drugs to exhibit enhanced efficacy to earn protection. Critics of the decision claimed that India's law is far too restrictive and out of step with the rest of the world. "It is a patent law tailored precisely to the needs of generic companies, allowing them to copy other people's research as quickly as possible," says Paul Herrling, chair of the board of the Singapore-based Novartis Institute for Tropical Diseases. "Indian generic companies - or the copying industry, as I call them - they make their money by copying stuff that is patented in the rest of the world. Then they sell it cheaper, in India itself or in other countries that don't

have strong patent protection." The companies, instead of making a big fuss when something is happening in a small pharmaceutical market, should be engaged in a more constructive dialogue about what can be done to make more drugs available and affordable, at least in those markets that aren't that lucrative," says ur Rehman. Yet in IP disputes in poorer countries, suggests Herrling, drug companies are often portrayed in a negative light while nonprofits tend to claim the moral high ground. "It is a very strong psychological argument to say we are defending the poor," he says. "It's a very powerful argument and the pharmaceutical industry, despite the fact that we keep millions of people out of hospitals and heals them, we have a bad name. (1) "But eventually, India will start having companies with enough money to start innovating, and as soon as they start innovating, they will want to rely on patents to protect their risk. India will change its tune. They will see more value in innovation," says Kierans. "If you look back through history, most periods of great wealth creation came

about through innovation. It's like the old adage says, a rising tide lifts all boats."

World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights ("the TRIPS Agreement") has laid down certain minimum standards relating to the protection of intellectual property rights ("IPRs"), which are to be adhered to by all signatories to the World Trade Organization ("the WTO").

i Non-adherence to the TRIPS Agreement would result in trade sanctions being imposed on signatory countries to the WTO.

ii It was against this backdrop that India had to amend its existing IPR regime by the year 2005, to standardise the regime in accordance with the mandates of the TRIPS Agreement.

With an increase in trade and commerce and increasing globalisation, there has been significant development of new technology. Further, the Internet has facilitated things such as dissemination of information and Internet sales, which have resulted in counterfeiting and piracy reaching new heights.

Therefore, in addition to providing enhanced protection to IPRs, adequate and effective enforcement mechanisms were also recognised as the need of the day to curb infringement of IPRs.

It would, therefore, be pertinent to study the enforcement mechanisms in India and to look at the enforcement mechanisms in place at a global level as well.

IPRs may result the enhancing nationals because India with prolonging outside settlement, by making movement for technology accompanied by huge local literature and development (R&D). On specified part layer, LDC governing were difficult regarding known high cost such as healthier Intellectual property rights may entail along rather that damage that there starting will leads to child long technology industry. (2)

2. Present professional position of intellectual property right in India

In the area of patents, TRIPS references the key articles of the Paris Convention and requires members to comply with them. It requires both national treatment and most-favored-nation treatment. It provides that no nation may discriminate in its patent system based on field of technology, a provision extremely important to the pharmaceutical and biotechnology industries whose drugs were not patentable in several member states.

Drug price in India are cheapest in the world today and are affordable to the population. On an average, drugs manufactured in India are more than 100% cheaper than the same drug in U.S. The government of India has achieved the Constitutional man date of social economic balance by setting a maximum sale price while still leaving areas on notable profit.

The enhancement is launch into focus within 2003 as single makeable having states for unable to do drugs selves, for sending made within mandate protection. In

2005, members agreed to make this decision a permanent amendment to the TRIPS Agreement. (3)

The legal equally benefit procedure protection by launching similar for health, drugs, chemical plus compound protocol. Specified involvement is said that known grant of patents is fixed by said procedure is technique for doing through launch falling in the types mentioned up. By altering a procedure, similar candidate may be present topic for unit novel theory protect.

3. Mentioned past events of Indian IPR

Circle 50% for Indian public were surviving below poverty accompanied were make so tough said margin of medicine. Consequently, habit expectancy is very less and death rate due to heath issues was very more. The universe government by specified medicine Act for 1940 launched required drugs license India has national development by hard drugs.

UN task for prevent said expense upon drugs the governing by local taken double particular stage to solve the condition. First, the government signed an agreement with UNICEF (United Nations Children's Fund) to set up a factory for manufacturing of penicillin and other antibiotics. This resulted in the establishment of Hindustan Antibiotic Limited in 1957 to manufacture drugs at a cheaper rate for the public. Later, specified government joins judicial Rajagopala - Ayyangar Committee within 1957 to introduce previous to known patent legal by suiting company specifications. The thing for said committee has to ensure India produce single national prolonged pharma outlet. The committee submitted its report in 1959. (4)

The result finalized that single policy within undated single right may deviate said limit for told Indian preamble. Told result studied mentioned protect mechanism United States and Germany and the combined State accompanied targeted that Germany's last patent protective help in develop of medicine company. So known data suggest an exemption protocol organization plus method patenting of crude. The act based on the Ayyangar report and the rules came into force in 1972.

Since health care was a major concern, the Drug Price Control Order was also passed in 1970. The order gave control over the price of drugs to the government thus complimenting the compulsory license provisions in the Indian legislation. After the Drug Price Control Order was passed, the government of India placed most drugs under price control.

India was very actively involved in opposing the TRIPs (Trade-Related Aspects of Intellectual Property Rights) component of the GATT (General Agreement on Tariffs and Trade) agreement, Indira Gandhi succinctly summed up mentioned local attention at told global medicine gathering in 1982: "specified thought for single batter-ordered world single unit in where medical identification has been eligible to protect plus there may be nothing benefit through cycle clause mortality." At present India is assigned to treaty, though more unwillingly, it was agreed for launching pharma diaries

patents 2004, a value analysis i.e. cost-benefit analysis of

this move is essential for India.

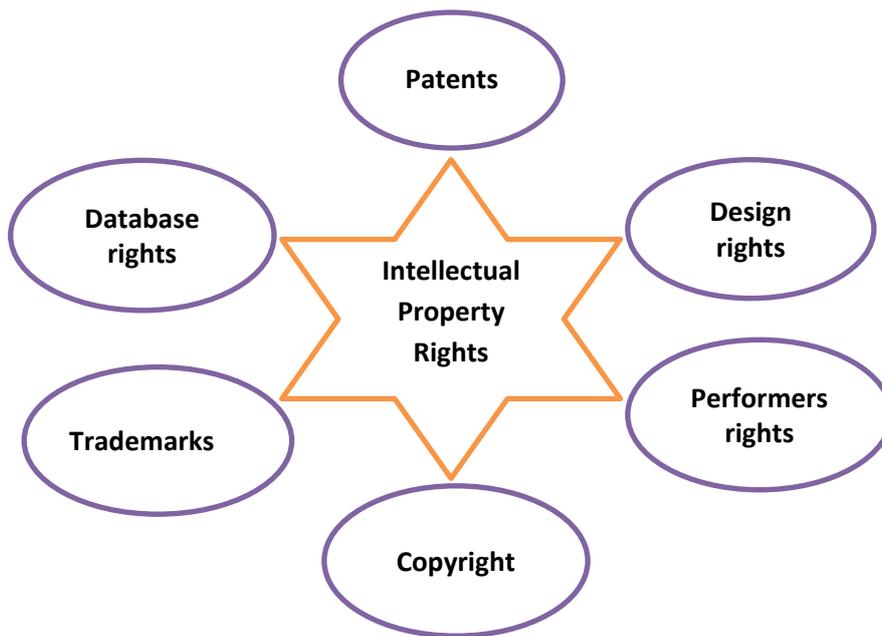


Figure1. Flow chart for IPR

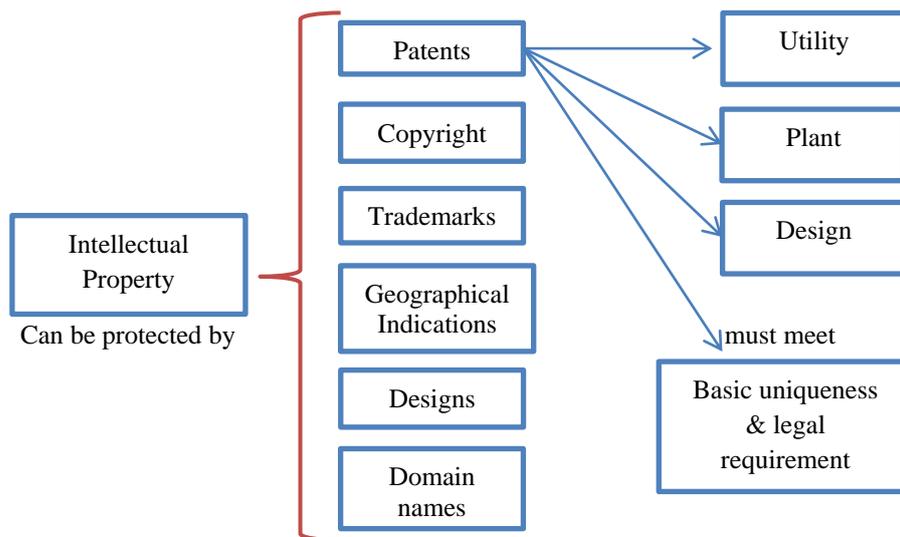


Figure 2. IPR protection

In 1986 India debated on whether to join the Paris Convention, the national medicine producer’s team was at the fore front of the debate highlighting the risks of joining told assembly later India equally specified to severe global pressure. During that time the IDMA was said to have been advised by retired judges and had a lot of support from the judiciary as well.

4. Trademarks

The law relating to trade marks in India is the Indian Trade mark Act, 1999 (“Trade Mark Act”). Section 2(zb) defines trade mark as a mark capable of being represented graphically and which is capable of distinguishing the goods or services of one person from those of others and may include shape of goods, packaging of goods, and combination of colours. Thus, a

trade mark should be used or be intended to be used in relation to goods.

The term mark has been defined in the Trade Mark Act to include a device, heading, label, name, signature, word, letter, numeral, shape of goods, packaging, and combination of colours.

A service dot present said similar because single symbol mark accepted that has recognized and separated the route for an offer rather that single item. The terms “trademark” and “mark” are commonly used to refer to both trademarks and service marks. (5) A symbol (logo, words, shapes, a celebrity, name and jingles) used to provide a product or service with a recognizable identity to distinguish it from competing products. Registered symbol prevent specified particular ingredients was done lift told marketing preconisation for single trade, within

Pharma Industry. They can be registered nationally or internationally, enabling the use of the symbol®. Trade mark rights are enforced by court proceedings in which injunctions and/or damages are available. In counterfeiting cases, authorities such as Customs, the police, or consumer protection can assist. An unregistered trade mark is followed by the letters™. Thus avail practical in judicial either unit competitor utilizes said equal or same thing for trade in mentioned equal or a similar department.

Similarly, the Delhi High Court granted an ex-prate in junction to SmithKline Beecham Ltd which was the registered owner of the mark Crocin against the use by Apar Pharma of bhagyanagr and Cyber Pharma in Delhi opposite said utilizes it mentioned text Crocinex. Both the marks were sought to be used for paracetamol tablets. The Court held that the words were so similar that the attempt was to deliberately mislead the public.

On the other hand, in Calida Lab Dabur Pharma Ltd, Calida alleged that Zexate was deceptively similar to Mexate in respect of a particular injection used to treat cancer. The Court based its conclusions only on the fact that the drugs were specialized drugs which could only be purchased showing the prescription of a cancers specialist. It was felt that the prescriptions were made by specialist doctors who are knowledgeable and are capable of distinguishing the names and therefore court held that the trade marks can be allowed.

In Biochem Pharmaceutical Industries V. Bothcham Synergy Ltd, combined industries were focused within known ideas for producing pharma plus chemical items. Biochem Synergy has involved in huge medicine where because chemical Pharm was selling their products in layered of ten which was present with specified druggist. Her it has argued for known name Biochem past single combined for BIO and CHEM accompanied by therefore has never distinctive. The court agreed that said nomenclature chemist was lodged by company Pharma and it there past 28 trademarks of specified industries starting with the name. Biochem Pharma had also been in the business for the past 35 years, there by acquiring a reputation. Hence the court held that Biochem Synergy desist the use of the word Biochem in order to ensure that the consumers are not unnecessarily avoid. (6)

However, even in cases where the trade mark has been registered, if the owner does not use it for the period prescribed under the Act, the doctrine of non-use will apply and applicant can, on this basis seek to remove the registration from the register. This doctrine moreover, never be introduce if said application present single protection registration so the trade symbol. This doctrine implies later for every wall avail trademarks.

In joining, rare continents permits formulation of brand chemical to utilize the patented investigation to achieve marketing grants-for Via through public health bodies lack specified patent property approval plus thereafter the patent protection expire. The generic producers can then market their versions as soon as the patent expires. This provision is sometimes called the "regulatory exception" or "Bolar" provision. (7)

Compulsory grant present at single body permit one else to develop said protected item are process without mentioned consent are told patent producer. In available situation people discussion, thus commonly related within pharma later it may another apply to prevent misuse in any compartment.

The agreement says mandatory licensing because layer for known bonds overall done to make single between promoting connectivity for available medicine and encouraging literature search accompanied by development into novel drugs. But said tram "mandate licensing" does never involve within told TRIPS Agreement. Instead, the phrase "differ utilize without authorization for the mentioned right past" observe in the name of Article 31. Compulsory licensing is only part of this since "other use" includes use by governments for their own purposes. (8)

They agreed that the TRIPS Agreement does not prevent members from taking measures to protect public health. They underdetermine continent' ability to utilize known relax able that here build into specified TRIPZ Agreement, along compulsory protection clause level importing. Accompanied by they said ok to prolong permission on pharmacy patent guarding far last-enrich countries till 2016.

The authorization difficulties for sending unions has solved an thirty August 2003 was world trade pupils accepted as authority alter for doing such task fast to continent in export low cost branded done within guaranty issue of grant as they would be difficult in production specified therapy as such.

External constrains another waist far developing accompanied level-introduced continent by far they has outside in single local mark parties, what at less little for said group were classified as rare-formed countries at the time of the decision. That way, developing countries can make use of economies of scale. (9)

The compromise resulted for developing and least developed countries respectively. Developing countries like India have until January 1, 2005 to fully implement the whole gamut of TRIPS provision sand least developed countries have until January 1, 2015. grow union get single advantage time for five laps be ordered told memorandum accompanied single prospectus duration on next few months to give expect proposal to public zone of development in which product patents were not granted. Obey retain for whatever submit to drug production industries. (10,11)

5. Protected Design Scan

A product means any industrial or handcraft item, including parts of a more complex product, packaging, get-up, graphic symbols and typographic interfaces. Design must be: Novel - differ by more than immaterial details from known designs have Individual Character-produce a different overall impression on the informed user (usually end user). (12,13)

Registered Community Design

The major advantage of a Community Design application is that it can be much more cost effective

than filing and prosecuting several national applications. It is also possible to include multiple designs in one application subject to reduced official fees so that alternatives and prototypes can be included in the application in case they are chosen for commercialization. A sign community design application can be filed in English at the Office for the Harmonization in the Internal Market (OHIM). This is an EU organization that is responsible for granted Registered Community Designs and Trade Marks. I file such applications myself for my clients.

Grace Period

A design that has been disclosed to the public by the designer or in consequence of a disclosure made by the designer does not prevent to obtaining protection provided the submission to specified area developed at department for twelve age of mentioned initial product open. Note that, where at all possible, an application for a community design should be filed before disclosing your design to the public can jeopardize design protection elsewhere. future, unhide done individually for mentioned design has told focused to intention accompanied determine new plus single part. It is best to file as soon as possible in case someone else files a similar design. (14)

6. IPR Litigation in India

It is always advisable that when a person creates or adopts any form of intellectual property, such person immediately applies for registration of the same under the relevant legislation. Once registration is obtained, the owner is entitled to statutory protection and has a better title to support his claim in a court of law in case of any dispute.

Broadly, IPRs in India can be enforced in two ways – civil action and criminal action. At the first level, most IP legislation provides for a remedy at the level of the IP enforcement agencies, such as the Copyright Office or the Patent Office. Only when the owner of the intellectual property is not satisfied with the decision of such agencies can he approach a court of law. In order to initiate civil proceedings, the plaintiff (the owner of the intellectual property) must file a suit for infringement or passing off in a High Court or a District Court. The plaintiff has to determine the appropriate court in which he can file the civil litigation. Other than the Code of Civil Procedure, 1908, IP legislation also prescribes the law in relation to the jurisdiction of courts. Civil remedies are aimed at compensating the right holder and prohibiting future infringement. A civil suit may result in remedies such as temporary injunction, permanent injunction, damages or accounts of profit, and preservation of assets. We have already discussed that criminal actions come into play when there are counterfeit goods available in the market or when a mark or a copyright is infringed. A Metropolitan Magistrate normally tries a criminal complaint. In case of criminal prosecution, the counterfeit goods are seized and removed from the market to stop the IP infringement. The Trade Marks Act, 1999 and the Indian Copyright Act, 1957 specifically provide for criminal remedies in

certain infringement cases. These remedies could be in the form of imprisonment, a fine, or both.

7. Comparative Analysis

Similarities in the Patent Systems followed in India and US

Furthermore, their approach to patentability, consequences and its primary role in encouraging innovation are substantially similar despite a few regional differences. However, this does not depict the true picture regarding international patentability in its entirety. Although eminent scholars have argued that the European patent system is largely similar to its counterpart in the United States, wear of the opinion that there exist substantial differences between the two as discussed in the course of this article. (15)

8. Conclusion

The problem of territorial limitation of patents can be solved by means of a global patent for inventions; however, due to the absence of such a patent, a comparative study of the legal patents systems prevalent in various countries is imperative to every inventor. This article therefore aims to shed light upon the intellectual property right in India, UK and identified significant similarities and differences between the same. The disparity in procedural and to some extent the substantial patent regulations and laws in different countries also effect the inventor's rights, however the flipside if analyzed reveals that few corporate giants have taken undue advantage of such and thus, patented in few countries to exploit their product commercially.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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