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INTELLECTUAL PROPERTY AND TECH. LAW UPDATES

S&A IP-Tech

JULY 2017

Contents

Revision of Patents CRI Guidelines

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Introduction

The Office of the Controller General of Patents, Designs and Trademarks (CGPDTM) issued new Guidelines on Examination of Computer Related Inventions (CRIs) on 30th June, 2017 replacing the earlier published Guidelines in February 2016. The spotlight of the said Guidelines is the removal of the requirement that computer related invention can only be considered for patentability if the same is claimed in conjunction with a novel hardware. Further, the three step test for patentability determination notified in 2016 Guidelines for CRIs was deleted from these new Guidelines. The changes notified by the IPO on examining the CRIs prescribe that it is important to focus on the underlying substance of the invention and not the particular form in which it is claimed. The following article discusses the new changes incorporated into the revised guidelines in details as well as its impact on innovation in the information technology sector.

Basic Concepts and Relevance of CRIs[1]

CRIs involve the use of a computer, computer network or other programmable apparatus, where one or more features are realized wholly or partly by means of a computer program. The provisions relating to CRIs under Section 3 are as follows:

Section	***Description***
3(k)	A mathematical or business method or a computer program *per se* or algorithms;
3(l)	A literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television productions
3(m)	A mere scheme or rule or method of performing mental act or method of playing game
3(n)	A presentation of information

The '*per se*' term of section 3(k) has been subject to various interpretations in the Courts so as to decide the granting of patents for inventions involving or related to computer programs. The main objective of publication of the said Guidelines for the examination of CRIs is to ensure uniformity and consistency in the examination of such applications. Also, the IPO provides a disclaimer that in case of any conflict between these guidelines and the provisions of the Patents Act or the Rules made there under, the said provisions of the Act and Rules will prevail over these guidelines. Further, these guidelines are subjected to revision from time to time based on the interpretations by Courts of law, statutory amendments and inputs from the stakeholders.

History Timeline of CRIs

Year	Highlights
2013	• Defined two terms- technical effect and technical advancement for testing the patentability of the invention • Examples of technical effect- higher speed, reduced hard-disk time, more economical use of memory, more efficient data base search strategy, more effective data compression techniques, improved user interface, better control of robotic arm, improved reception / transmission of radio signal. • Technical advancement comes with technical effect, but it is to be noted that all technical effects may or may not involve technical

[1] https://www.omicsonline.org/open-access/patents-on-computerrelated-inventions-in-india-2375-4516-1000S1-009.php?aid=82521

	advancement • Novel software may not qualify for a patent if applied on a known hardware. • The guidelines mentioned careful consideration of how integrated is the novel hardware with the computer program.
2015	The 2015 Guidelines clarified that for being considered patentable, the subject matter should involve either a novel hardware or a novel hardware with a novel computer program or, a novel computer program with a known hardware which goes beyond the normal interaction with such hardware and affects a change in the functionality and/or performance of the existing hardware. Technical advancement of the inventions relating to CRIs may not fall within Section 3(k) if: • The claimed technical feature has a technical contribution on a process which is carried on outside the computer; • The claimed technical feature operates at the level of the architecture of the computer; • The technical contribution is by way of change in the hardware or functionality of the hardware. • The claimed technical contribution results in the computer being made to operate in a new way; • In case of a computer program linked with hardware, the program makes the computer a better computer in the sense of running more efficiently and effectively as a computer • The change in the hardware or the functionality or hardware amounts to technical advancement. Also, "mathematical method" exclusion may not apply to any computing / calculating machine encoding / decoding, method of encrypting / decrypting, method of simulation though employing mathematical formulae for their operations.
2016	In 2016 CRI Guidelines, a three step test was introduced, which included that "if the contribution lies in the field of computer program, check whether it is claimed in conjunction with a novel hardware and proceed to other steps to determine patentability with respect to the invention." The said test did not help much as 'hardware' in any event does not fall within the exclusion of section 3(k), and hence, determination of the invention related to computer programs *per se* remained ambiguous.

CRI Guidelines of 2017[2]

The major changes witnessed in 2017 guidelines are as follows:

1. The three step test as mentioned in the 2016 guidelines highlights above was deleted. In this context, the Revised Guidelines do not expressly lay down any specific tests, indicators or determinants on patentability of CRIs.
2. The new guidelines exclude the layout of integrated circuits as patentable subject matter in the CRIs.
3. The definition of "new invention" has been moved from 4.1 in the previous Guideline to 2.1 under the new CRI Guidelines.

[2] http://www.ipindia.nic.in/writereaddata/Portal/Images/pdf/Revised_Guidelines_for_Examination_of_Computer-related_Inventions_CRI_.pdf

4. Under 4.2, Industrial Applicability, the detailed description pertaining to 'Industrial Applicability' is now deleted. Accordingly, in comparison to the previous version, under the present CRI Guidelines the meaning of "industrial applicability" is not restricted to any specific examples.
5. Under 4.4.1, which mentions sufficiency of the disclosure, the description detailing about what should be the contents of the disclosure has been deleted.
6. Under 4.5, which mentions about the determination of excluded subject matter relating to CRIs following is added: *Hence, along with determining the merit of invention as envisaged under Sections 2(1) (j), (ja) and (ac), the Examiner should also determine whether or not they are patentable inventions under Section 3 of the Act.*
7. Under 4.5.1 mentioning about claims directed as mathematical method, following portion is added*: mere manipulations of abstract idea or solving purely mathematical problem/equations without specifying a practical application also attract the exclusion under this category.*

   Also, such exclusions may not apply to inventions that include mathematical formulae and resulting in systems for encoding, reducing noise in communications/ electrical/electronic systems or encrypting/ decrypting electronic communications
8. The examples on non-patentable and patentable claims have also been removed in the present guidelines.

In addition to above, the new CRI Guidelines also provide for replacement of provisions in Chapter 08.03.05.10 of the Manual pertaining to section 3(k) with these new provisions as given under the new Guidelines.

Coming Soon: Intellectual Property Exchange in India

By -Shrimant Singh

In yet another remarkable development in fostering innovation, creativity and intellectual property protection in India, the Government has announced that an ***Intellectual Property Exchange*** will be developed under the Ministry of Science and Technology through the National Research Development Corporation (NRDC). The Exchange will enable the individuals and/or corporate entities to buy and sell IP rights across various sectors.

The said move by the Government of India is welcomed by the inventors and the industrial houses alike, the same would facilitate monetization of IP, benefiting the inventors and resulting in manufacturing and availability of better technologies to the public at large. The said exchange would not only be limited to inventions or patents but may also include facilitating monetization or commercialization of copyrights, designs, trademarks, geographical indication, etc.

As per news reports, the idea of setting up a patent exchange similar to those in Hong Kong and the UK was floated in the Government Ministry around two months ago. The project has already got in-principle approval from the Ministry of Science and Technology. "We have been mandated with the task of creation of the proposed IP exchange and the process will take around 8-9 months for collecting data and setting up the exchange. We are already undertaking exercise of collecting necessary data and information on patents filed worldwide on multiple technologies, predominantly on agriculture and allied sectors," said the NRDC Chairman and Managing Director- H. Purushotham[3].

The Annual Report by Controller General of Patents, Designs and Trademarks (CGPDTM) of 2015-16, India stated that there is about 30% increase in filing of intellectual property applications compared to previous years. In the years 2015-16, about 3,41,086 applications were filed for IP rights as against 2,35,306 in the years 2011-12. Accordingly, while there has been a continuous increase in filing of intellectual property, a need is felt for a viable platform supported by the Government for commercialization of registered intellectual property. This requirement of commercializing the IP would be catered by the Intellectual Property Exchange of India. The effectiveness of the said move to setup the Exchange would certainly depend upon execution of the proposals on paper to be effected by the Government functionaries.

The challenge would be to keep the process and working of the Exchange transparent with accountability on the Executives of the Exchange. The processes and/or protocols to be adopted for the same would be crucial in the functioning and success of the said Exchange. One of the salient objectives and benefit for such a centralized IP Exchange would be to monitor and reduce the arbitrary negotiations amongst the parties and to facilitate constructive talks so as to result in reasonable benefits to both the parties. The IP Exchange would also act as a centralized library or market wherein the patent or right holders would showcase their IP and the interested parties can approach the said IP

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[3] http://www.livemint.com/Technology/q5KSoAyOpBqLZQX8AH9VPN/India-may-get-Intellectual-Property-Exchange-soon.html

right holders for licenses or purchase of the same.

According to India Brand Equity Foundation's Innovation and Patents Report[4] of June 2017: India's research and development spend is estimated to reach $71.5 billion by 2016 from $66.49 billion in 2015; In 2015, India became the world's sixth largest annual research and development spending country, accounting for 3.53% of global R&D expenditure; The R&D spending in India is anticipated to grow from 0.9% to 2.4% of the country's GDP from 2014 to 2034 respectively; The number of multinational corporations with R&D Centres in India has grown at a CAGR of 4.57% from 721 in 2010 to 943 in 2016; During 2010-16, the workforce in MNC R&D Centres increased at a CAGR of 10.08% and reached 363,000, which is estimated to further increase to 387,000 by 2017 in India.

In view of the promising numbers in terms of growth of innovation and patents in India, the Exchange would certainly propel the country's agenda of providing equitable and transparent platform for reaping benefits out of the intellectual property creations/registrations in India.

[4] https://www.ibef.org/industry/indian-innovation-and-patent-industry-analysis-presentation

Fair Remuneration for Compulsory Licensing

By- Monika shailesh

Research and development especially in the pharmaceutical sector is a time consuming, expensive and a resource intensive process. To top it all, said R&D also involves a considerably high risk of failure. On the other hand, innovation in the pharmaceutical is imperative for tackling the ever-growing growing health problems around the world. The under developed and developing nations are often deprived from the expensive lifesaving drugs unless there is a statutory legislation for their protection or the innovators are altruistic. The monopoly enjoyed by the Pharma Companies because of the patent protection laws enable the said Companies to dictate the market price of the certain life saving drug. The framework allows pharmaceutical companies to justify their supra competitive prices based on the need to recuperate innovation expenses. The genius of the patent system is that it harnesses the market system to determine the reward for patent holders. However, this means that access is determined by the ability to pay, and some people may be deprived of access. The 2001 Doha declarations on the Trade Related Intellectual Property rights (TRIPS) agreement and public health declared that WTO members should implement intellectual property laws in a manner that promotes access to medicines for all. The TRIPS Agreement allows WTO Members to use a number of different restrictions and exemptions to patent rights, including cases where governments can authorize persons to use patents, even when the patent owner does not give permission. Although TRIPS agreement enable countries with wide-ranging preference and freedom over what grounds the compulsory license is granted, it also takes care of the interest of the innovator by requiring the member nations to negotiate with the innovator on "Reasonable commercial terms and condition" Many refer this as fair remuneration. The terms "reasonable commercial terms" and "adequate remuneration" are not defined in the TRIPS Agreement. WTO Members are free to determine the appropriate method of implementing the TRIPS Agreement, within their own legal system and practice, and this extends to the standards they apply for "reasonable" royalties, or "adequate" remuneration.

Practice of the State

Looking at the legislations of different nations and upon study of related judgments by respective Courts, it is evident that there is no single universal practice towards the "fair remuneration" approach for compulsory licensing; these practices change from nation to nation and sometimes within a nation too. Different industries observe different practices over the reasonable commercial terms approach toward Compulsory Licensing. Recently a number of countries have issued mandatory licensing for HIV/AIDS drugs. For example Malaysia set a royalty rate of 4%; Mozambique establishes a 2% royalty; Zambia set a 2.5% royalty; and Indonesia arrived at 0.5% royalty.[5] There have been a number of royalty systems being proposed across the world and have established a useful framework for consideration. The evidence of compensation for private, market – based license arrangements provide an important context for making determinations of royalty and remuneration arrangements in case of compulsory license. It has been observed that there are quite a number of conflicts for cross-industry licensing averages. The

[5] http://www.who.int/hiv/amds/WHOTCM2005.1_OMS.pdf

pharmaceutical industry has however shown a much of a uniform agreements for royalty ranging from 4% to 5%, it is one of the higher licensing rates among all industries. While it is the duty of the State to make available the lifesaving drugs to all, the State should also ensure that a fair remuneration is given to the inventor or owner of the new drug. Approaches addressing the practical concerns regarding the administration of a system, as well as policy objectives shall be undertaken by the State. It should ensure that the remuneration system established for compulsory licensing shall keep into consideration the two paramount issues, first the remuneration system so established should not be too complex and second being that the royalty system should not present barrier for access to medicines. For countries able and willing to make somewhat more complex determinations of royalties, a range of appropriate factors should be assessed, though not all are required, and not all will apply in any given circumstance. These include but are not limited to:

- Therapeutic value of the medicine, including the extent to which it represents an advance over other available products;
- The ability of the public to pay for the medicine;
- Actual, documented expenditures on development of the medicine;
- The extent to which the invention benefited from publicly funded research;
- The need to respond to public health exigencies;
- The importance of the patented invention to the final product;
- Cumulative global revenues and profitability of the invention;
- The need to address anti-competitive practices.

Recommended Approach to Adequate Remuneration[6]

Different nations may prefer dissimilar methodologies to compensation based upon administrative capability, resource constraints, global norms concerning support for R&D, and policy objectives concerning access on one hand and innovation on another. The following approaches are considered reasonable and appropriate methods of setting remuneration.

UNDP Guidelines 2001

This method calls for a simple system where the base royalty rate is fixed at 4% of the generic product price. This can also be increased or decreased up to an extent of 2% based on the special factors like a product being particularly innovative or if the government has been paying the R&D expenditures. This remuneration system is simple and easily predictable. The administration of this system is not complex while on the same time it is also flexible to take care of the special conditions.

Japanese Patent Office (JPO) Guidelines 1998

Japanese Patent Office in the year 1998 published the guidelines for royalties for the non-voluntary licensing system for government owned patents. JPO guidelines allowed the use the patents for normal royalty of 2% to 4% of the price of the generic product. This can be altered by 2% i.e. increased or decreased by as much 2% giving an absolute range of 0% to 6%. The 1998 JPO guidelines include a "utilization ratio", which is used to allocate royalty payments among patent owners, when the product consists of

[6] http://www.who.int/hiv/amds/WHOTCM2005.1_OMS.pdf

combination of multiple inventions. This is particularly useful when setting remuneration for fixed-dose combinations or other medicines that combine many different patented inventions. (The utilization ratio can be used independently with any of the other methods of setting royalties.) JPO guidelines are considered more complicated in terms of administration while they are also termed as an elaborate version of 2001 UNDP guidelines.

Canadian Export Guidelines 2005

The Canadian Government established the system and guidelines for commercial compensation to inventors in case of compulsory licensing. The Canadian government did this in order to export to countries that lack the capacity to manufacture medicines. These guidelines are a sliding scale of 0.02 to 4% of the price of the generic product, based upon the country rank in the UNDP Human Development Index (UNHDI). For most developing countries, the rates are less than 3%, and for most countries in Africa the rate is less than 1%. The Canadian methodology can be understood as advantageous norm for those countries facing severe resource constraints in providing access to medicines for all. The rate is easy to calculate, and the rates are relatively low, thus avoiding large deviations from the marginal costs of medicines. The Canadian method is less useful for middle or high-income countries that have both the capacity to pay more and the need for a remuneration system that will appeal for global norms concerning the sharing of R&D costs.

Tiered Royalty Method (TRM)

This methodology of royalty for compulsory licensing adopts a whole new approach, here the royalty calculation is not based upon the price of the generic product, but it is dependent on the price of the patented product in the high income country. The base royalty is 4% of the high-income country price, which is then adjusted to account for relative income per capita or, for countries facing a particularly high burden of disease, relative income per person with the disease. In this method the value of the royalty is based on the therapeutic value (the high income price) and capacity to pay. It is a more rational framework that caters to sharing the actual R&D cost that has incurred in developing the new patented idea. It can be viewed as a more sustainable idea for some middle or high income countries that are concerned with sharing the R&D cost. The TRM provides for much higher royalties in middle- and high-income countries with low burdens of disease, and the lowest royalties for countries that have the lowest incomes and the highest of disease burden.

Medical Innovation Prize Fund (MIPF)

The MIPF technique involves making all drugs available to consumers at generic prices. With the MIPF methodology, compensation is not awarded to pharmaceutical innovators by a royalty or per-unit profit. Rather, they receive a portion of a national budget for rewarding medical innovation among owners of competing products. These payments are allocated according to each product's contribution to improved health outcomes. The MIPF can also be implemented to provide for remuneration for products that more closely address health care priorities, including products that are developed to address global neglected diseases, or medicines that are developed in anticipation of future needs, such as treatments for a disease like Severe Acute Respiratory Syndrome (SARS) that is currently contained, but which presents an important health care risk. The MIPF approach provides the greatest rewards for products that are actually used

and that provide incremental health care benefits. The MIPF approach can be implemented in countries of different levels of development, income and health care priorities. It is recommended that the overall level of funding for a MIPF approach increase with national income and the level of development.

Federation of Indian Chambers of Commerce & Industry (FICCI)'s Position on Compulsory Licensing[7]

GENERAL COMMENTS

- Compulsory Licensing provisions in Indian patent law appear to be liberal and make use of the flexibilities provided in the TRIPS Agreement almost fully.
- The effectiveness of these provisions in the post TRIPS era has not yet been tested properly. There have been no applications for Compulsory Licensing except two requests under Sec 92 A. But those two requested suffered from initial infirmity in that they did not have minimum essential documentation such as notifications by the least developed country concerned.
- There has been no instance of any application on account of either national emergency or non-availability of an essential drug or on account of the price of an essential drug.
- There has been no empirical study to find out the reasons for non-resorting to Compulsory Licensing by Indian pharmaceutical sector. Only a thorough investigation into the whole matter can bring out the shortcomings of the existing provisions on Compulsory Licensing including the procedural aspects. This study should look into the legal, economic and public health aspects of the issue. This study should particularly examine whether public health in India suffered for want of use of CL and whether it would have been better had the Compulsory Licensing provisions been used. It should also bring out the reasons for Indian pharma companies not exploring the Compulsory Licensing route.
- Compulsory Licensing procedure should be simple and easy to follow.
- It is not necessary to have Compulsory Licensing for all diseases. For common sicknesses without any significant health impact and for which multiple medicines are available, it is not necessary to go for Compulsory Licensing.
- It is also ordinarily not necessary to go for Compulsory Licensing for generic medicines, unless there is an acute shortage of such medicines or they are priced very high.
- Compulsory Licensing should be reserved for health emergencies such as epidemics and non-availability of essential drug at a reasonable price.
- Use of Compulsory Licensing should not serve as a disincentive to investment in drug discovery.
- Individual cases will have to be examined on their own merits.
- Guidelines should not make things more constrictive. The objective should be facilitation of entry of newer and better drugs in the market and their easy availability at reasonable price. Therefore, Compulsory Licensing should not be used routinely, but only in exceptional circumstances.
- In the absence of an application procedure, selection of a company to manufacture a Compulsory Licensing product will lead to many complications. For one a company should be capable and

[7] http://ficci.in/SEdocument/20143/Compulsary-Licensing.pdf

willing to manufacture the product and for another there should not be any discrimination among companies.

FICCI has suggested supplementing the Manual of Patent Practice and Procedures (MPPP) with exhaustive reference and learning material. The learning material can be in the form of booklet that could contain the cases of grant of Compulsory License abroad by countries like USA, Canada, Japan etc. and explain the conditions under which those Compulsory License were granted.

CONCLUSION

It is evident that that the respective government policies and practices plays a vital role for formulating a rational and practical approach towards determining a reasonable structure for adequate royalties and remuneration for the manufacture or sale of a product under compulsory licensing.

- The method of determining the royalties or remuneration for the patent holders whose patent is used under compulsory license arrangement shall be simple and practical. It should not be difficult or unclear to govern. Well-structured royalty guidelines will not only reduce the intricacy but will also provide assistance for adjudicators. It will also serve to increase transparency and predictability.
- The Government guidelines or the laid down rules and regulation for deciding the royalties and remuneration for the patent holder, shall formulate the entire process in such a way that it shall cater to divide the remuneration in a rational and transparent way among patent holders in case a product uses multiple patents. So that in case if a product uses multiple patents the interest of all the stake holders are assured. The scheme for setting fee for compulsory licensing, should forestall and take care of the need to divide fee payments among various patent holders when the product is subject to multiple patents. This could either be based on the value added to the product by each individual patent or in the simplest way equal distribution of fee to all the patent holders.
- The most important aspect of setting up of a system of deciding the fee or the remuneration for the patent holders in case of compulsory licensing is to keep the interest of the users of the product intact. Since the main focus of compulsory licensing is to make available the costly product to the general masses which otherwise do not have access to the critical life support systems like medicines and medical equipment's. The system shall concentrate on striking a balance where the product remains in reach of the poor masses while upholding the patent holder's interest.

Patent Application duly restored by the High Court

"Iritech Inc. v. The Controller of Patents"-

By- Suchi Rai

Introduction:

Recently a patent application "Deemed to be Withdrawn" by the Controller of Patents under Section 11B of the Patents Act, 1970 was duly restored by the Delhi High Court. Request for Examination (RFE) is one of the most critical formal requirements with regards to a Patent Application in India, and if not filed within the prescribed time limit of 48 months from the earliest priority date, the application is considered deemed to be withdrawn by the applicant. There is no recourse to resurrect the patent application once the applicant misses the deadline to file request for examination in an application.

Summary:

In the recent case of *Iritech Inc. v. Controller of Patents*[8], the Delhi High Court quashed the "Deemed to be withdrawn" status of the Patent Application and duly restored the Patent application passing the judgment to consider the application now as pending with Patent Office. The clerical error in Request for Examination application and supporting documents are to be considered as corrected and filed in respect of Patent Application No. 5272/DELNP/2008. The issue involves the incorrect mentioning of the number of the patent application in Form 18 as well as in its covering letter i.e. 5272/DELNP/2008 being mistakenly mentioned as 6272/DELNP/2008. Accordingly application 5272/DELNP/2008 in absence of Form-18 filing was considered by the Patent Office as "Deemed to be withdrawn". However, the Agents on record noticed the clerical error in Form18 and filed the request for correction of the clerical error under Section 78 with the Patent Office within the time period of 48 months from priority date. There was no response received from Patent Office with regards to correction in clerical error and subsequently the status of the application was updated as "Deemed to be withdrawn".

The Delhi High Court rejected the contention of the Patent Office that the power of the Controller to correct clerical errors can only be exercised when patent application is in examination procedure, and hence no office action was possible in present case. The Court mentioned that if the Patent Office had examined the application under Section 11B, in time and the examiner submitted his report, it would have been brought to the notice of the Petitioner well before the expiry of 48 months prescribed period and the petitioner could have taken steps to remedy the error. If the Patent Office had stuck to the timelines for examination, the patent application would have been in the examination procedure. The Court also observed that since there is no form prescribed by the Act or the Rules for seeking correction under Section 78, even a letter would be sufficient, and that a request under Section 78 is not dependent on the examination or any office action in the patent application. In this case the "erroneous" request for examination was filed within the time period of 48 months and also the request for correction of clerical error was filed well before the expiry of said period.

Case Note[9]:

The Petitioners filed the Indian National Phase Patent Application on 18/06/2008. The petitioner made a request for examination

[8] Judgment dated 20-4-2017 in W.P. (C) 7850/2014, Delhi High Court

[9] 2017 (70) PTC 237 [Del]

under Section 11B of the Patents Act, 1970, on 30/06/2008.

On 02/01/2010, the petitioner/applicant filed a request for correction of the aforementioned error in the patent application, as prescribed under Section 78 of the Act. Along with the said request for correction, the petitioner enclosed the corrected Form 18 and the covering letter with the prescribed fee of INR 2000. The petitioner contends in the present case that there was no communication to him by the respondent.

On 02/02/2010, the petitioner obtained the search report from the website of the IPO which stated the application was 'deemed to be withdrawn'.

The respondent/ the Patent Office declined to entertain the request of the petitioner for correction of the application number which led to filing of the petition.

The respondent submitted that the request for correction made by the petitioner by letter dated 02.01.2010 was not the proper procedure to make corrections under the Act.

It is to be noted that the request for examination was filed within the 48-month period and the request for correction of the clerical error of the patent application number was also made prior to the expiry of the period of 48 months and prior to the application being "deemed to be withdrawn".

In view of the above, the High Court ordered to set aside the status of the application as "deemed to be withdrawn" and restored the said patent application and the same shall be considered as "pending" at the Patent Office.

Trademark Protection for Buildings: Hotel Taj Mahal Palace, Now a Registered Trademark

By- Shrabani Rout

Introduction

On May 19, 2017, the Indian Hotels Company Limited (IHCL) created history by securing a trademark registration for the exterior design of the Taj Mahal Palace Hotel. While securing trademarks for buildings are a common phenomenon around the world, the iconic landmark of Mumbai is the first of its kind in India to get a registered trademark under its hood. Other famous landmarks that are registered as trademarks are the Empire State Building in New York, the Eiffel Tower in Paris, Sydney Opera House in Australia to name a few.

The primary reason behind securing trademarks for buildings is to protect copycat architecture and protect the unique design of the building and preserve its uniqueness and heritage. Buildings satisfy the dual test of graphical representation, along with the capability of functioning as an indication of source and are hence eligible for trademark protection. By registering buildings as trademarks, the proprietors also attempt to control and limit the depictions of those landmarks in artistic works, pictorial representations, unfair commercial use etc.

Another reason for securing a trademark for the iconic structure can be that the IHCL wanted to protect the structure from being used in productions that could tarnish and dilute the image. For example, if an alcohol manufacturer would put the design of the Taj Mahal Palace Hotel on its whisky bottles, it could tarnish the reputation of the building and dilute its trademark status.

Now that the building is successfully registered as a trademark, the IHCL has the following powers in relation to the building:

1. Nobody can use the trademarked image for commercial purposes without a license from the company. Selling any object with the trademarked image on it will be considered as an infringement action.
2. Any sort of commercial use will be with the permission and may include the payment of a licensing fee to the company.

The IHCL had sought registration for the iconic building under Class 43 for the following services namely, “services providing food and drink; temporary accommodation”.

A pertinent question that can be raised here is why the IHCL chose to secure a trademark registration rather than a design or copyright registration. Copyright registration only protects the aesthetic value of the building; design registration only helps in increase of commercial revenue generation. A trademark registration on the other hand however, not only increases the commercial revenue generation through licensing, it also signifies that a particular landmark denotes the source or acts as a source indicator while also protecting the distinctiveness of the landmark. Also, the term of protection of a trademark is much longer than that of a copyright or design protection.

Requisites to be fulfilled by a landmark building to be eligible for registration

1. It must be used on or in connection with the promotion and sale of goods and services, or displayed on materials used in offering the goods or services

for sale, rather than merely as a landmark per se.
2. The public must recognize such building or landmark as indicating and designating the source of particular goods or services.

Thus, trademark protection "cannot be enforced in the absence of evidence that the public recognizes it and associates it with the owner's services."

Legal Precedents:

1. In the case of *Rock and Roll Hall of Fame and Museum v. Gentile Production*,[10] the Museum's building design was registered with the State of Ohio and the United States Patent and Trademark Office as a trademark. Photographer Charles Gentile took a picture of the Museum against a colorful sunset and began selling the photograph as a poster. The Museum filed a lawsuit against Gentile over the depiction of the Museum in the poster. The court in this case said that "in order to be protected as a valid trademark the building must create "a separate and distinct commercial impression which . . . performs the trademark function of identifying the source of the merchandise to the customers."
   However the Museum could not produce evidence to demonstrate that the public actually identified the building as a trademark. If the public does not rely upon the landmark to identify the source then the landmark cannot be held to be a trademark and thus it cannot be registered.
2. Another interesting case is that of *ESRT Empire State Building, L.L.C. v. Michael Liang*[11], the Empire State Building LLC, owns federal registrations for the word mark EMPIRE STATE BUILDING for observation deck, sightseeing and real estate services, as well as design mark registrations for the same services for this two dimensional depiction of the building exterior. The respondent's company used the picture on their beer bottles without the official permission or any form of licensing agreement form the ESRT. The beer logo in this case belonged to trademark applicant Michael Liang who applied for the trademark on January 8, 2011 with the intent to use the mark in commerce for alcoholic and non-alcoholic styles of beer. The Trademark Trial and Appellate Board found that ESRT's mark is "famous for purposes of dilution", that its mark is inherently distinctive or acquired its distinctiveness through its exclusive use of its mark and have a "strong degree of recognition. After considering all the evidence found, the Trademark Trial and Appellate ruled that applicant's mark is likely to cause dilution by blurring ESRT's mark, hence ruled in the ESRT's favor.

<u>The road ahead:</u>

Now that the Taj Palace Hotel is a registered trademark, no one can use the image of the building for any commercial purpose. If any individual or entity wants to use the image on any of their products, they will have to get a license from IHCL.

[10] 134 F.3d 749 (6th Cir. Ohio 1998)

[11] http://ttabvue.uspto.gov/ttabvue/ttabvue-91204122-OPP-95.pdf

Few articles online have criticized this move of IHCL and stated that by getting trademark registrations for landmark buildings , the IHCL is curtailing the right of the public to cultural heritage by not allowing even pictures of the Taj Palace to be depicted on t-shirts and photographs. It is to be kept in mind here that getting a registered trademark for the image does not take away the right of citizens from clicking pictures before the iconic building; they can just not use the pictures for commercial purposes without a license from IHCL.

The adverse impact of this move will be felt by photographers who will now have to pay a licensing fee to the IHCL even if they take a picture of the building and sell it to a magazine.

The reasons as to why the building was registered as a trademark have been stated earlier and are not repeated here for the sake of brevity. However to prove that dilution has occurred, the claimant must show that when the general public encounters the mark in almost any context, it associates the mark at least initially with the mark's owner. The IHCL can therefore justify the move of securing a trademark registration for the Taj Mahal Palace Hotel on the grounds that they did it not only to protect the building's architecture and distinctiveness but also to protect the image of the iconic building from dilution by blurring or tarnishment.

Conclusion

Being the first Indian building to get a trademark, the Taj Mahal Palace Hotel has certainly ushered in a new era for the development of Intellectual Property in this field of securing trademark protection landmarks and there can be an exciting road ahead for companies and entities who wish to trademark their famous structures to protect its distinctivity.

Therefore, it is safe to conclude that the move of IHCL in securing trademark registration for easily the most famous building in Mumbai was a smart one.

Xtandi patent fight may delay entry of essential drugs at affordable prices

By- Vijaylaxmi Rathore

The Indian pharmaceuticals with its proven product standards and national and International regulatory compliance is the 3rd largest producer and suppliers of cost-effective generic medicines worldwide. The effort to make affordable lifesaving drugs availability for the general population is a huge task performed only if pharmaceutical firms and regulatory authorities go along. In India, the affordability of drugs is monitored and regulated by National Pharmaceutical Pricing Authority (NPPA), a regulatory agency under Department of Pharmaceuticals. NPPA plays a major role in bringing down the prices of essential lifesaving medicines in the country. As a result, the lifesaving drugs are available in India at a more reasonable and economical price compared to other countries. Moreover, the Indian Patents Office (IPO), while being dedicated towards the innovation support by grant and protection of patents, also allows for certain exclusions to monopoly especially with respect to innovations in pharmaceutical sector. Here we are discussing the measures taken by IPO and NPPA towards drugs affordability in India.

National Pharmaceutical Pricing Authority (NPPA):

NPPA is a regulatory and executive agency to implement Drug Price Control Order (DPCO), 1913, under Essential Commodities Act, 1955. The NPPA regulates the price of schedule-I drugs, thereby list of essential medicines updated by regulators time to time. The NPPA fix the maximum ceiling price of Schedule-I drugs and publish through National List of Essential Medicines (NELM) periodically. Moreover, apart from the price control of scheduled drugs, the certain provisions of DPCO are specifically to monitor the price of non-scheduled drugs.

Non-scheduled drugs and NPPA: The NPPA's right to control the prices of non-scheduled drugs (drugs not listed in schedule-I) is performed under Para 19 of DPCO, 2013. Likewise, the NPPA monitors the price of non-scheduled drugs under Para 20 of DPCO, 2013, as explains below-

- Paragraph 19 of DPCO prescribes that, notwithstanding anything contained in this order, the Government may, in case of extra-ordinary circumstances, if it considers necessary so to do in public interest, fix the ceiling price or retail price of any drug for such period, as it may deem fit and where the ceiling price or retail price of the drug is already fixed and notified, the Government may allow an increase or decrease in the ceiling price or the retail price, as the case may be, irrespective of annual wholesale price index for that year.

  Note- the internal guidelines of Para 19 of the DPCO, 2013 was withdrawn by immediate effect on 19.09.2014 vide letter no. 31026/ 53/ 2014-PI-II[12]. However, Department of Pharmaceuticals (DoP) has formed a new inter-ministerial committee and instigated them to examine and frame a method that targeted to bring down the exorbitant price of patented drugs within the country either by negotiation or reference pricing[13].

[12] http://www.dpco2013.com/files/data/pricefixationunderpara19/20331472541493.pdf

[13] http://pharmaceuticals.gov.in/sites/default/files/CommitteePatentedDrugs_0.pdf

- Paragraph 20 of DPCO, 2013: Monitoring the prices of non-scheduled formulations-

    1) The Government shall monitor the maximum retail prices (MRP) of all the drugs, including the non-scheduled formulations and ensure that no manufacturer increases the maximum retail price of a drug more than ten percent of maximum retail price during preceding twelve months and where the increase is beyond ten percent of maximum retail price, it shall reduce the same to the level of ten percent of maximum retail price for next twelve months.

    2) The manufacturer shall be liable to deposit the overcharged amount along with interest thereon from the date of increase in price in addition to the penalty.

Patented Drugs and NPPA: The non-applicability of the provisions of DPCO is being prescribed under Para 32 of DPCO, 2013.

- Paragraph 32 of DPCO, 2013: Stipulates that the provisions of DPCO shall not apply to certain cases :

    1) A manufacturer producing a new drug patented under the Indian Patents Act, 1970, (product patent) and not produced elsewhere, if developed through indigenous Research and Development, for a period of five years from the date of commencement of its commercial production in the country.
    2) A manufacturer producing a new drug in the country by a new process developed through indigenous Research and Development and patented under the Indian Patents Act, 1970 (process patent) for a period of five years from the date of the commencement of its commercial production in the country.
    3) A manufacturer producing a new drug involving a new delivery system developed through indigenous Research and Development for a period of five years from the date of its market approval in India.

    Provided that the provisions of the above paragraph shall be applicable only when a document showing the approval of such "new drugs" by the Drugs Controller General of India (DCGI) is produced before the Government.

The Indian Patents Act (IPA):

There are certain provisions of the IPA, which play a major role in pharmaceutical related invention, and its affordability and availability. Sections such as Section 3(d) and Section 3(e) are important with respect to pharmaceutical inventions, and Section 84(1b) and 92(1) encapsulates for drug affordability and availability respectively under special circumstances.

Section 3(d) and 3(e) narrows down the scope of patentability for insignificant or incremental pharmaceutical discoveries and supports the true innovations in terms of efficacy.

- Section 3(d) prescribes that the mere discovery of a new form of a known substance which does not result in enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or

employs at least one new reactant is not patentable.

- Section 3 (e) prescribes that a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance is not patentable.

The Section 84(1) relates to compulsory licensing provisions under IPA, whereby, the Controller of Patents is empowered to grant compulsory licenses after expiration of three year from the date of the grant of the patent under prescribed grounds-

a) That the reasonable requirements of the public with respect to the patented invention have not been satisfied, or
b) That the patented invention is not available to the public at a reasonably affordable price, or
c) That the patented invention is not worked in the territory of India.

It is to be noted that the clause (b) above mandates the patentee make the patented drug available to the public at a reasonably affordable price, so as to avoid the said patent from being considered for compulsory licensing.

Further, Section 92(1) prescribes that if the central government is satisfied that in circumstances of national emergency or in extreme urgency or in case of public non-commercial use, it is necessary that the compulsory license should be granted to work the patent, it may make a declaration to that effect by notification in the official gazette, whereupon-

i. The Controller shall on application made at any time after the notification by any person interested grant to the applicant a license under the patent on such terms and conditions as he thinks fit;
ii. In settling the terms and conditions of license granted under this section, the Controller shall endeavor to secure that the articles manufactured under the patent shall be available to the public at the lowest prices consistent with the patentees deriving a reasonable advantage from their patent rights.

Accordingly, in case of said extreme circumstances and upon Gazette notification by the Central Government the Controller is empowered to grant compulsory licenses with respect to the notified patents and while doing so the Controller is required under aforementioned provision (ii) to make the patent available to the public at lowest prices consistent with the patentees deriving a reasonable advantage from their patent rights.

Upon considering the provisions of the NPPA and IPA, it can be said that the affordability and availability of pharmaceuticals is directly and/or indirectly affected by DPCO, 2013 and Indian patent system, which is to the benefit of public at large in India. However, it has been seem at some instances that the said systems create a hurdle in pharmaceutical growth and expansion in the country, since the pharmaceutical companies do become indecisive with respect to launching of their products in India as compare to U.S. and European countries.

Xtandi Vs Indian Patent Office:

Xtandi (generic name-Enzalutamide), a synthetic non-steroidal, anti-androgen drug developed by a group of researchers from University of California, Los Angeles (UCLA), who then licensed its patents to a US based biopharmaceutical company called Medivation. Later in 2009, Medivation in a joint venture with Astellas, a Japanese

pharmaceutical company started developing, marketing and commercializing Enzalutamide globally[14]. In August 2012, USFDA approved MDV3100 (Enzalutamide) for the treatment of metastatic castration-resistant prostate cancer. At present apart from Medivation and astellas, Pfizer also got the right over Xtandi as a result of medivation acquisitions in 2016[15].

Xtandi is a potent, best-seller but also a high-priced anticancer medicine by Astellas for the treatment of the second most common cancer in men. Despite the claims of providing coupons, Medicare and some patient assistance programs to uninsured or underinsured cancer patients by Astellas [16]. The Drug still appears costly especially for economically disadvantaged African-Americans in U.S., as Xtandi price is much higher costing around $129,000 in a year in USA than the other high income countries. As a result, the US congress and lawmakers are demanding an open and transparent public hearing on Xtandi pricing; and the major concern of demand is the exorbitant pricing of Xtandi in USA despite its being developed in their own country by using their own funds[17].

In India, Astellas is selling Xtandi at the estimated cost of $45 for each 40 mg pill and $179 (Rs. 11521.33) per day, a way expensive then the daily income of a person in India (As per the World Bank report 2015, the estimated daily income of a person in India is $4.36 (Rs. 280.00)). However, these exorbitant pricing and ongoing patent fight for Xtandi has been opposed at various level. For e.g. the Union for Affordable Cancer Treatment (UACT) together with 56 organizations has requested the reagent of University of California, Los Angeles (UCLA) to back off its petition filed to Delhi high court against the IPO decision of patent denial. As this ongoing patent fight may delay the generic version of Enzalutamide (Xtandi) in the country; and its supply to other low economic countries where the said drug has no patents and/or not affordable anyway[18].

Unfortunately, It's been a decade for Xtandi patent fight in India, the UCLA application for Xtandi patent was first filed at Indian Patent Office (IPO), Delhi in 2007 (Application Number – 9668/DELNP/2007). Thereupon, Indian Pharmaceutical Alliance, Fresenius kabi, BDR Pharma and few individuals filed opposition against this application on 2012, 2013 and so on. Later in 2016, the IPO rejected the application on the grounds of; lack of inventiveness, section 3(d) and Section 3 (e) of the Patents Act. Consequently the reagent of UCLA filed a petition before the Delhi high Court challenging the IPO decision of patent refusal and looking forward for the next hearing.

CONCLUSION

Xtandi will either win the patent fight or not, but in both the situations it will have a vital impact on the affordability of said drugs amongst the cancer patients in India. The ongoing fight for patent is already a reason for delay in availability of the generic version of Enzalutamide (Xtandi) for the cancer patients in India.

[14] http://files.shareholder.com/downloads/MDV/1855075331x0x326521/3a8e7d97-2e58-43fd-8e13-f0022dcf224d/MDVN_News_2009_10_27_General_Releases.pdf

[15] http://www.latimes.com/business/la-fi-pfizer-medivation-acquisition-20160822-snap-story.html

[16] https://www.keionline.org/node/2485

[17] http://www.fiercepharma.com/regulatory/updated-astellas-cancer-med-xtandi-draws-fire-as-u-s-lawmakers-demand-a-pricing-hearing

[18] https://cancerunion.org/2017/05/24/uact-55-others-ask-university-of-california-to-drop-appeal-of-prostate-cancer-patent-in-india/

If Xtandi does not receive the patent protection-

- The Pharmaceutical industries in India may manufacture the generic version of Enzalutamide on the grounds of no patent, and
- The provision to bring down the price of non-scheduled formulations under paragraph 19 and 20 of DPCO, 2013 will be also applicable.

If Xtandi receives the patent protection- The Indian government will have two options to bring down Xtandi's price:

- The provision to grant compulsory license after expiration of three year from the date of the grant of the patent based on aforementioned circumstances under Section 84(1) and Section 92(1), will be applicable.
- The provision to bring down the price of non-scheduled formulations under paragraph 19 and 20 of DPCO, 2013 will might be applicable. As Xtandi has not developed through indigenous/ domestic R&D process would be out of the Paragraph 32 exclusion as stated above.