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Infringement of Patents : An Analysis of Compulsory Licensing Through Pertinent Case Laws

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Introduction:

Patent is granted for inventions. It a legal right which an inventor has for his inventions. An invention must satisfy the following three conditions of: (i) Novelty (ii) Inventive-Step (Non- obviousness) (iii) Utility/Usefulness 1) Novelty: An invention will be considered novel if it does not form a part of the global state of the art.15 The courts in India have decided a few cases concerning to novelty, however none of the case is directly dealing with the novelty. In the case of Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries wherein the plaintiff instituted a suit for injunction and damages against defendants forthe process of manufacturing utensils, particularly shallow dishes of which it owes a patent , the issue came up was- Whether an alleged invention involves novelty and an inventive step?, it was held that A patent is granted only for an invention which must be new and useful, a patent is granted to encourage scientific research , new technology and industrial process. [1]

A mere application of an law contrivances in the old way to an analogous subject without any novelty or invention is the mode of applying such old contrivance to the new purpose not being a valid subject matter of patent, the patent granted in such a case is liable to be revoked. Novelty is assessed in a global context. An invention will cease to be novel if it has been disclosed in the public through any type of publications anywhere in the world before filing a patent application in respect of the invention. Prior use of the invention in the country of interest before the filing date can also destroy the novelty. Novelty is determined through extensive literature and patent searches. It should be realized that patent search is essential and critical for ascertaining novelty as most of the information reported in patent documents does not get published any where else.[2]

Inventiveness (Non-obviousness): A patent application involves an inventive step if the proposed invention is not obvious to a person skilled in the art i.e., skilled in the subject matter of the patent application.17 The prior art should not point towards the invention implying that the practitioner of the subject matter could not have thought about the invention prior to filing of the patent application. Inventiveness cannot be decided on the material contained in unpublished patents. The

1 Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries, (1979) 2 SCC 511: AIR 1982 SC 1444 (Concerning a case of revocation of patent and discussing in detail, the history of Patent Law in India and the scheme of the Patents Act of 1970).

2 See Johan Ragnar, supra note 115. Also See Hon'ble Mr. Vijender Jain, Chief Justice of Punjab and Haryana High Court, Chandigarh supra note 53. Also See "Abduction of Turmeric Provokes India's Wrath" Good News India (January 2002)

complexity or the simplicity of an inventive step does not have any bearing on the grant of a patent. In other words a very simple invention can qualify for a patent. If there is an inventive step between the proposed patent and the prior art at that point of time, then an invention has taken place. A mere 'scintilla' of invention is sufficient to found a valid patent. In M/s. Gujarat Reclaim & Rubber Products Ltd. v. M/s Kamini Metal Oxides Ltd18wherein, A notice of opposition was made to the applicant concerning their application for an invention 'A process for separation of rayon or nylon fibers from cracked waste tyres and an apparatus ., the issue was Whether on the facts, evidences and circumstances can it be said that the patent should not be granted to Applicant?, it was held that the opponents failed to provide any evidence for the support of their assertion that the application should be rejected on the grounds of prior publication, prior public knowledge, prior public use, obviousness, lack of inventive step, and insufficiency of description 3) Usefulness: An invention must possess utility for the grant of patent No valid patent can be granted for an invention devoid of utility. No case directly as regards utility was found out by the researcher[3].

Research Objective:

1. To understand infringement of patents and litigative issues related to it
2. To comprehend the role of compulsory licensing .

Research Methodology:

Researcher has relied on secondary sources of research like books, journals, articles, online blogs and legal databases. The researcher has also made an in-depth analysis of the topic and and reached a conclusion which is mentioned in the latter part of the paper.

Research Questions:

1. What is infringements in case of Patents?
2. What is the role played by Compulsory licensing when it comes to Patents?
3. What are the pertinent Case laws regarding it ?

Infringement of Patents :

In India, patent infringe ent with respect to a patented invention without the prior permission from the patent holder is a prohibited act. A patent holder can grant a permission, if required, in the form of a license. A patent infringement, usually with respect to usage or sale of the patented invention, may vary by jurisdictions. In several countries, a use is intended to be commercial in order to constitute patent infringement.

Generally, the defined claims of the invention comprise the scope of the patented invention or the extent of protection required. In other words, the terms of the claims inform the public of what is not allowed without the permission of the patent holder. [4]Patents are meant to be protective, and infringement is only possible in a country where a patent is enforced upon. The scope of protection varies from country to country, as the respective patent office examines the invention according to their rules and regulation depending upon the differences for rules of patentability. There are two types of infringements as mentioned below:

Direct infringement - occurs when a product is substantially close to any patented product or in a case where the marketing or commercial use of the invention is carried out without the permission of the owner of the invention.

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https://www.wipo.int/patents/en/

Indirect infringement - occurs when some amount of deceit or accidental infringement happens without any intension of infringement.Whenever there is a case where monopoly rights of the patentee are violated, the rights of the patentee are secured by the Act through judicial intervention. The patentee has to institute a suit for infringement. The reliefs which may be availed in such a suit are:

1. Interlocutory/ interim injunction

2. Damages or account of profits

3. Permanent injunction

Section 104 of the Act provides that a suit for infringement cannot be instituted in any court inferior to a District Court having jurisdiction to try the suit other than High Court, in an appropriate

3 F. M. Abbott, Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision, Quaker United Nations Office, Geneva, 2002, pp. 160.

situation. When an action for infringement has been instituted in a high court and district court and the defendants make a counter claim for revocation of the patents, the suit is transferred to the High Court for decision because high court has the jurisdiction to try cases of revocation. Further, section 104A provides for burden of proof in case of suits concerning infringement.

From the period of a patent being sealed, a suit for infringement can be instituted. Further, during the period where the opposition is being decided, the applicants cannot institute a suit for infringement. However, the damages sustained due to the infringement, i.e. between the date of publication of complete specification and the date of grant may be claimed in a different suit.

In a situation where the term of the patent has expired and the infringement occurs during the said term of the patent, a suit can be instituted even after the expiry of the term. Further, in a case where a patent is obtained wrongfully by a person and is granted to the true and first inventor, no suit for infringement can be enforced before the period of such grant to the true and first inventor.

Reasons for which Patent can be rejected :

The provision of this sub section can be applied in a case if it is shown that a claim in the Patent to be revoked is the subject of an identical claim in a Patent of earlier priority date and that the earlier claim is valid[5]. In Monsanto Co. (De Penning and De Penning) v. Coramandal Indag Products (P) Ltd. [6], the issue before the Honorable Supreme Court was - Whether the 'Butachlor' used by the appellants were already in the public domain and their granted patents are liable to be revoked?, the court held that Under Sec. 64 (1) (d) a patent may be revoked on the ground that the subject of any claim of the complete specification is not an invention within the meaning of the Act. Under Sec 64 (1) (e) , a patent may be revokes if the invention so far as claimed in any claim of the complete specification is not new, having regards to what was publicly known as publically used in India before the date of the claim. Under Sec. 64 (1) (f) , a patent may be revoked if the if the invention so far as claimed is obvious or does not involve any inventive step having regard to what was publically used in India. Section 6 specifies the categories of persons entitled to apply for Patents. If a person made an application for a patent, other than those mentioned in Sec. 6, the Provision of See 2(1)(y) applies which defines the term 'true and first inventor' which excludes first importer of an invention into India or a person to whom an invention is first communicated from out side India.

4 http://ip-science.thomsonreuters.com/support/patents/patinf/patentfaqs /history/

5 1986 AIR 712, 1986 SCR (1) 120

Accordingly people of these categories are not entitled to apply for Patent under this Act. However, if a patent was obtained under this Act by them, it could be revoked under this sub-section.

Patent was wrongfully obtained by a person other than the person entitled When a Patent has been wrongfully obtained by any person, the person entitled to apply for a Patent may file a petition under this sub section for revocation. This Petitioner however must be a person entitled to apply for the patent. Subject of a claim is not an invention If the Patent granted does not satisfy the provision of Sec 2(1)(j)[7] it may be revoked under this sub section. Invention is lacking in novelty with regard to prior knowledge or prior use This sub section provides for a ground for revocation based on lack of novelty. Novelty of an invention is an essential prerequisite for grant of a Patent. In fact, the very definition of invention under section 2(1)(j) states that the invention must be new. The search for novelty is carried out by the examiners under section 13 to ascertain whether any claim made in the complete specification is anticipated by any prior publication of the subject matter either in Patent specification or in any other documents published in India or elsewhere. Under Section 15 Controller can refuse any patent on the ground that the invention is not new. Accordingly, if any Patent has been obtained for an invention, which lacks in novelty, it could be revoked on this ground. This subsection provides for ground of revocation, when a Patent has been obtained for an invention, which is not useful. It is again an essential prerequisite for a patent that the invention must be useful as is evident from the definition of invention under sec 2(1)(j). However the utility of Patent must be judged with reference to the state of art at the date of Patent. 'Not useful' means that the invention will not work i.e. either it may not operate at all or it may not provide the desired result as mentioned in the specification. Here the practical usefulness or commercial utility of the invention does not matter. Section 64 (1) (h) provides for a ground of revocation if the invention has not been sufficiently described in the specification as specified in this section. The complete specification must describe an embodiment of the invention claimed in each of the claims and that the description must be sufficient to enable those in the industry concerned to put it in effect "without their making further invention" and that the description must be fair and must not be unnecessarily difficult to be followed. The claim should be as clear as the subject admits but in order to protect it from infringement it need not be so simplified as well. Any hard and fast rule cannot be laid down for the sufficiency of description and should be judged individually on merit of the specification. Here it is pertinent to mention that it is obligatory for an applicant to describe the

6 Section 2(1)(j) in The Patents Act, 1970.invention sufficiently and fairly in the specification. Section 64 (1) (i) contains two independent grounds for revocation i.e. (i) that the scope of any claim is not sufficiently and clearly defined and

(ii) the claim is not fairly based on the matter disclosed in the specification. Both these aspects are also specified in sec 10 of the Act.

Compulsory Licensing:

Compulsory licenses are authorizations given to a third-party by the Controller General to make, use or sell a particular product or use a particular process which has been patented, without the need of the permission of the patent owner. This concept is recognised at both national as well as international levels, with express mention in both (Indian) Patent Act, 1970 and TRIPS Agreement. There are certain pre-requisite conditions, given under sections 84-92, which need to be fulfilled if a compulsory license is to be granted in favour of someone.[8]

As per Section 84[9], any person, regardless of whether he is the holder of the license of that Patent, can make a request to the Controller for grant of compulsory license on expiry of three years, when any of the following conditions is fulfilled –

1. the reasonable requirements of the public with respect to the patented invention have not been satisfied

2. the patented invention is not available to the public at a reasonably affordable price

3. the patented invention is not worked in the territory of India.

Further, compulsory licenses can also be issued suo motu by the Controller under section 92[10], pursuant to a notification issued by the Central Government if there is either a "national emergency" or "extreme urgency" or in cases of "public non-commercial use".

Compulsory licensing allows a government to produce, import, sell and use generic products before expiry of the patent by licensing a company, government agency or other party the right to use a patent without the consent of the patent holder. The objective of granting compulsory licenses is to prevent the abuse of monopoly granted by the patent, and to safeguard the public welfare and health care issues prevailing in the nations. In the present context, the exercise is sought to obtain permission to manufacture the generic versions of a patented drug

7 Section 84 in The Patents Act, 1970

8 Section 92 ,The Patents Act, 1970.

The Controller takes into account some more factors like the nature of the invention, the capability of the applicant to use the product for public benefit and the reasonability, but the ultimate discretion lies with him to grant the compulsory license. Even after a compulsory license is granted to a third party, the patent owner still has rights over the patent, including a right to be paid for copies of the products made under the compulsory license.

In certain cases recently, the Indian courts have ruled that the provision against anti-competitive practices in the competition act and the provision of compulsory licensing in the patent act are not in exclusion of each other; in fact they have to be read conjunctly. The question whether a patentee had adopted anti-competitive practices could also be considered by the Controller. However, if CCI has finally found a patentee's conduct to be anti-competitive and its finding has attained finality, the Controller would also proceed on the said basis and-on the principle akin to issue estoppel-the patentee would be estopped from contending to the contrary.

The judicial approach with respect to grant of compulsory license is that the provision is for public welfare and it cannot be misused to diminish the rights of the patent holders. There must a balance between thee rights and making use of the product for welfare purposes.

Case Study of NATCO VS Bayer:[11]

Facts:

In March, 2008, Bayer Corporation ("Bayer") was granted an Indian patent for the drug "Nexavar", which is used for treating patients suffering from advanced stages of kidney cancer (Renal Cell Carcinoma) and liver cancer (Hepatocellular Carcinoma). On December 6, 2010, Natco Pharma Ltd. approached Bayer for grant of a voluntary license. However, the negotiations did not conclude. After the expiration of three years from the date of the grant of the patent to Bayer Corporation with respect to the drug, Natco applied to the Controller General of Patents for a grant of a compulsory license as per Section 84(1) of the Patents Act 1970 proposing to manufacture and sell the drug at a price of INR 8800/- per month of therapy. Despite the opposition by Bayer, the Controller granted the compulsory license to Natco to manufacture and sell the drug. An appeal was filed by Bayer challenging the order of the Controller before the Intellectual Property Appellate Board (IPAB).

9 Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013 (Intellectual Property Appellate Board, Chennai), available at http://www.ipab.tn.nic.in/045-2013.htm (Last visited on May 12, 2013)

However, this appeal was dismissed in March 2013, upholding the decision of the Controller, whilst the rate of royalty for the compulsory license as prescribed by the Controller was reduced from 7% to 6%. Thereafter, a writ petition was filed by Bayer before the Bombay High Court ("BHC") challenging the order of the IPAB but the BHC held in Natco's favor.

Section 84:

Under Section 84 of the Patents Act, [12]1970 an application for Compulsory License ("CL") can be made by any person interested after a period of three years have elapsed from the date of grant of a patent on any of the following grounds: i. the reasonable requirements of the public with respect to the patented invention have not been satisfied, or ii. the patented invention is not available to the public at a reasonably affordable price, or iii. the patented invention is not worked in the territory of India. Bayer's contention before BHC in relation to the above requirements: Firstly, Natco did not make a bonafide effort to obtain a voluntary license due to the reason that they failed to approach Bayer again after the rejection of the application for a voluntary license and hence, failed to satisfy the conditions for an application for CL considered by the Controller. Secondly, the onus was on Natco to establish reasonable requirement of the public so as to obtain a CL has not been satisfied. Bayer also contended that the sales made by Cipla Limited ("Cipla"), who were producing the patented drug, infringing the rights of Bayer should also be taken into account while considering the total quantum of the patented. drug made available in India. Thirdly, prior to determining whether the drug was available to the public at reasonably affordable price, it was important to first determine what can be construed as reasonable affordable price in relation to the drug and this determination was done by the Patent Controller. Along with this, Bayer also contended that Bayer had made available some of their patent drugs at much lower costs through their patient assistance program. Finally, Section 84(1)(c) of the Indian Patents Act, 1970 i.e. working requirement does not indicate that the patented product has to be locally manufactured.

Decision:

Regarding the first contention, the BHC was of the view that Bayer had clearly declined the request for licensing and Bayer's vague statement after rejecting the application of voluntary licensing of the drug was merely a request to add to the existing application of the voluntary license. Hence, the 12 Ibid.

Court stated that Natco had satisfied the requirement under Section 84 of the Indian Patents Act, 1970. [13]Regarding the second contention, the BHC observed that "reasonable requirement of public" test cannot be met on a mathematical basis and it can only be determined based on the evidence produced. As per the evidence provided, (affidavit of Dr. Manish Garg, Country Medical Director of Bayer), an aggregate of 8842 patients suffering from kidney cancer and liver cancer would require the drug. However, Bayer had sold only 593 boxes of the drug which was sufficient only for 200 patients. Furthermore, the BHC held that the sale by Cipla cannot be considered as Bayer had filed an infringement suit against Cipla. The BHC held that even if the supply of the drug by Cipla was added to Bayer's supply, the BHC held that it would still be insufficient and the reasonable requirements of the public would not have been met. It concluded that in respect of medicines the adequate extent has to be 100%. On the third contention, the BHC held that the Indian Patents Act, 1970 does not bestow any investigative powers on the Controller. The Controller can only ensure that the patented article is available at a reasonably affordable price based on the relative price offered by the patentee and the applicant. The BHC held that a patent controller can determine what is a reasonable affordable price based on the evidence produced before him. Bayer had not reproduced accounts before the patent controller even after his request for the book of accounts and Balance Sheet in determining the reasonable price at which Bayer could have made the drug available to the public. Further, the BHC also observed that 50% of the cost had already been reimbursed by the US government since the drug had been classified as an orphan drug. Thus, the BHC held that Bayer was not selling the drug at a reasonably affordable price since Natco was offering the drug at INR 8,800 per month of therapy as compared to Bayer's price of INR 284,000 per month of therapy. This shows that the reasonably affordable price is that of Natco and not Bayer.

With respect to the final contention, the BHC held that the patentee is required to make some effort to manufacture the patented product within the territory of India. The BHC agreed with the view of IPAB that the matter should be considered on a case to case basis and manufacturing in India is not the sole method of working a patent in India. A patent can be worked in India by importing the patented article in adequate quantity and supplying it. However,

working by import can be accepted

13 Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013 (Intellectual Property Appellate Board, Chennai), available at http://www.ipab.tn.nic.in/045-2013.htm (Last visited on May 12, 2013).

only after the patentee provides satisfying reasons for not manufacturing the patented product in India.

Case Study of Ericson vs Xiaomi [14]:

Facts:

Telefonaktiebolaget L. M. Ericsson ("Ericsson") is a Swedish Multinational company and is the registered owner of eight patents pertaining to AMR technology, 3G technology and Edge technology in India. It is amongst the largest patent holders in the mobile phone industry along with Qualcomm, Nokia and Samsung.3 The patents owned by Ericsson are considered to be Standard Essential Patents. Standard Essential Patents are those patents that form a part of a technical standard that must exist in a product as a part of the common design of such products. In the past two years, Ericsson has been suing various mobile handset companies on the ground of patent infringement in India. Companies such as Xiaomi Technology ("Xiaomi"), Micromax Informatics Limited ("Micromax"), Mercury Electronics ("Mercury") and Intex Technologies (India) Limited ("Intex"), which are major handset and smartphone provider companies in India and are being issued with ex-parte injunction orders by courts in India with respect to selling, advertising, importing and/or manufacturing devices that infringe the patents owned by Ericsson. Ericsson contended that the licenses on the standard essential patents were offered to be granted to these companies on fair, reasonable and non-discriminatory (FRAND) terms, however, these companies had refused to undertake such licenses and were using these patents without license and accordingly were infringing Ericsson's patents.

Decision:

The High Court of Delhi, held that prima facie Micromax and Xiaomi were dealing with a patent infringing product and therefore granted ex-parte injunction orders against them.6 Furthermore, the court also directed the Custom Authorities to take note of any consignment of the products undertaken by these companies. In the case of Xiaomi, Flipkart was also impleaded in the order and directed Flipkart to get rid of all the products of Xiaomi that may be patent infringing. Although,

14 IA 3074/2015 in CS(OS) 3775/2014

Xiaomi managed to acquire an order allowing the company to import and sell the devices that use the chipsets imported from Qualcomm Inc., a licensee of Ericsson, it was asked to deposit an amount of INR 100 for the sale of every device February 3, 2015. Furthermore, the High Court of Delhi also directed Micromax to pay certain set royalty rates to Ericsson pending the final outcome of the patent infringement suit, if Micromax wanted to continue selling the devices. Surprisingly, in the case of Intex, the High Court of Delhi did not issue an injunction and instead held that a hearing would be scheduled for the case of infringement as both the companies, Ericsson and Intex, were engaging in negotiations since 2008 and had also communicated on the previous day before filing the suit.

Conlcusion:

This statement may be correct for the Indian Judiciary as well. It can be seen that there has been very few litigated cases per decade; the reason is also described in the section above.60 Also it can be noted that the cases (mainly of Patent infringement) are mainly settled at the High Court level as almost 60% cases of the study are being decided by the Judiciary, and there was further appeal in only 3.3% cases to the Supreme Court, this shows the self content attitude of the Litigants showing lack of faith in the Judiciary. The researcher wishes to make following suggestion as regards improving the Patent Litigation system in India.

1) Formation of special courts for Patent Litigation. 62 Presently we have IPAB which under Sec 116 takes the appeal from the decision of the Controller. However, it is being recently that it is functional.63 I view that there should be Special Court for Patent Disputes (for both Patent Administrative disputes and Patent Infringement disputes) on the lines of CAFC in USA which have their own unique standards for examining and determination and appreciation of evidences, witness and expert testimony etc.

2) For any and all patent disputes cases, regardless of the first trial or the second trial, public trial is implemented whereby the public are allowed to observe, and the media are allowed to interview and report objectively. Such a doing can increase the transparency of the trial and ensure judicial fairness; and can educate and publicize legal knowledge about intellectual property rights to the mass and community, enhance citizen and legal person respect and the awareness of protecting the intellectual property rights.

3) A patent litigation pertains to expertise and technologies of various disciplines, and is characterized by difficulty of trial. Generally, a patent case is tried by an Indian court according to general procedures as stipulated in the Civil Procedure Code and Patent Ruled 2003. However, in my view for resolution of Patent disputes a collegial panel should formed by several judges for trail of such a case instead of one single judge. All and any judge forming the collegial court shall review and examine the files of the case, participate in the trial and collegial discussion, and jointly understand the responsibility of conclusion
of fact and application of law for the case.

4) In this regard it is put forward that even if Corporations or individuals owns Patents still there is piracy and large scale reverse engineering of Patented products, which leads to the conclusion that there is no point in claiming Patents. Therefore, to combat this type of system a separate Chapter should be included in the Patent Act for better enforcement purposes.

5) The provision of compulsory licensing[15] must be used judiciously as it is an exception and flexibility to the general rule of patent. The provision falls mid-way; neither full patent protection is granted, nor is it denied altogether it directly affects innovation funding and unfettered use of this provision may result in global pharmaceutical companies being hesitant to introduce new medicines in other countries. Hence the companies have to fix the cost of their patented module according to the economic status of the country if they want to protect their product from compulsory licensing.

6) Compulsory licensing has now become the hope for financially challenged patients in underdeveloped countries. India needs this provision owing to the economic condition of the majority population. But the challenge is that on one hand, it has to comply with the international standards of patent protection and on the other, it has to safeguard public health.

15 Alberto do Amaral, Compulsory Licensing and Access to Medicine in Developing Countries, 3 (SELA (Seminario en Latinoamérica de Teoría Constitucionaly Política) Paper No. 47, Yale Law School, 2005), available at http://digitalcommons.law.yale.edu/yls_sela/47/ (Last visited on May 12, 2013).

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