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Gunjan Chawla

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Abstract:

The objective of granting patent rights is to confer monopoly rights, the rights to exclusive use and exploitation of one's invention to the exclusion of all the others. However, this essentially requires that the rights claimed may only be realised once the claimed invention satisfies the three step test of Novelty, Inventive step and Industrial application. Any similarity or identity in the claims as made by the applicant may be challenged before the patent office in an infringement suit against such infringer. After the plaintiff establishes a prima facie case in his favour, the burden of proving non-infringement shifts upon the defendant. Moreover, in India, there is no presumption against the validity of the grant of patent by mere registration. Hence, the validity of a registered patent may be challenged by the defendant when charges of infringement have been levelled against him, and thus, he may absolve himself of the liability. Hence, the two major categories of defences shall either involve a proof of non-infringement - which shall require the defendant to prove that his patent claims don't fall within the suspicion of the claims made by the patentee in his application, or invalidity of the patent - wherein the defendant shall have to defend himself by raising doubts and questioning the grant of the patent. Although the rights of the patentee and their enforcement do find a place in almost all the legislations across the world, not much emphasis is laid on the defences that may shield the defendant in successfully combating an allegation of infringement levelled against him. Hence, the present paper is an endeavour to identify and meticulously discuss the various defences that may be availed by the defendant while he is caught up in a legal battle against the plaintiff, a brief critical analysis of the same and the reforms that may be made in order to ensure an effective and successful application by the defendant.

Key Words: *Class defences, Individualised defences, Gillette defence, Prosecution History Estoppel, Reverse Doctrine of Equivalence, Bolar Exemption, Parallel Importation.*

A right is realised when it becomes enforceable under the law, and a right to defend oneself is realised when the grounds for defence are allowed to prevail under the law. A defence is a right that enables the defendant in an actionable suit to absolve himself of the liability. Since it is a direct attempt to avoid what would otherwise constitute a liability, the burden of proof shifts on the defendant. It is this burden that is sought to be removed by arming him with the defences that shall shield the defendant against the accusations levelled against him. As in like the other laws, in Patents the defendant is conferred with an equal right to defend himself against any or all the allegations levelled against him by the plaintiff in regard to determining his liability for infringement of the patent.

A patent infringement suit comprises of two separate battles - one where the plaintiff alleges infringement and claims damage for the same, and the other where the defendant attempts to terminate the patent rights by proving invalidity of patents or disproving infringement on his part. Hence, although the initial burden of proving infringement lies upon the plaintiff, the real burden of disproving any infringement lies upon the defendant, and hence, as such, a tacit application of one or more of the several defences that are available becomes crucial in deciding the fate of the allegation.

NUANCES OF A PATENT INFRINGEMENT SUIT

Unlike the Indian Copyright and Trademark Laws that specifically define "infringement,"[1] the Patents Act provides it in the form of an enforcement right under Section 48, implied under the exclusive rights granted to the patentee against a third party's unauthorised use. In *Monsanto Canada Inc.* v. *Schmeiser,*[2] it was defined to mean 'any act that interferes with the full enjoyment of the monopoly granted to the patentee' or 'any activity that deprives the inventor, in whole or in part, directly or indirectly, of full enjoyment of the monopoly

1 The Copyright Act, 1957, S. 2(m) r/w Section 51; The Trademark Act, 1999, Section 29

2 [2004] 1 S.C.R. 902 at para. 34-35

conferred by law.' Hence, it is the invention that defines the boundaries of the monopoly rights that shall be conferred upon the patentee.[3] However, this monopoly shall end if the limits of the claims as specified in the specification by the patentee fall under the mischief of any of the grounds that culminate to revoke his patent under section 64 or if the claims are absolutely beyond the ambit of the patentable inventions. Hence, under these circumstances his claim for infringement shall fail if the defendant succeeds in invalidating the patent or proves non-infringement if the use by him falls under any of the express limitations and exceptions that are excluded from amounting to infringement.

Patent Law imposes liability for an independent development. This implies that even if a single claim made by the defendant falls within the subject matter and scope of the claims made by patentee, the former may be held liable. The fact of "intention to infringe" is irrelevant.[4] Whereas "the fact of accidental similarity" and "an honest concurrent use" is an admissible defence under copyright and trademark laws, respectively; patent law merely offers the alleged infringer to challenge the validity of the patent in order to defend the allegation of infringement, thereby shifting the onus on the defendant. The presumption as to the presupposition of the defendants' involvement in the act of copying the patent is much higher than the presumption against the validity of the patent.[5]

Patent infringement occurs when a product or process developed by the defendant is claimed to infringe one or more patent claims made by the patentee. Determination of patent infringement involves a two-step process - *firstly* a product or process is analysed and compared with all relevant patents and their specific claims in an invention similar to the product. *Secondly*, the product or the process is scrutinized to see if the product or the process 'reads on' one or

3 *Free World Trust v. Électro Santé Inc.*, [2000] 2 S.C.R. 1024 at para. 31

4 Christopher Cotropia, Mark A. Lemley, *Copying in Patent Law*,2008,(available at- https://pdfs.semanticscholar.org/fb4d/f45b93bd87b242b7b07c2f9d2a3c1f4dad4b.pdf)

5 This is not applied and adhered to in all the jurisdictions, and in India this principle of presumption against validity of the patents is not followed. It is the patentee who has to prove the fact of infringement by the defendant when he files a suit claiming infringement.

more patents and substantially describes itself in the language of the claims of the one or more patents. Hence, the patentee has to prove that the very essence of his invention, the claims and specifications that constitute the 'pith and marrow' of his invention have been copied or taken by the alleged infringer.

DEFENCES TO PATENT INFRINGEMENT SUIT

It is axiomatic that a suit for patent infringement entails a strict liability upon the alleged infringer, and the Court shall grant an injunction against the defendant if the fact of infringement is proved, and may also be held liable to pay damages or account of profits at the option of the plaintiff.[6] The defences to patent infringement may broadly be categorised into three forms: **Direct, Indirect and Contributory Infringement.**[7]

Direct Infringement implies an infringement where the alleged infringer commits the acts of selling, using, making or importing of the patent for commercial purposes without the consent of the patentee during the term of the patent. In case of an **Indirect Infringement,** there is a third party who makes, uses or sells an embodiment of the invention without the consent of the patentee as a consequence of deceit or accidental patent infringement. Further, if such a product is knowingly supplied or sold then the same amounts to **Contributory Infringement.** The fact of infringement shall have to be proved by comparing the claims made by the defendant with that of the plaintiff. It is here that the question of establishing infringement shall involve an imperative enquiry into the validity of the patent.

In response to this, the defendant shall have to argue on two grounds: Invalidity of the patent and/or Non-infringement.[8] The non-infringement defence

6 *Indian Patent Act, 1970,* Section 108

7 *Patent Infringement in India*, IPRO services Ltd. India., p.4-5 (available at-http://www.ipproinc.com/admin/files/upload/dc8904b7508e51355b25f6ca0d386e8e.pdf) 2009

8 Roger Ford, *Patent Invalidity versus Infringement*, CORNELL LAW REVIEW, 2013(available at-https://www.kentlaw.iit.edu/Documents/Academic%20Programs/Intellectual%20Property/PatCon3/Ford%20Paper.pdf)

focuses on whether or not the defendants' product or process falls within the monopoly rights that are conferred upon the inventor in lieu of his invention and disclosure. It also includes cases where the defendant proves an authorised use of the patented invention in the form of Government use, Bolar exemption or parallel importation.[9] On the other hand, the defence of invalidity re-examines the fulfilment of pre-requisite criteria for the grant of patents, i.e., whether the invention is novel, non-obvious and has been disclosed to the world in compliance with the provisions of the patent law.[10]

The defence of non-infringement merely argues on the line that the alleged infringers' product doesn't fall within the suspicion of the limits claimed by the patentee in the patent application and, hence, a case of infringement is far from being made out. This can be determined by the application of the "all elements rule" or "doctrine of equivalence" wherein the Courts shall begin with construing the language in the claims made by the patentee and then a comparison with the alleged infringing product to see if it covers every limitation of the claims of the patent. In case it doesn't, then no infringement is ruled out.

The invalidity defence questions the validity of the patent and its grant, based on the "state of art" available at the time when the patent was granted and the threshold limit of the PHOSITA. Hence, it strikes at its authenticity on the grounds of lack of novelty and inventive step - a sine qua non for getting patents. This invalidity defence is further based on three doctrines[11]:

- Doctrine that satisfies the novelty and non-obviousness requirements,[12]
- Doctrine that fulfils the disclosure requirement[13]
- Doctrine that covers those inventions which are patentable.[14]

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9 *Indian Patent Act, 1970,* Ss. 107(b) 107A(a) and 107A(b)

10 Roger A. Ford, *Patent Invalidity Versus Noninfringement*, 99 Cornell Law Review, p.7 (available at-https://www.kentlaw.iit.edu/Documents/Academic%20Programs/Intellectual%20Property/PatCon3/Ford%20Paper.pdf)

11 Andres Sawicki, *Better Mistakes in Patent Law,* 39 FLA. ST. U. L. REV. 735, 742–44 (2012)

12 See, *Indian Patent Act, 1970,* S. 64(e)-(f).

13 *Ibid,* S. 10(4).

14 *Ibid,* Ss. 3 and 4

As far as the provisions under the Indian Patent Act are concerned, the invalidity defence is implied under the following provisions:

i. *Section 64* which seeks to provide for revocation of a patent after it has been granted. If the pre-requisite conditions prior to the filing of the patent application and grant of such patent have not been fulfilled as per the provisions under the Patents Act,[15] such grant may be revoked.

ii. *Section 25* which enumerates the grounds for pre-grant and post-grant opposition of a patent after its publication. The oppositions levelled by any person interested relate to the non-fulfilment of the conditions prior to the filing of the patent application or after the patent has been granted.[16]

iii. *Section 107* which enumerates the grounds for defences to a patent infringement suit under Section 64 in the form of counterclaims.

The most basic asymmetry between litigating invalidity and non-infringement lies in the burden of proof; invalidity must be proved by clear and convincing evidence, while infringement must be proved only by a preponderance of the evidence.[17] Therefore, in an invalidity defence, the burden on the defendant is substantially greater than that in the case of the latter. It is because of this reason that generally the non-infringement defence is preferred over the invalidity defence. Invalidity is a question about the asserted patent, so it depends on information about that patent—its claims, specification, and prosecution history—and information about the state of the world when the patent was granted, and to that extent, the invalidity argument can be said to be based on prior art. Non-infringement, on the other hand, is a question about the accused product or process, so it depends on the features and workings of that product or process. In fact, it is the claim construction in both these cases that

15 *The Patents Act, 1970*, Ss. 3, 6, 8, 9, 10, 35, 48

16 *ibid*

17 *Microsoft Corp. v. i4i Ltd. Partnership*, 131 S. Ct. 2238 (2011) (invalidity); *Centricut, L.L.C. v. Esab Group, Inc.*, 390 F.3d 1361, 1367 (Fed. Cir. 2004) (infringement).

plays a very crucial role in determining the invalidity (on the basis of claim construction of the prior art and the patent in question) or non-infringement (determined on the basis of claims made by the alleged infringer and that of the patent it is alleged to infringe).

(A) THE META-THEORY ON CLASSIFICATION OF DEFENCES

Apart from the above categories, according to the meta-theory of law, all forms of intellectual property can be said to be encompassed under three conceptual categories of defences, namely: General, Individualised and Class defences.[18] This classification is based on the nature of the alleged infringement and the nature of the infringer itself.

1. **General defences** are those that challenge the validity of the patent itself and the right of the patentee as the conditions for obtaining a patent remain unfulfilled. It is such a defence that altogether negates the validity of the patent in front of the entire world and annuls not only the defendant, but also the entire world, of the duty to comply with it. Such defences are enumerated under S. 107 r/w 64 of the *Indian Patents Act, 1970,* as discussed above. Application of these defences requires a comprehensive and detailed enquiry on part of the defendant into the claims made by the patentee and prior art. Such defences may be likened to the concept of rights in rem when applied inversely to the defences against the plaintiff.[19]
2. **Individualised defences** are those where the defendant absolves himself of the liability of any infringement on his part. Such defences are much narrower because they are bent upon only defending the alleged infringer in the particular suit itself and are generally classified as non-infringement defences, where the defendant seeks to prove no liability on his part, rather

18 Gideon, A. Stein, *Intellectual Property Defences*, COLUMBIA LAW REVIEW, VOL. 113, NO. 6 (OCTOBER 2013)(available at- http://www.jstor.org/stable/23561268)

19 *Rights in rem* are rights that are available against the whole world. This conception, when applied inversely to the defenses available against the plaintiff, shall have a similar effect of being applicable by all the prospective defendants against the plaintiff in the matter relating to negating the validity of the patent.

than attacking the rights of the patentee in relation to the patent. Thus, the rights of the patentee remain intact. Hence, a successfully pleaded individualised defence defeats the specific infringement claim in that particular suit. These defences provide immunity to the defendant and justify the use of the impugned patent. The benefit of an individualized defence accrues exclusively to the defendant who raises it, and his victory does not change the legal status of other potential defendants. Examples of such defences include: A claim that a later invention doesn't fall under the claims made by the defendant, Inequitable conduct on the part of the plaintiff, Government use, Gillette defence, Reverse doctrine of equivalents, etc. Conceptually, therefore, individualized defences are inverse of rights in personam,[20] rights that avail only against a particular individual.

3. **Class defences:** Class defences form an in-between category. They create an immunity zone for a certain group of users to which the defendant belongs, without nullifying the plaintiff's right. Unlike general defences that have the potential to negate the right asserted by the plaintiff, and individualized defences that do not impact the plaintiffs right against any future defendants, class defences, when successful, block claims against a specified class of defendants. Examples include Research and Experimental use or Bolar Exemption and Parallel Importation. It thus tends to set up a categorical bar against certain infringement claims, thereby protecting a specified class or category of defendants. There are various Universities and research institutes that make use of the inventions for the purpose of further research or teaching. Similarly, the importation of patented drugs by way of a legal sale for the purpose of distributing it at lower and cheaper prices to ensure its access to all shall provide immunity to such

20 *Rights in personam* are available only against the person who is responsible for violating the right of the plaintiff. There is only one defendant who is held liable for violation of rights. In a similar way, an inverse application of this concept to the defences available at the disposal of the defendant against the plaintiff can be said to be a defence which only he can use as a shield in a suit for infringement such that he can absolve himself of the liability.

generic companies or organisations against any claim of infringement. Class defences are thus a conceptual mirror image of *quasi-property rights,* as they protect the entire genre or category to which the defendant belongs.

Hence, the above discussion gives rise to the following propositions:

- That general defences are a form of invalidity defence that invalidate a patent and an infringement claim as against a specific defendant only.
- That the individualised and class defences are forms of non-infringement defences. They negate the claims of infringement by proving that the alleged infringement falls outside the scope of the claims made by the patentee.

(B) TYPES OF INDIVIDUALISED DEFENCES

As has already been explained, these are such defences, the usage and application of which depends upon the facts and circumstance of the case at hand and are such that only protect the defendant against the claims of infringement, such that he is able to prove non-infringement by pleading these defences, so as to absolve himself of the liability alleged against him. Some of such defences include the following:

a) Gillette Defence

This is such a defence that can be said to be a combination of both the defences of invalidity and non-infringement and, in fact, is somewhat like striking at the validity of the patent based on proving non-infringement of the patent, and is a way of arguing non-infringement by proving invalidity without requiring the patent claims to be construed. The argument is that in circumstances where the patent is capable of two constructions – one wide and one narrow – the defendant gives the plaintiff a Hobson's choice: if you construe the claim narrowly, the defendant does not infringe; construe the claim broadly and it encompasses the prior art which invalidates the patent.[21]

21 Janice M. Mueller, *An Introduction to Patent Law,* (Aspen Publishers Inc., 4th ed., ISBN-10: 1454822449) 2012

According to Terrell,[22] Gillette defence is, "An Infringement not Novel' (Gillette defence). Since no relief could be obtained in respect of an invalid patent, if the defendant could prove that the act complained of was merely what was disclosed in a publication which could be relied on against the validity of the patent, without any substantial or patentable variation having been made, he had a good defence."

The defendant argues that the patentee had been using a product or process that was known at the time of the patent (i.e., patentee is recreating the prior art), and since the product or process is covered by the patent then, the patent is invalid on the grounds of obviousness and prior art. The defendant's argument is that if the plaintiff asserts a broad interpretation for its patent claims so as to read onto the allegedly infringing product, the patentee runs the risks of having its patent anticipated by the prior art. If the claims are interpreted too narrowly to avoid a novelty attack, the alleged infringing product might fall outside the scope of such an interpretation. Either way, the defendant wins if the Gillette defence is effectively deployed.

The court shall then make a comparison of three-versions of the invention. Firstly, the alleged prior art within the claims of which the defendant alleges that the patented invention rightly falls. Secondly, the patented invention itself as is claimed, by broadly construing the claims as far as the prior art is concerned and narrowly construing it as far as the defendants patent is concerned. Thirdly, the court shall construe the claims of the defendant and determine whether the defendants patent is broad enough to fall within the suspicion of the claimed invention or that the patented invention is itself something that is mere extension of the prior art and is something that is already there in the public domain.

This defence was propounded by the court in the case of *Gillette Safety Razor Co v Anglo American Trading Co Ltd,*[23] where the alleged infringement was

22 Terrell, *Terrell on Patents*, 8th edition p.170

23 [1913] 30 R.P.C. 465

defended on the grounds that the infringement was obvious. Gillette alleged that the defendant had infringed its 1902 patent for an improved safety razor. The difficulty for Gillette was that the alleged infringement was almost identical to an item in the prior art base. The patent in this case was for an improvement of safety razors, the main feature being a thin flexible razor blade clamped in a curved holder by the handle. The effect of such clamp was to make the blade rigid. The alleged infringement by the defendant also consisted of a similar razor in which the blade was flat. The defendant pointed out the existence of American prior patent which involved the use of the handle as a clamp to hold the razor blade. He argued the defence of invalidity and non-infringement. Hence, this way, if the claims of the patent were interpreted widely so as to catch what defendant had done, the patent would be invalid because it was anticipated by prior art. On the other hand, if the patent was narrowly construed, the defendant patent would fall outside the limits of patentees' claims.[24]

Further in *Page v. Brent Toy*,[25] the Court explained the limits of the Gillette defence and stated that it is not a separate defence, but rather a convenient form of raising an alternative plea of invalidity and non-infringement.

Gillette Defence in India

As far as its application to the Indian law is concerned, the issue came for consideration before the court in *J. Mitra and Company Private Limited v. Kesar Medicaments*.[26] The case involved a claim of infringement of the patent of the plaintiff in respect of a device for detection of antibodies to Hepatitis C Virus in human serum and plasma. The defendant in his turn submitted that even if his products or diagnostic kit falls within the four corners of the said patent, it would not constitute infringement as the impugned product was based on a prior US patent. In the instant case, ruling out the possibility of the application

24 Helen Norman, *Intellectual Property Rights,* (Oxford University Press, 2014 , ISBN-0199688109, 9780199688104) (available at- https://books.google.co.in/books?id=m0VZAwAAQBAJ&dq=gillette+defence+patent&source=gbs_navlinks_s)

25 (1950) 67 RPC 4

26 2008 (36) PTC 568 (available at-indiankanoon.org/doc/947992/)

of the Gillette defence, the Court held that the defendants product directly fell within the limitations of the claims made by the plaintiff, and that the patent was not based on prior art as alleged by the defendant.

There has not been much significant development in this regard, and it is only on the basis recognition of persuasive value of its application abroad can the inherent meaning and intent of the same be realised in the Indian context. In India, such defences are only employed by way of proving that the invention has its roots in prior knowledge, or prior use and art and hence is devoid of any element of novelty.

b) Prosecution History Estoppel and Reverse Doctrine of Equivalence[27]

The essence of inventions applied for the grant of patent lies in the claims and it's the claim construction that forms the genesis of decision in a patent infringement suit. Something that is not claimed is deemed as being disclaimed, and something that has been amended is deemed to have further limited the scope of the claims. It is this determination of infringement that may either be 'literal infringement' or may be said to have been infringed by virtue of 'doctrine of equivalence' (DOE). The former occurs when each and every element in the claim is proved to have an identical correspondence in the allegedly infringing invention. Under DOE, an accused article or method that may not literally meet the limitations of a claim, may nevertheless infringe if the accused article is equivalent to the claimed invention.[28] *Therefore, even if there is no literal infringement, but the accused product functions in the same way, to produce the same result as that of the patent in question, liability entails.* Hence, these are such means at the disposal of the patentee that expands the scope of patent protection and enhances the chances of liability of the defendant. The test to determine equivalency is *whether the difference between the feature in the accused device and the limitation literally recited in the patent claim is "insubstantial" and so there is infringement.*[29]

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27 Elizabeth Verky, *Law of Patents*, (Eastern Book Company, ed. 2005, ISBN-81-7012-870-6) p.320

28 *Graver Tank & Mfg. Co. v. Linde Air Products Co.*,339 U.S. 605 (1950)

29 *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997)

However, as against this the defendant has at his disposal two defences that act as a limitation to the DOE - the Prosecution history estoppel (PHE) and the Reverse Doctrine of Equivalence (rDOE).

i. ***Prosecution History Estoppel:*** The PHE, also known as the file-wrapper defence,[30] is a judicially created doctrine that estoppes the plaintiff from employing the DOE to prove infringement if he had amended the scope of his patents during the prosecution of his patent application so as to limit the scope of his claims to be brought within the ambit of the patent law. A patentee shall be precluded from contending infringement by way of DOE against an alleged infringement *if the subject matter of the claims were surrendered by the patentee* during the prosecution of his patent by way of amendments. The PHE, therefore, restricts or bars the patentee from claiming a right which he has earlier waived and arms the defendant to escape from any liability of infringement. The defence can be raised - where there is no literal infringement, the patent owner asserts infringement by equivalents, and the accused affirmatively asserts the defence of PHE that it prevents the patentee from asserting the DOE, as the relevant subject matter has been disclaimed during prosecution. Even unmistakable assertions made by an applicant shall also operate to preclude the patentee from asserting equivalency.

It was in *Warner-Jenkinson Company, Inc. v. Hilton Davis Chemical Co.*,[31] that for the first time the court limited the scope of application of the DOE in cases where the reasons for the amendments remained unexplained in the prosecution history; the burden lies on the patentee to establish the reasons thereof. Where no such reasons are accorded the presumption shall rely on the fact that such amendment was essential to fulfil the criteria of patentability, and such an unrebutted presumption of the PHE acts as a complete bar to application of

30 The term was for the first time coined in *Kellogg Switchboard & Supply Co. vs. Michigan Bell Tel. Co.* [5 F. Supp. 118, 119 (E.D. Mich. 1933)], whereas, the term PHE appeared for the first time in *Hughes Aircraft vs. United States* [717 F.2d 1351, 1362 (Fed. Cir. 1983)]

31 520 U.S. 17 (1997)

DOE in a disputed claim limitation. It was held that the DOE is to be applied to each individual element of the claim, and not to the invention as a whole.

Later, it was in *Festo Corporation v. Shoketsu Kinzoku Kogyo Kabushiki Co. Ltd.*[32] that pertained to invalidity and infringement claims in an invention for 'magnetically coupled rodless cylinder' that the Court described in its entirety the scope and application of PHE as against the DOE. Initially, the Federal Circuit observed that the PHE was a complete bar to the application of the DOE, and that in cases where the scope pf the patent was narrowed by way of amendments for the sake of patentability, there remains no scope for infringement on the grounds of equivalence. However, on appeal the Supreme Court reversed and remanded, and preferred a 'presumptive bar' approach to DOE. This presumptive bar approach holds that where claims are amended, "the inventor is deemed to concede that the patent does not extend as far as the original claim" and the patentee has the burden of showing that the amendment does not surrender the particular equivalent. For this the patentee shall have to prove that:

- the equivalent was unforeseeable at the time the claim was drafted;
- the amendment did not surrender the particular equivalent in question; or
- there was some reason why the patentee could not have recited the equivalent in the claim.

Hence, due to such an observation, the initial burden has shifted upon the patentee to prove the fact of infringement on the grounds of DOE, and in case of failure of the same, the defendant shall easily have the defence on the grounds of PHE.[33] The test is a three-stage test:

- Whether the amendment narrows the scope of the claims?
- If so, was it carried out to meet the criteria of patentability?

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32 535 U.S. 722 (2002)

33 *See,EMD Millipore Corp. et al. v. Allpure Techs., Inc*(Fed. Cir. Sept. 29, 2014); *Pacific Coast Marine Windshields Ltd. v. Malibu Boats, LLC*, Fed. Cir. Jan. 8, 2014); *Trading Techs. Int'l, Inc. v. Open E Cry LLC*,(Fed. Cir. Aug. 30, 2013)

- If the presumption is deemed true, then the patentee is presumed to have surrendered and waived all that was claimed earlier and is barred under PHE.

ii. ***Reverse Doctrine of Equivalence:*** Another defence available to the defendant as far as his defence relates to negating allegations of infringement on account of identity of claims is that of Reverse Doctrine of Equivalence (rDOE). The "normal" DoE extends the scope of a patent beyond the literal bounds defined in the claims to prevent an infringer from making insubstantial changes or unforeseeable minor improvements in the invention as a way to avoid infringement. The reverse DoE, on the other hand, contracts the scope of a patent to allow a literal infringer to escape sanctions such as to prevent a patentee from extending the reach of the claims beyond the fair scope of the invention.

In *Hoffmann-La Roche Inc. v. Apotex Inc.,*[34] the Supreme Court observed that, "*Where a device is so far changed in principle from a patented article that it performs the same or similar function in a substantially different way, but nevertheless falls within the literal words of the claim, the reverse doctrine of equivalents may be used to restrict the claim and defeat the patentee's action for infringement.*" But, it was also added that '*this doctrine is* ***rarely applied, and this court has never affirmed*** *a finding of non-infringement under the reverse doctrine of equivalents.*'

Thus, where an invention relies on the fundamental concept embodied in a patent but is more sophisticated than the patented device due to a significant advance, the accused device does not infringe by virtue of the rDOE. It is applied by the courts to find that an invention does not actually infringe on a patent even if it technically does. In determining whether or not to use the reverse doctrine of equivalents, a court will consider several factors:

- What is the actual scope of the patent? Does it cover the new invention?

34 Fed. Cir. Apr. 11, 2014(available at-www.patentdocs.org/.../hoffman-la-roche-inc-v-apotex-inc-fed-cir-2014)

- If so, should that patent extend to the new invention? This is the major issue that the reverse doctrine of equivalents must address. What is the fair scope of the patent?
- Has the new invention sufficiently transformed the original invention such that it should fall outside the scope of the patent of the original invention?

PHE and RDOE under Indian Law: Under the Indian patent Act, 1970, the provision for amendment to the application of patents or complete specification (CS) or any document thereof can be made under the provisions of ***S.57 and 59*** of the Act at any time either before or after the grant of the patent. It is imperative that such an application proposing amendment must state the nature of the proposed amendment and shall give full particulars of the reasons for which the same is being made. An application for amending the CS may also include an amendment of the priority date of the claim. However, every such amendment must be made in accordance with the following guidelines[35]:

- They must only be made by way of a disclaimer, correction or explanation;
- No such amendment shall be allowed except for the purposes of incorporation of actual fact;
- In case of amendment of CS, an amendment shall not be allowed if is such as to give effect to something in the specification that claims or describes a matter not in substance disclosed or shown in the specification before the amendment;
- No such amendment must be such that any claim of the CS that is amended would not fall wholly within the scope of any claim of the specification before amendment.
- The scope of the invention must not be widened by such an amendment, as a patentee cannot be allowed to make a claim for a

35 *Indian Patent Act, 1970*, Section 59

monopoly right which was not included in the specification earlier. Apart from these, S.54 provides for improvement of, or modification in, the invention described or disclosed in the specification when an application for grant of patent has also been filed for such invention the applicant has also filed before the Controller, who may grant in favour of such improvement as a Patent of Addition. However, it is important that such improvement must be more than a mere workshop improvement.

In *Ravi Kamal Bali vs. Kala Tech,*[36] it was held that finding of equivalence is a determination of fact, and proof can be made in any form through testimony of experts skilled in the field or an authoritative document on the subject. The proofs are highly technical in nature and involve a detailed analysis of the scope of claims, and it is crucial that the court understand the issue before granting an injunction order. In this case, although the court initially applied DOE, injunction was not granted on the ground that the material aspect was represented erroneously. It was also implied that if there is question of validity of the patent itself, then the injunction on the modification or improvement later will not be granted. In this case, it was stated that DOE is an important principle to cover direct or literal infringement under patent law.

Until now, in India there has not been any significant application of the PHE or rDOE in any case at hand, and nor is there any explicit provision under the provisions of the Act to infer its application and use. As such, the relation of such provision under the Patents may be made in relation to the Doctrine of Estoppel as enumerated under the ***Indian Evidence Act, 1872 u/s.115.***[37] A

36 [2008(110) Bom.L.R.2167]

37 *Indian Evidence Act, 1872,* Section 115 states: *"When one person has, by his declaration, act or omission, intentionally caused or permitted another person to believe a thing to be true and to act upon such belief, neither he nor his representative shall be allowed, in any suit or proceeding between himself and such person or his representative, to deny the truth of that thing."*

bare reading of the provision indicates that once a statement has been admitted to which has the effect of forcing another person into believing into the truth of the statement, then the person making such statement is estopped from denying the truthfulness of the same. Hence, once you have admitted a thing, the same cannot be denied at other time. The intent and purpose of this provision is similar to the intent underlying the doctrine of PHE. Moreover, since in the cases of infringement, it is the evidence of both the parties that has to be taken into consideration, and since PHE is one of the primary evidences to be considered by the court while interpreting the claims in an infringement suit,[38] the principle objectives underlying its application and use may also be imported to the Patent Act, and the courts may take into consideration the criterion stipulated under the Evidence Act to be synonymous with the one required to bar the patentee from declaiming the fact of the claims and limitations incorporated into the claims of the invention by way of amendment, when the same is without any reason or justification.

The fact that ***u/s.57*** a pre-condition for application of amendment is that the amendment must state the reasons for the proposed amendment and, also, provide the full particulars of the reasons for the same. This may be related to the principles underlying the PHE doctrine that may be successfully pleaded by the defendant as a defence in cases where the patentee fails to assign reasons for amending his patent and amends the same for fulfilling the patentability criteria. In such cases, the patentee shall be barred by application of PHE to plead DOE to prove infringement. This may indirectly be construed as indicating the application of either DOE or PHE based upon the fulfilment or non-fulfilment of the conditions stipulated therein, respectively. Further, ***S.59(3)*** provides that while construing the amended specification, reference may be made to the specification as was originally accepted, i.e., the initial specification. This may also be deemed as being an indirect reference to the PHE.

38 *Markman v. Wetview Instruments Inc.,* (52 F.3d 967 (1995) 63 USLW 2663, p.7(available at-http://www.oceantomo.com/system/files/MarkmanvWestviewInstrumentsInc_0.pdf)

(C) TYPES OF CLASS DEFENCES

Class defences are such that they help in defending the entire class of the probable infringers who are engaged in the use and exploitation of the patented invention. These are such uses that are in the public interest, and this is one of the most crucial factors that may help in defending against the infringement allegation. Two of such defences that have been expressly laid down under the Indian Act are those relating to Parallel Importation and Bolar exemption, while another defence is that of research or experimental use which is not expressly provided under the Indian Act, but is followed in US and UK. The following shall be discussed at length in the present section.

a) Parallel Importation

The term parallel importation is nowhere defined or used under the Indian Act, but the same is implied in the wordings of the ***Section 107A(b)*** which provides for international exhaustion, thereby providing a considerably liberal patent infringement defence. The term finds mention in the Statement of Objects and Reasons appended to the Patents (Second Amendment) Bill, 1999, which became the Patents (Amendment) Act, 2002.[39] Parallel importation is in fact an antithesis of the doctrine of Exhaustion that is widely recognised under other jurisdictions, under which the rights of the patent owner are deemed to have exhausted over the royalty or other such monetary gains that accrue in subsequent sales after the very first sale of his patented invention. It may be said to be a natural consequence of doctrine and represents a form of price arbitrage whereby a legitimate product is imported from the market intended

39 *The Patents (Second Amendment) Bill, 1999* (which eventually became the Patents (Amendment) Act, 2002) was introduced in the Parliament on 20th December, 1999. (available at- http://rajyasabha.nic.in/ journals/188/20121999.htm.) Thereafter, a motion was passed and adopted by the Rajya Sabha on 21 December 1999 and by the Lok Sabha on 22 December, 1999, to refer the Bill to a Joint Committee of both Houses of Parliament (available at- http://www.parliamentofindia.nic.in/ls/bulletin2/ 01/D151101.htm. The Bill was placed before the Rajya Sabha for consideration on 9 May, 2002. (available at- http://commerce.nic.in/pressrelease/pressrelease_detail.asp?id=880)

by the patent holder to another market where it can be sold at a higher price.[40] Parallel importation is closely associated with the exhaustion, because parallel importation can be defined as: "the importation of a good or service as to which exhaustion of an IPR has occurred abroad is commonly referred to as Parallel Importation.[41]

'Exhaustion' refers to the lapse of the exclusive right of distribution of the right holder, who loses or 'exhausts' certain rights with regard to one specific product after the first use of the subject matter, once the product has entered the market with the consent of the right holder.[42] The doctrine of exhaustion imposes certain limits on the patentees' exclusive rights. According to this doctrine, "a patented item's initial authorized sale terminates all patent rights to that item."[43] Consequently, the patentee cannot control the resale or re-distribution of the particular item that has already been sold once.

The term "parallel importation" refers to goods produced and sold legally and, subsequently, exported. Grey and mysterious may only be the distribution channels by which these goods find their way to the importing country.[44] It is here that such imported good, or for that matter the patented invention when imported in a country, are not considered infringing and, thereby, in competition with the invention of the patent holder due to the application and prevalence of the exhaustion doctrine in the country to which such goods are imported. Lawfulness of parallel imports, defined as imports without authorization from the right holder of patented goods from the third country,

40 Gene M. Grossman & Edwin L. C. Lai, *Parallel Imports and Price Controls*, 39 RAND J. ECON. 378, 378 (ISSN 0741-6261) 2008

41 UCTAD-ICTSD, *Resource Book on TRIPS and Development*, (New York: Cambridge University Press 2005, ISBN- **ISBN-13:** 0521850445-978)), p.93.

42 Hiroko Yamane, *Interpreting TRIPS : Globalisation of Intellectual Property Rights and Access to Medicines*, (Hart Publishing Ltd., UK, 2011, ISBN-)

43 *Quanta Computer, Inc. v. LG Electronics Inc.*, (No. 06-937) 453 F. 3d 1364, reversed (Supreme Court June 9, 2008

44 Christopher Heath, *Parallel Imports and International Trade,* Vol. I (1999), (available at http://www.wipo.int/edocs/mdocs/sme/en/atrip_gva_99/atrip_gva_99_6.pdf)

depends on the exhaustion regime of a country, i.e., whether the country adopts policies of national, regional or international exhaustion. Depending on the policies that a country adopts, right holders may be unable to enforce particular rights in another jurisdiction.[45] Were it not for such "exhaustion" of rights, a purchaser of a patented article might be prevented from selling the said item or even "using" it, since such "sale" or "use" implicates the exclusive rights of the patentee.[46]

Hence, these goods that are imported are not unauthorised, per se, but are such goods where there is no express authorisation but are legitimate goods brought from the legitimate sale of the good. The only right that the importer of such good is conferred with is that of the right of distribution of such goods, without further obtaining consent from the right holder of the said good. The alleged infringer may bypass the exclusive rights of the patentee and make use of the patented invention to his advantage without any liability, but for this defence of parallel importation.

b) Regulatory or Prior Use defence (Bolar Exemption)

Another exception to the patent rights is the Research Exemption which may be used as a credible class defence. These can be of two types: Purely scientific in nature and Developmental research aimed at generating experimental data with a commercial objective.

It is this latter type that is called the Bolar Exception in the patent parlance and has derived its name from the famous case in the US *"Bolar v. Roche Pharmaceuticals"* in 1984.[47]

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45 UCTAD-ICTSD, *Resource Book on TRIPS and Development*, (New York: Cambridge University Press, 2005), p.92

46 Shamnaad Basheer, *TRIPS, Patents and Parallel Imports in India: A Proposal for Amendment,* INDIAN J. INTELL. PROP. L.p.3 (available at-http://www.nalsar.ac.in/IJIPL/Files/Archives/Volume%202/4.pdf)

47 Suresh Kumar, *Patent laws and Research Exemption imperatives- do scientists have enough freedom to operate?* CURRENT SCIENCE, Vol.99, No.11, December, 2010 (available at-www.currentscience.ac.in/.../article_id_099_11_1523_1529_0.pdf)

It was in order to comply with the TRIPS mandate that the Patents (Amendment) Act, 2002, introduced the Bolar provision to allow the use and sale of the patented product during the term of the patent for obtaining regulatory approvals. The amended Act 2005 has revised this to include the act of importing as well. The provision has been selectively transposed from the US law.[48]

The origin of this exception dates back to the decision by the US Supreme Court in *Roche Products Inc. v. Bolar Pharmaceutical Co.*[49] where the Court of Appeal held the competitors' use of a patented drug for the purposes of Food and Drugs Authority (FDA) approval of its generic version to be infringing, in spite of the fact that the generic drug was not marketed until the expiration of the patent term, thereby closing doors for the generic companies to enter into the market immediately after expiry of the patent term. After this judgement, the US Congress passed the Hatch-Waxman Act, 1984,[50] that sought to amend the Federal Food Drug and Cosmetic Act and introduced a process for New Drug Application (NDA) that extended the patent term after the grant of the FDA approval and created an Abbreviated New Drug Application (ANDA) process for generic drug developers to obtain the FDA approval.[51]

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48 Saurabh Chandra, IMPACT OF TRIPS OVER INDIAN PATENT REGIME VIS A VIS INDIAN PHARMACEUTICAL INDUSTRY, GJLS Vol.1, No.1, p.4(ISSN. 2321-1997) (available at-aw.galgotiasuniversity.edu.in/pdf/issue4.pdf) 2013

49 733 F. 2d.858(C.A. Fed, 1984). In this case, Bolar intended to submit an Abbreviated New Drug Application (ANDA) to the FDA for a similar drug containing the same active ingredient upon the expiry of Roche's patent. A short time before the expiry of the patent, Bolar obtained some of the active ingredient from a foreign manufacturer and began the bioequivalency studies necessary for compiling the ANDA. Roche responded by filing a suit for patent infringement. The District Court of the Eastern District of New York found that no infringement had taken place owing to the "experimental" nature of Bolar's works.

50 The Drug Price Competition and Patent Term Restoration Act, 1984

51 *35 USC Section 156* provides for the extension of the term of a patent for compensating the time lost in FDA approval, while *Section 271(e)(1)* allowed generic companies to enter the market as soon as the patent term expires by permitting them to conduct the tests for FDA approval during the patent term.

The so-called Bolar or early working exemption deals with the use of the patented pharmaceutical product to conduct tests and obtain market approval from the health authority, before the expiry of a patent, for commercialisation of the generic version, just after such expiry. This is done by submission of information to the drugs control authority and generating data by demonstrating the bioequivalence of the patented drug while the patent is still in force without obtaining consent of the patentee.[52]

Bolar Exemption under TRIPS

The recognition of this exception is implied under the Exceptions to Patent Rights under *Article 30 of the TRIPS*. The consistency of the Bolar exemption with the provision under Article 30 came for consideration before the WTO panel in *Canada (Canada-Patent Protection for Pharmaceutical Products)*[53] in which, while upholding the incorporation of the Bolar provision under its domestic law in Canada,[54] the panel observed that the practice of allowing the development and submission of information required to obtain market approval for pharmaceutical products carried out without the consent of the patent holder fulfilled the Three-step test under Article 30 of the TRIPs and maintained an equitable balance between the rights of the patent holder and public interest.

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52 Carlos M. Correa, *Trade-Related Aspects of Intellectual Property Rights - A Commentary on the TRIPS Agreement,* (Oxford University Press, Edition 2007, ISBN-9780199271283)

53 *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R, 17 March 2000

54 *Section 55.2 of Canadian patent law, which provided:*

> *"(1) It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.*
>
> *(2) It is not an infringement of a patent for any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1) to make, construct or use the invention, during the applicable period provided for by the regulations, for the manufacture and storage of Articles intended for sale after the date on which the term of the patent expires."*

Application and Use of Bolar Exemption in India

The 2005 Amendment to the Indian Patents Act, 1970, was made to give effect to the Bolar exemption provision in those instances when an invention is used or sold by a third party for purposes related to research and development.

A plain reading of the bare provision u/s.107A(b)[55] implies that any act of making, selling, importing of the patented invention when is related to purposes involving the development and submission of information under any law that seeks to regulate such manufacture, construction, sale or import, in India or elsewhere, shall not be an infringement.

The provision came for consideration before the Delhi High Court in the case of *Bayer Corporation (Bayer)* ***v. Union of India & Ors*** *(NPL)*[56] in which the question for consideration was not exactly related to the interpretation of the provision under S. 107A(a), but whether its scope and application were broad enough to include the export of patented drugs to other countries for the purpose related to research and development. The court had to consider whether Section 107A covered export of a patented product for use by an overseas importer to conduct studies and generate data for the purpose of seeking regulatory approval in that country. Opining in the affirmative, the Court upheld the export by NPL of the generic version of the drug patented by Bayer, Sofranet, to China on the grounds that the provision under the Act was broad enough to include sale of the patented product for development and submission of information under any law in force in a country, apart from India, and hence the sale of the drug to HPCL in China for submission of studies and data related to bio-equivalence and bio-availability of the said drug

55 Section 107A(a) provides that: "any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product, shall not be an infringement of a patent."

56 CM 9687/2014 in W.P.(C) 1971/2014 (available at-http://lobis.nic.in/dhc/VIB/judgement/07-11-2014/VIB05112014CW19712014.pdf)

in a generic version is said to be related to the studies required for regulatory approval. While interpreting '*reasonably related to*' used in Section 107A to mean a reasonable nexus, it held that the same exists between the sale of Sorafenat by NPL to HPCL and submission of information under the law in force in China.

CONCLUSION

It is an undeniable fact that the defences do play a very crucial role in deciding the fate of an infringement action against the defendant, especially in cases when the defendant seeks to prove non-infringement by striking at the validity of the patent. However, employing a successful defence involves a proof beyond doubt that the claims made by the defendant fall outside the limits set by the plaintiff in his claims. It is the claims and their interpretation that defines the boundaries and limitations of the invention that culminates into determining the liability of the defendant.

FINDINGS

The defences available under the Act challenging the validity of the patent have not been precisely and succinctly worded in a language that may be identified with the intent and purpose of that defence, and some of such inherent ambiguities lie in the following provisions due to absence of any definitional clarity about the same and, hence, leaving wide scope for a subjective interpretation on a case to case basis:

- The word infringement has nowhere been defined in the Act and is to be governed indirectly by interpreting the provision u/s.48 that confers exclusive rights on the patentee undermines the completeness of the Indian Patent Act.
- The provision u/s.3(d) which may be employed as a ground of defence based on invalidity of patent fails to delineate the meaning and purpose inherent in the word 'enhancement of known efficacy.' Despite the Novartis judgements' clarification that it is synonymous with therapeutic enhancement, what factors shall constitute such enhanced efficacy remains

undefined as far as other products and processes are concerned. Moreover, there can't be a strait jacket formula for the same, as determination of the same shall have a subjective interpretation, rather than an objective one.

- Section 107 r/w. S. 64(e) seeks to invalidate a patent on the grounds that the claims are not new owing to a '*prior public knowledge or public use in India before the priority date.*' What shall constitute such public use and whether it includes any commercial exploitation is not clear. Judiciary interprets it to mean '*a use in a public manner,*' but this also seems vague and incomplete when an allegation of infringement is to be defended by proof of a prior knowledge about the same.
- Absence of any clarity on what may be deemed as a ground for invalidating a patent obtained by false suggestion or misinterpretation under S.107 r/w. S.64(j) casts a doubt on the wisdom of the examiners and patent officers who are enjoined with the responsibility of undertaking a thorough examination of the patent before its grant.
- S.64(d) and (k) are repetitive in the sense that they provide for the same grounds of invalidity on the basis of non-patentability of invention u/s. 3 and 4 of the Act.
- Further S.64(l) implies a secret use of the invention in India by a patentee to be a conduct that shall not provide immunity to the patentee in a suit for infringement.

With regard to the Class defences, namely Parallel Importation u/s.107A(b) and the Bolar Exemption u/s.107A(a) also exhibit the following ambiguities:

i) *Parallel Importation*

- The fact that importation of the patented invention may be employed as a defence outrightly undermines the exclusivity in rights conferred upon the Patentee in regard to importation of his patented invention u/s.48.
- There is no clarity in the language that may indicate that it is in fact the patentee who has authorised the first sale, and therefore the

subsequent sales or importation thereof may be considered to be a legal importation and, therefore, a valid defence.

- The basic principle of Intellectual Property is that they are territorial in nature, but the defence of PI overshadows this age-old principle of IPRs.

ii) *Bolar Exemption*

- The fact that such development and submission of information is merely for the purpose of obtaining market approval is not indicated in the language of the provision u/s.107A(a).
- Nowhere in the provision has the term 'market approval' been expressly referred to, and thus there arises ambiguity with regard to what has been interpreted and construed by the courts to infer the meaning that such information is for purposes of market approval.
- That such market approval may be taken for the purpose of sale and export is inconsistent with the very object of Regulatory or prior use defence that only permits obtaining a market approval without any commercial exploitation before the expiry of the term of patent.
- The term 'uses reasonably related to development' is a subjective term that doesn't find any clear definition or meaning under the statute, thus giving rise to doubts about what constitutes reasonable use, the quantity of the drug to be used for such purposes, issues of permitting stock-piling of drugs, etc.
- That the information for submission and development as required under the law in India or in any other country indicates that such research experiments may be carried out either in India or outside India. Hence, this indicates that there shall definitely be a commercial intent behind such submission of information and the work that shall be done upon that.
- That there is no mention about the time period after which such application for market approval needs to be made by the generic

companies, and there is no mechanism to monitor that such drugs are not commercially exploited before the expiry of the patent term.

- That the provision doesn't specify clearly whether such Regulatory use should be 'on' the patented product or 'with' the patented product, as it is in the former that the true essence of the Bolar Exemption can be realised.
- Section 64 Clause3(a) excludes a reasonable trial or experimental use from constituting a secret use for the purpose of invalidity of the patent. However, it is not clear if such secret experimental use shall include the experiments on the patented invention u/c.107A(a) also.

The provisions related to individualised defences have not been expressly provided for under the Act, but the same may be inferred from the interpretation of the inherent meaning of the provisions under the Act.

- The Gillette defence that employs a combination of both types of defences such that it seeks to prove non-infringement by attacking the validity of the patent may be inferred as being synonymous with the defence that seeks to challenge the validity on account of prior art or prior public knowledge and use of the elements constituting the invention alleged to have been infringed.
- That although the Govt. is deemed as being bound to the rights conferred on grant of patent upon the patentee, the exceptions that are reserved by the Patent office to be imposed as conditions against such grant by way of allowing the use of such invention by the Govt. adversely affects the rights of the patentee. Moreover, on u/s.99 and 102, the Govt. has been empowered to acquire the invention on payment of remuneration to the patentee. However, even an adequate compensation for such use shall be nothing in comparison to the labour, effort, time and intellect employed by the patentee in making the invention.

- *That, since there is no explicit mention about the use of PHE as a defence to infringement suits, the same may be inferred from the wordings of S.57 and 59 that stipulate specification and description of the reasons for the amendment. This may be related to the concept under PHE which doesn't allow the patentee to contend infringement in cases where the amendment has been made on grounds that required fulfilment of patentability. Moreover, the fact that PHE involves evidential proof of the claims and the amendments incorporated during the prosecution of the patent, the rules governing Doctrine of Estoppel under the Evidence Act may be imported to be applied to patents.*

SUGGESTIONS AND RECOMMENDATIONS

As with all laws, the devil is in the details. So is the case with the Indian Patent Act, 1970, in which although the intent of the framers and legislators was to protect the rights of the patentee and accord him the exclusivity against all unauthorised use of the invention developed by him, but the same is not very succinctly inferred from the provisions of the Act as the same are shadowed with certain inherent ambiguities. It is the language of the provisions which have not been drafted with precision and accuracy that has left open certain gaps which create confusion and interfere with the rights of the patentee to realise his rights in the true spirit of the term.

The following are the changes that may be incorporated to the statute as far as the provisions under parallel importation are concerned57:

- The provision must clearly state that the defence is in regard to parallel importation and exhaustion of the rights of the patentee and that the rights of the latter shall stand exhausted after the first sale of the article under authorisation from such patentee.

57 Shamnaad Basheer, *'Exhausting' Patent Rights in India: Parallel Imports and TRIPs, Compliance*, 13 JOURNAL OF INTELLECTUAL PROPERTY RIGHTS, (available at-http://nopr.niscair.res.in/bitstream/123456789/2037/1/JIPR%2013(5)%20486-497.pdf)2008

- The same may be limited in scope in case of any contractual agreement when such agreement relates to fulfilling of purposes related to, or incidental to, the functions of the Govt. or public interests.
- The importation shall only be valid when there has been an express authorisation on the part of the patentee and it has been agreed to share the profits such as may be adequate and reasonable.
- There shall be exhaustion of the rights of the patentee once there is a sale of the components that 'substantially embodies' or 'essentially embodies' any patent granted under the Act and the sale of such component was made with the express authorisation of the patentee.
- The exception shall encompass both method and process patents, apart from product patents, also.

Since Bolar Exemption is only one part of the remedy for ensuring generic drugs be rolled out in the market as soon as the patent shall expire, there must be incorporated provisions for giving effect to the Data exclusivity provisions in the Act, so that there are rights of the patentee with respect to ensuring an extended term of protection and market exclusivity of the patent in question. Although vide the 2001 Amendment to the Drugs and Cosmetics Act, 1940, the provisions for Data protection have been included to ensure an easy and expeditious entry of generic drugs by a proof of bio-equivalence of the patented drug and are granted approval on the basis of the test data already submitted by the previous applicant or the patentee himself, but this still goes on to affect the exclusivity in rights as maintained and ensured by the minimum standards laid under the TRIPS.

Also, the sense and the purpose of this exemption shall become well defined once it is clearly specified that the research and development and the submission of the information for the purposes of obtaining market approval is 'on' the patented drug, rather than 'with' the patented drug. Although this may be a small difference, it is capable of causing huge implications upon the way the information is used and the further ramifications that the Bolar exemption

seeks to create. In cases where it is specified as being a use for research and development and submission of the information obtained 'on' the patented drug, any sort of 'use' of the drug in the generic sense of the term is ruled out, paving way for an unblemished and an unbounded exemption that encourages generic development of the drugs for purposes solely connected to and related with public health and public interest.

In cases where the research is not expressly for generic companies, consideration with regard to use of the patented drug and the information thereof must be considered in the light of licenses, or acquisition may be considered in the interim. Thus, there is a need to include the provision regarding Data exclusivity in the Act, so as to also protect the rights of the patentee which is the sole objective behind the enactment of the Act.

Since, under law, a person may be both legal and natural and such legal entities are inclusive of Companies and agencies or partnership firms, under patents, also, it may be inferred that such persons are also eligible for holding a patent and being conferred with the exclusive rights. It is in this context that the implication and intents of the 'shop-right' defence may be included and given statutory recognition. With the proliferation and promotion of more and more industrial and technological development, the companies may also be considered eligible enough to hold patents. Although S.124 underlines the offences by the companies, such as to include acts that are in contravention of the provisions of the Act, a similar provision recognising its rights to hold and enjoy patent rights by way of shop rights may prove beneficial.

The defences seem to have been incorporated with a biased intention in favour of the defendant without paying sufficient heed towards interests of the patentee. It is thus imperative that in order to give effect to the policy objectives under the TRIPS, which seeks to ensure a balance between the rights of the patent holder and that of the society, it must be such that the promotion of science, technology and research and development may also be endeavoured to be simultaneously fulfilled.