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SECTION 3(D) FOR PRECLUDING PATENT EVERGREENING: INDIA'S ATTEMPTS TO IMPROVE ACCESS TO MEDICINES

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Abstract. In the year 2013, India created a stir in the world of pharmaceutical patents by rejecting patent application of Novartis' anticancer drug, Glivec[1]. This rejection was based on section 3(d) of the Indian patent act[2] which precludes evergreening of pharmaceutical patents yet claims to promote incremental inventions. This report discusses the necessity of a bright line statute like section 3(d) in a country like India, which has become pharmacy of the developed world, and yet needs to promote access to cheap medicines due to low human development index. This necessity has been examined by studying India's unique position between the developing and developed status, infrastructure and human resource at the patent office, training of patent examiners and the awareness about patent litigations in India. The report also compares provisions of precluding patent evergreening by some other countries, with a statute like section 3(d). After giving due
Keywords: Pharmaceutical patents, patent evergreen, section 3(d) of Indian Patent Act, Glivec.

Consideration to all these factors, the paper concludes that a bright line statute like section 3(d) is needed in India to maintain the fine balance between monopoly on medicines and access to medicines. However, the paper also states that this statute should be modified for removing the ambiguity of its crude wording.

[1] Novartis AG vs Natco Pharma and Others, Indian Patent Office, Application No. 1602/NAS/1998 (25 January 2005). URL: http://lists.essential.org/pipermail/ip-health/2006-March/009200.html

[2] Patents Act. 1970. § 3(d). Amended by Patents (Amendment) Act. 2005.

Patent Evergreening

'Evergreening' is the strategy used by patentees in order to extend the life of the patent. The patentee files secondary patents over related or derivative technologies during or after the life cycle of the primary patent[1]. Such secondary patents can significantly extend the monopoly term over the primary patent. The practice of evergreening has been criticized as an abuse of patent rights, as it effectively extends protection beyond the initial term, though there are only trivial changes to the invention itself. This practice of patent evergreening has proliferated in the field of Pharmaceuticals and many multinational pharmaceutical companies have been accused of abusing the patent system in this way. This raised a serious concern in countries which have been struggling to improve access to medicines and prompted India, Philippines, Argentina, Brazil and many more countries to introduce amendments in their respective patent regimes to cope with this menace.

Section 3 (d) of the Indian Patent Act[2]

Section 3 of the Indian Patent Act enlists what are not inventions for the purpose of this act. Section 3(d) reads as: "*the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such process results in a new product or employs at least one new reactant*".

Explanation: For the purpose of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regards to efficacy.

[1] Hemphill S. B.N. SAMPAT. J. Empir. Legal Stud. 2011. Vol. 8. 613 p.
[2] See supranote 2.

The Glivec case[1]

July 17, 1998	Novartis applied for the patent "Crystal Modification of a N-Phenyl-2-Pyrimidineamine derivative, processes for its manufacture and its use", application No.1602/MAS/1998 through the mail box provision
May 2005	Natco Pharma, Cipla, Hetero Pharma and Cancer Patients Aid Association file oppositions to the patent
January 25, 2006	The patent application refused by the Assistant Controller of patents and designs. Novartis challenges refusal in Madras High Court
April 2, 2007	IPAB comes into existence, the then controller general of Patents and Designs appointed as chairman of IPAB
July 2007	IPAB rejects the challenge of Novartis arguing Chandrashekharan dealing with the case
August 7, 2007	Madras High Court rejects the Novartis' challenge to constitutional validity of section 3d
November 13, 2007	Madras High court upholds the Novartis' challenge to Chndrashekharan and orders IPAB to constitute a special bench
January 28, 2008	Supreme court orders that the challenge not be heard by the IPAB
October 8, 2008	Supreme court rules that the IPAB hearing must include a technical expert
June 26, 2009	IPAB rejects Novartis' appeal
September 11, 2012	Supreme court hearing scheduled
April 1, 2013	Supreme court rejects Novartis' appeal

Debates involved regarding section 3(d) During the Glivec Case

Constitutional validity of section 3(d). It was argued that this section confers uncontrolled power on the statutory authority and hits the principle of equality in the Indian constitution, and vests the patent office with the uncanalised power to devise its policy on deciding the meaning of the term 'enhancement of efficacy'. However, supreme court upheld the constitutional validity of section 3 d.

1. The efficacy debate:

1) What is efficacy? Does it mean therapeutic efficacy?[1] Can increase in heat stability, bioavailability[2] or improvement in processability be considered as efficacy?[3]

[1] See supranote 1.

2) How much enhancement in efficacy can be considered as significant? 30%? 40%? If 40% enhancement is significant, then is 39% enhancement insignificant?[4]

3) What is a known substance with which the substance's efficacy be compared. If three or four patents already existed on various salts or forms of the substance, which one is a known substance? The one that was patented the first or the one that was patented the last?

TRIPs Compliance. It was argued that section 3(d) contravenes the provisions of article 27 of TRIPS which states that patents shall be available for any invention, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. It is being argued that section 3(d) has been included to weed out pharmaceutical patents in particular, and hence denies patent to a specific class of inventions, and does not comply with article 27 of TRIPS agreement.

Decision of the supreme court. Supreme court upheld the constitutional validity of section 3d:

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[1] In a healthcare context, efficacy indicates the capacity for beneficial change (or therapeutic effect) of a given intervention (e.g. a medicine, medical device, surgical procedure, or a public health intervention). See http://en.wikipedia.org/wiki/Efficacy (last visited on Feb. 25, 2014).

[2] The extent to which a drug or other substance is taken up by aspecific tissue or organ after administration; the proportion of the dose of a drug that reaches thesystemic circulation intact after administration by a route other than intravenous. See http://dictionary.reference.com/browse/bioavailability (last visited on Feb. 25, 2014).

[3] The Madras High court ruled that Efficacy should be interpreted as therapeutic efficacy. However, if a drug candidate is less toxic over the other, or more stable over the other, these too are desirable properties, though they do not account for increase in therapeutic efficacy. According to the Madras high court decision, these substances are not patentable, though they involve an incremental invention. This sounds erroneous and thus demands that the term Efficacy be more clearly defined in section 3d rather than relying on the courts to interpret it. Here lies the first flaw in the drafting of section 3(d).

[4] In the Madras high court decision it was claimed that 30% enhancement in bioavailability is not a significant improvement in efficacy. Whereas in bioequivalence studies, a compound showing more than 25% increase in bioavailability is not considered to be bioequivalent with the standard compound i.e. not same biologically. Which itself means that 30% enhancement in bioavailability is significant. Here lies the third flaw in drafting of section 3(d).

1. It stated that efficacy is therapeutic efficacy. It also mentioned that known substance is last known substance.

2. TRIPS compliance: It is beyond the jurisdiction of the Indian Supreme court.

Why does India need section 3(d). After examining certain parameters it can be concluded that India is making big strides as far as the technological advancements in Pharmaceutical sector are considered. However, as far as the Human development indices[1] of WHO are considered, India still ranks amongst few of the bottom line countries. Considering this, the IP policies of such country should be framed to improve access to medicine, but should also support its own generic Pharma Industry.

The Indian patent offices are still understaffed and they are not adequately trained[2]. With a spiraling increase in the number of patents being filed, it would be extremely difficult to apply the non obviousness test, or follow the guidelines, and a brightline statute like section 3(d) is extremely essential.

What were the changes brought in by the Novartis case?

1. There is a greater global awareness that the Patent system is being abused by the pharma industry to block the entry of the cheaper generic drugs into the market[3]

2. Steps being taken in countries like Argentina, South Africa and EU by using new approach to examine secondary patents.

3. The judgement of the Novartis case created a precedent and helped civil society groups to campaign for affordable medicines.

4. A study[1] reported a rise in rejections based on the precedent set by the Supreme Court in dealing with Section 3(d) of the Indian Patent Act

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[1] United Nations Development Program (UNDP) publishes Human Development Index (HDI), which measures the national development by in turn measuring level of income and rate of The Human Resource Development Index (HDI) measures three basic dimensions of human development , namely, health, education and income and thus defines the state of well being in a broader way.

[2] Annual reports of the previous years, available at the Indian Patent Office website: www.ipindia.gov.in

[3] See: https://www.ip-watch.org/2018/05/20/five-years-indian-supreme-courts-novartis-verdict/ (Last visited August 12, 2019).

in the Novartis case. "Section 3(d) was raised in 69% of the cases where the exceptions to patentability were cited indicating its use as a policy tool by the IPO in rejecting applications that fell within the exceptions," noted the report released in December 2017.

Problems with the drafting/ application of section 3(d):

1. The statute is crudely worded[2] and needs to be modified by clarifying the ambiguities regarding definition of the term 'efficacy' or clarifying the word 'significant enhancement'. These modifications would empower the patent office and the courts to apply this statute with clarity in examining and adjudicating issues related to pharmaceutical patents.

2. A report[3] which studied the patents granted by the IPO found that Section 3(d) has not been effectively utilised in preventing secondary patents from being granted. The study analyses the challenges that have led to Section 3(d) being under-utilised despite the landmark judgment of the Supreme Court. There have been inconsistencies in the way the 'Novartis standard' is dealt with by the Indian Patent Office. One of the reasons mentioned for not following of the Novartis standard was that the pharma guidelines developed by the Indian Patent Office do not capture the essence of the Novartis judgement. The guidelines do not include the standard developed by the Supreme Court, which lists various steps to determine whether an invention falls within the ambit of Section 3(d).

Conclusion

It can be concluded that considering India's unique position, somewhere between a technologically developed but otherwise developing country, her patent policies are correctly drafted to improve access to medicines. Precluding the grant of evergreening of pharmaceutical patents using

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[1] Ali F., Rajgopal S., Prabhu C. Rejected in India: What the Patent Office Got Right on Pharmaceutical Patent Applications (2009–2016). URL: https://accessibsa.org/media/2017/12/Rejected-in-India.pdf

[2] Bashee R.S., Reddy T.P. The "Efficacy" of Indian Patent Law: Ironing out the Creases in Section 3(d). SCRIPT-ed. 2008. Vol. 5, is. 2. P. 232–266.

[3] Ali F., Rajgopal S., Raman V., John R. Pharmaceutical Patent Grants in India: How Our Safeguards Against Evergreening Have Failed, and Why The System Must Be Reformed. URL: https://accessibsa.org/media/2018/04/Pharmaceutical-Patent-Grants-in-India.pdf

section 3(d) is one such major that has proved to be very effective. Considering the understaffed and undertrained patent office, a bright line statute like 3(d) is more effective than the guidelines or applying criteria of non obviousness. However, the crude wording of the section 3(d) needs to be redrafted and the guidance of the supreme court about application of section 3(d) in the supreme court judgement needs to be captured by the Indian Patent Office in the guidelines for examining of the pharmaceutical patents.