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BALANCING THE CONFLICTING INTERESTS: ADVOCATING PUBLIC HEALTH THROUGH EVERGREENING AND COMPULSORY LICENSING*

ABSTRACT

Patent laws throughout the world have been introduced to promote inventions and innovations which are non-obvious and novel in nature and serve as an incentive to the patentees. As has been well said *"Power tends to corrupt, and absolute power corrupts absolutely"*. The rights granted to a patent holder is no exception to this general premise. Therefore, this right of the patentee needs to be restricted in furtherance of which certain restrictions are embodied within Indian Patent Law which "limits" the monopoly granted by the same. This paper attempts to analyse the approach adopted by Indian judiciary in dealing with the conflicting rights of the patent holder vis-à-vis the rights of general public. In this parlance, a special reference has been made to a recent case of *Novartis* vs *Cipla* wherein the approach of judiciary has been studied and its divergence with the earlier judgements such as that of *Novartis AG* vs *Union of India* has been looked upon. Thus, an attempt has been made to study the suitable interpretation of the Courts under various circumstances and their endeavour to promote public health while keeping in mind the rights of the private parties. This paper widely discusses the issues of Evergreening and Compulsory Licencing and how does a mutual collaboration between them functions so as to promote the interest of the private parties while adopting a balanced approach towards ensuring public health and welfare at large.

Keywords: Evergreening, Compulsory Licensing, Public health, Patentees right, pharmaceuticals.

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I. INTRODUCTION

Whenever the art of Medicine is loved, there is also a love of Humanity.

Hippocrates 400 BC

Health is a right that every human being accrues by the very nature of his/her being born as a part of the race. This preordained right of an individual is respected widely throughout the International arena. Indian Constitution recognises this as a fundamental part of right to life provided under Article 21[1] which reads as "No person shall be deprived of his life or personal liberty accept according to the procedure established by law."

The apex court in cases like *Maneka Gandhi* vs *Union of India*[2] and *Francis Coralie* vs *Union Territory of Delhi*[3] approached liberally and held that "The right to life includes the right to live with human dignity." Further in case of *Consumer Education & Research Centre* vs *Union of India*[4] Supreme Court has held that right to health and medical aid to protect the health is a fundamental right under Article 21. This view was upheld in the case of *Parmanand Katara* vs *Union of India*[5] where it was held that right to health and medical assistance is a fundamental right under Art.21.

The accessibility & affordability of medicines in a particular country can be said to be one such means of ensuring public health to a large extent. This access to medicine is co-related with the Intellectual Property Rights (hereinafter referred to as IPR) policies of the drugs. Introducing a new drug into the market is quite an expensive procedure.[6] Because of the high ratio of research and development costs to imitation costs, there would be little incentive for innovator pharmaceutical companies to develop new drugs in the absence of effective legal protection against imitators.[7] The patent[8] system guarantees one such form of protection.[9]

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[1]The Constitution of India, Part III.
[2]AIR 1978 SC 594.
[3]AIR 1981 SC 746.
[4](1995) 3 SCC 42.
[5]AIR 1989 SC 2039.
[6]Ouellette L. L., *How Many Patents does it take to make a Drug? Follow-on pharmaceutical patents and university licensing* 17 Mich. Telecomm. & Tech. L. Rev. (2010-2011), p. 302.
[7]Burk D. L. & Lemley, M. A., *Policy Levers in Patent Law*, 89 VA. L. REV. (2003), pp. 1616-1617.
[8]Patent laws recognize intellectual property rights relating to invention; Basu, I., *A Brave New World Indian Drug Industry*, Wash. Times (Jan. 11, 2005).

A reference to the Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter referred to as TRIPS) is vital in this context. It is the most comprehensive agreement pertaining to IPR which sets out the minimum standards for protection and enforcement of IPR.[10] It has been at the centre of controversy because of the inevitable implication on the public health regime. One of the avowed objectives of TRIPS unequivocally affirms the promotion of technological innovation and transfer of technology.[11] The concern of public health has been taken care of in TRIPS in form of sufficient scope to the members to adopt necessary measures to protect public health and nutrition.[12]

After almost three decades of relatively little patent protection, India, in 2005, adopted a modern patent regime that finally puts India in conformity with World Trade Organization (WTO) standards.[13] Earlier, the Patent Act, 1970 provided that *in the case of inventions being claimed relating to food, medicine, drugs or chemical substances, only patents relating to the methods or processes of manufacture of such substances could be obtained*.[14] With the commencement of the Patent (Amendment) Act, 2005 (hereinafter referred as the Act), this provision was deleted and the present position is that in case of food, medicine drugs or chemical substance patent can be granted to final product. This new law signifies a very dramatic shift in intellectual property policy in India and promises to impact India's pharmaceutical industry significantly.[15] Albeit, India had secured the interest of inventors by providing patents for their final products but, it was, time and again contested that it can lead to a corrupt practice of evergreening.[16]

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[9]Patents are not the only way to provide incentives for new medical technologies; recent proposals advocate de-linking research and development costs from manufacturing costs by rewarding a new innovation based on its health impact. See Medical Innovation Prize Act of 2007, S. 2210, 1 10th Cong. (2007); Hollis, A. & Pogge, T., *The Health Impact Fund: Making New Medicines Accessible for All* (2008); Barbados, Bolivia, Suriname & Bangladesh, *A Prize Fund to Support Innovation and Access for Donor Supported Markets* (Apr. 15, 2009).

[10] *Novartis AG* vs *Union of India*, Civil Appeal no. 2706-2716 of 2013 arising out of SLP(C) no. 20539-20549 of 2009 at para 59.

[11] TRIPS, Article 7.

[12] TRIPS, Article 8.

[13]Press Release, Government of India, Enough Safeguards in Patents Act to Prevent Price Rise - Domestic Pharma Industry Interests Fully Protected: Kamal Nath (Apr. 4, 2005).

[14] The Patent Act, 1970, Section 5.

[15]Jeffrey D. H., *Patent Law in India Focuses Strongly on R&D: Industry Shifts to New Paradigm*, Genetic Engineering News (2005).

[16]Memorandum from Amit Sen Gupta, National Working Group on Patent Laws, Changes in New Patents Bill (Mar. 22, 2005).

Evergreening refers to renewals of expired patents by pharmaceutical companies by citing a new use for the same drug, thereby extending the patent monopoly.[17] Various provisions have been inserted in the Act to curtail the rights of patentee, such as section 3 (d) of The Act and Compulsory Licensing[18], in order to prevent the patentee from establishing perpetual monopoly over the product. Evergreening and compulsory licensing are two important domains wherein the controversy as to public health and private rights arises. This paper attempts to look into thedichotomy in rights created through the practices of evergreening and compulsory licensing in India.

II. EVERGREENING IN INDIA

Evergreening refers to the slew of business strategies and legal maneuverings to extend market exclusivity of products, and in the process continuing to extract their monopoly rent-seeking practices.[19] In the domain of pharmaceutical products, evergreening may cover practices such as taking out new patents by not making major changes rather changing form and method of administering dosage of a particular medicine without changing the active ingredients, or taking out new patents on a mixture of delivery mechanism and non-substantive mixture in the originally patent drug, thereby delaying the patent of the original patent.[20] Thus, the phenomenon of evergreening, neither recognized in judicial opinions nor codified within statutes, can be seen as a maneuver utilized by patent holders to use existing legal and regulatory loopholes to extend patent exclusivity of their products.[21]

[17]Devraj, R., *India: Lesser-Than-Evil Patent Law Pleases Drug Firms*, Inter Press Service News Agency (Mar. 24, 2005).
[18] The Patent (Amendment) Act, 2005, Section 84.
[19]Harding S., Perpetual Property, 61 FLA. L. REV., (2009), pp. 285, 303-05, 315-16.
[20]Faunce, T., *The Awful Truth about Evergreening*, The Age, (Aug. 7, 2004), available at http://www.theage.com.au/articles/2004/08/06/1091732084185.html.
[21]Amin, T. & Kesselheim, A.S., *Secondary Patenting of Branded Pharmaceuticals: A Case Study Of How Patents On Two HIV Drugs Could Be Extended For Decades*, 31 HEALTH AFFAIRS 2286, 2286-87 (2012) (explaining this concept by showing how pharmaceutical companies engage in evergreening by sequentially seeking patent protections, either via incremental improvement to a single drug, or patenting multiple characteristics of a single drug. Examining the effects of manufacturers modifying products that are branded and approaching patent expiration in order to delay competition posed by generic brands).

However, in general parlance Evergreening is a way for MNCs to disguise a drug that has already received a patent in order to receive a "secondary patent" on an allegedly new drug that restarts the twenty year period of exclusivity anew.[22]

To avoid this misconception, section 3(d) of the Act lays down qualification of "efficacy" to be met by the companies in order to get a secondary patent. Section 3(d) of the Act reads as under:

"The mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant."

Thus, it bars the grant of patent to the invention which are mere "discovery" of a "new form" of a "known substance" and at the same time it allows those inventions which result in increased efficacy of a known substance. In *Lallubhai Chakubhai Jariwala* vs *Chimarial*[23], the Bombay High Court held that mere collocation of two or more things, however, without some exercise of the inventive faculty in combining them is not subject matter for patent. Further, in case of *Shining Industries* vs *Shri Krishna Industries*[24]more or less same thing was asserted by Supreme Court which had opined that "*An improvement in an old device or method is not patentable merely because it permits a product to be produced more cheaply, or because it produces something which is more merchantable, or more compact or more efficient, or more attractive in appearance. While a greater degree of control may be an improvement, such a change in the absence of performance of a new function, is generally not regarded as an invention.*"

Again in *Bishwanath Prasad Radhey Shyam* vs *Hindustan Metal Industries*[25]it was held that the invention must be inventor's own discovery as opposed to mere verification of what was already known before the date of the patent.

The purpose of this provision, as has been expounded *ad nauseam* in the literature, is to limit "evergreening."[26] However, it is contested that Section 3(d) puts an extra qualification of

[22]Du, D., *Novartis AG* v *Union of India: "Evergreening," Trips, and "Enhanced Efficacy"' under section 3(d),* 21 Journal of Intellectual Property Law, 2013-2014, p. 238.
[23] AIR 1936 Bom 99.
[24]AIR 1975 All 231.
[25]AIR 1982 SC 1444.

"enhanced efficacy" which is unclear for two reasons. *First*, it is unclear what is meant by "efficacy".[27] *Second*, it is unclear "what kind of data will be required to establish 'efficacy' to the satisfaction of Section 3(d).[28]India's Patent Rules, comparable to Title 37 of the Code of Federal Regulations (C.F.R.), and the Indian Manual of Patent Office Practice and Procedure, comparable to the U.S. Manual of Patent Examining Procedure (MPEP), contain no guidance on what would satisfy the enhanced efficacy requirement, leaving it unclear to inventors and practitioners to show how much they must invest in research and development (R&D) before they can obtain a patent.[29]

For the reasons abovementioned, the constitutional validity of section 3(d) was challenged in *Novartis AG* vs *Union of India*[30] on the ground that it is vague, arbitrary and confers unguided powers on the Statutory Authority. This argument was rejected by the court stating that the limits and guidance is provided in the Act itself. The explanation to section 3(d) provides that *"For the purposes 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 regard to efficacy."*[31] And hence upholding the validity of the section, the Court finally held that "*Article 14 can be invoked only when it is shown that in the exercise of a discretionary power there is a possibility of a real and substantial discrimination and such exercise interferes with the fundamental right guaranteed by the Constitution. When the validity of an Act is challenged on the touchstone of Article 14 of the Constitution of India, the decision has to depend upon the provisions of the concerned Statute itself, which are in challenge."*[32]

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[26]Ouellette, L.L., *How Many Patents Does It Take to Make a Drug? Follow-On Pharmaceutical Patents and University Licensing* 17 MICH. TELECOM. & TECH. Law Review. (2010), available athttp://www.mttlr.org/volseventeen/ouellette.pdf; *see also* Bhaven N. Sampat, Kenneth C. Shadlen& Tahir M. Amin, Challenges to India's Pharmaceutical Patent Laws, SCIENCE (2012), p. 414.
[27]Mueller, J.M., *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. Law Review (2007), p. 553 ("India has been a net exporter of drugs since 1988-89..."); *Novartis AG* v. *Union of India*, AIR 2013 SC 1311.
[28]Id.
[29] Id at 554; The Office Of Controller General Of Patents, Designs & Trademarks, Manual Of Patent Office Practice And Procedure §5 2(1) (j), 3(d), 3(e) (2011).
[30](2007) 4MLJ 1153.
[31] The Patent (Amendment) Act, 2005, Explanation, Section 3(d).
[32]*Novartis AG* vs *Union of India* (2007) 4 MLJ 1153.

Another aspect that was challenged by the plaintiff in *Novartis AG* vs *Union of India*[33] *was* that section 3(d) is not in consonance with TRIPS. Article 27.1[34] reads as *"patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."* There is non-discrimination clause in this article which provides that *"patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."*[35] However, the Madras High Court held that it lacked jurisdiction to review whether Section 3(d) is TRIPS compliant.[36] It concluded that it lacked authority to decide whether a domestic Indian law is compliant with an international treaty because the Indian government had not "domesticated" TRIPS. In other words, India had not officially made the treaty binding law domestically.[37] It found that Article 64 of TRIPS provides for dispute resolution through the World Trade Organisation's Dispute Settlement Body (DSB) and recommended that the Swiss government take its case there.[38] Thus, the court did not decide over the consistency of impugned section 3(d) of the Act with Article 27 of TRIPS.

WTO panel had also rejected a restrictive reading of Article 27.1 as forbidding any different treatment of the various fields of technology.[39] Rather, unfair discrimination must be distinguished from differential treatment for legitimate reasons.[40] In *Canada Pharmaceuticals*,[41] the European Union claimed that the Canadian Patent Act violated Article 27.1's non-discrimination clause because "*it treated drug patents less favorably than patents for inventions in other fields.*"[42] Canada's patent statute contained a "*Stockpiling Exception*" which stated that it is not patent infringement to make, instruct, use, or sell a patented invention during a period set by regulation for the purpose of preparing a stockpile of

[33] Id.
[34] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments-Results of the Uruguay Round Vol. 31, 33 I.L.M. 81 (1994) (setting forth obligations for patent protection).
[35] Id.
[36] Linda L. Lee, *Trials and TRIPS-ulations: Indian Patent Law and Novartis AG v. Union of India*, 23 BERKELEY TECH. Law Journal (2008), p. 300.
[37] Id.
[38] Id.
[39] Stout, M.V., Crossing the TRIPS Nondiscrimination Line: How CAFTA Pharmaceutical Patent Provisions Violate TRIPS Article 27.1, 14, B.U. J. Sci. & TECH. L. (2008), p. 181.
[40] Id. at 182.
[41] Panel Report, Canada-Patent Protection of Pharmaceutical Products, WT/DS114/R (Mar. 17, 2000).
[42] Supra note 39 at 184.

products to sell after the patent expires.[43] The only regulations promulgated under the exception, however, applied to medicines, enabling generic manufacturers to stockpile identical generic versions of a drug beginning from six months before the drug patent expired.[44] The dispute panel of the WTO found that a law that differentiates between different fields of technology is not necessarily in violation of Article 27.1 as long as it is supported by a *bona fide* reason to differentiate.[45] But this exception will only apply when it will satisfy the three cumulative criteria: (1) the exception must be 'limited'; (2) the exception must not 'unreasonably conflict with normal exploitation of the patent'; (3) the exception must not 'unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties'.[46]

Evergreening, if allowed, is an evil practice indeed, but there are certain misconceptions with respect to its various theories and general understanding wherein evergreening is seen as a patenting of derivative of pre-existing patented substance without making any major changes in the active ingredients of the drug. However, this theory does not hold water since as far as Indian Patent Office is concerned, it allows patent only for "inventive step" and "novelty" of new patent.[47] Indian patent law is reluctant to grant patent for those substance which is only for the extension of time period of pre-existing patent.[48]

Yet another conceivable theory of evergreening which is cited by many scholars[49] is that by deliberately staggering patent applications, pharmaceutical companies can patent different aspects of a single drug to preclude the production of the drug after the expiration of the original patent.[50] In fact, a later patent on the packaging of a particular patented drug would

[43] Id. at 183.
[44] Id.
[45] Id. at 185.
[46] Id.
[47] *Novartis AG* v. *Union of India* A.I.R. 2013 S.C. 1311 at p. 40 (quoting Patents (Amendment) Act, 2002 (Act No. 38 of 2002), Section 20)0)) ("invention" means "a new product or process involving an inventive step and capable of industrial application').
[48] Parmar, D.P.S., *Legislaive Framework of IP Administrafion,* Office Of The Controller General Of Patents, Designs & Trade Marks, pp. 10-11.
[49] Bazzle T., *Pharmacy of the Developing World: Recording Intellectual Property Rights in India with the Right to Health: TRIPS*, India's Patent System and Essential Medicines, 42 GEO. J. INT'L L. (2011), pp. 785, 802 (describing the "pernicious practice of 'evergreening' pharmaceutical patents, a process whereby drug companies artificially extend their period of patent exclusivity by patenting trivial secondary elements of their patented drug when the underlying patent is set to expire").
[50] Supra note 22 at 240.

not prevent generic companies from selling the drug in different packaging after the expiration of the patent on the drug itself.[51]

Lastly, most mistaken theory is that taking out patent of newer version of the pre-existing drug which is no better than the previous one, with the intention to persuade the patient to buy newer version at higher price, even if, the generic version of previous drug is available in the market.[52] However, this seems less likely to occur in India because the average Indian consumer is much more price-sensitive than the average consumer in a developed country when it comes to on-patent drugs.[53]

III. COMPULSORY LICENCING

Although the 2005 amendment Act brought about significant changes but the most controversial of it is the introduction of product patents for pharmaceutical inventions. Compulsory licenses are considered to play an instrumental role in promoting public health needs and larger public policy objectives. Compulsory licensing[54] is a method that allows the production of patented material without authorization from the patent holder.[55] Countries such as Brazil, Thailand, and India have used the policy to procure life-saving drugs for millions of patients.[56] With the help of compulsory licenses, a government may allow patents to be broken if cheaper generic drugs are required in a health emergency.[57] It acts as a means to increase output and decrease price by creating marketplace competition within a patent-

[51] Id.
[52] Id.
[53] Supra note 49 at 808-809.
[54] The term 'compulsory licensing' is used here, but there may be other legal forms used by government to authorise use of a patent.
[55] Dean, S., *India's Controversial New Patent Regime: The End of Affordable Genetics*? The International Lawyer, Vol. 40, No. 3 (FALL 2006) pg. 730; In general, TRIPS Art.31 allows compulsory licenses after negotiations for voluntary licenses have failed. In cases of emergency, TRIPS allows governments to grant compulsory licenses without first trying to negotiate. The World Trade Organization (WTO) Doha Declaration of 2001 emphasized developing countries' rights to issue compulsory licenses: "Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted" (WT/MIN (01)/DEC/1, Art. 5.b)
[56] Thailand and Brazil have used compulsory licenses to produce anti- retrovirals for AIDS patients and India has indicated plans to use compulsory licensing to combat swine flu (Kremer 2002; Galvão 2002; Gostin 2006; Steinbrook).
[57] Supra note 3.

protected pharmaceutical,[58] therefore can be termed as a potent weapon in the hands of developing countries to put limitations on the exclusive rights of the patent holder. There are rules governing compulsory licenses in the Paris Convention[59] and more substantially, in the TRIPS agreement.[60] The Paris Convention provides that it is permissible to grant compulsory licenses,[61] but that no license can be granted for failure to work until four years have elapsed from the date of filing (or three years of grant, if later) and no compulsory license can be granted where the inaction is justified by a good reason.[62] Further, the convention provides that such a license must be non-exclusive, may not permit sub-licence, and cannot be assigned except with a business.[63]

Article 30[64] of the TRIPS agreement recognises certain exceptions to the right of patent owner. Article 31 of the agreement lays down the conditions for other use without authorization of the right holder, but does not list or define exhaustively the case where a license may be granted(except for semiconductor technology[65]). Negotiators weighed both options and preferred to leave open cases where compulsory licensing may be allowed.[66] Para 5(b) of The Doha Declaration[67] recognizes flexibilities that each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.[68]

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[58] Because a patent grants a monopoly on the claimed invention, eliminating the monopoly through a compulsory license should reduce prices and increase output of the invention. See Phillip Areeda, *Introduction to Antitrust Economics*, 53 Antitrust L.J. 523- 525 (1983).

[59] The Paris Convention, adopted in 1883, applies to industrial property in the widest sense, including patents, trademarks, industrial designs, utility models, service marks, trade names, geographical indications and the repression of unfair competition. This international agreement was the first major step taken to help creators ensure that their intellectual works were protected in other countries.

[60] Roughton, A. & Johnson, P., Cook, T. The Modern Law of Patents, 2nd edition, p. 396.

[61] Paris Convention art 5(A) (2); it further provides that a patent cannot be forfeiture unless two years after a compulsory licence it does not resolve the problem: art 5(A) (3).

[62] Paris Convention art 5(A) (4).

[63] Id.

[64] Article 30 which states that Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

[65] Article 31 (c):The scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive.

[66] Confirmed in the Declaration on the TRIPS agreement and public health, WT/MIN (01)/DEC/2.

[67] The Doha Declaration on the TRIPS Agreement and Public Health was adopted by the WTO Ministerial Conference of 2001 in Doha on November 14, 2001. It reaffirmed flexibility of TRIPS member states in circumventing patent rights for better access to essential medicines.

[68] Supra note 66.

The list in Article 31 of TRIPS essentially provides a check list for member states to follow while granting compulsory licenses.[69] It is generally believed for the purpose of paragraph (b) it is for member states to determine whether there is national emergency. Furthermore, the rules on non-discrimination as to the area of technology (except in relation to semi-conductors) apply to compulsory license.[70] The restrictions that compulsory license must be for supply of the domestic market in paragraph (f) have been affected in the area of public health.[71]

Sections 84, 92 and 92A have been incorporated under the Indian Patents act, 1970 which lay down the provision for compulsory licensing. Section 84 enlists three conditions wherein compulsory license may be granted against a patent holder:

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

Section 92 lays down special provision for compulsory licenses on notifications by Central Government. The circumstances envisage the existence of emergency or public non-commercial use. Such provision is useful in any form of medical emergency such as in spread of an epidemic disease. Section 92A takes care of larger interest of other countries that do not have sufficient capacity to manufacture and market pharmaceutical products.

Thus, it can be said that India has used the flexibilities in TRIPS for promotion and protection of public health. The judgement in *Natco* vs *Bayer*[72] deserves special mention on this point, wherein India granted its first ever compulsory license to Natcopharma Limited, an Indian generic manufacturer, to produce and market Sorafenibtosylate, a patented cancer drug of the multinational pharmaceutical company, Bayer Corporation. The court here held that the domestic Indian Companies can produce generic copies of drugs at significantly lower rates than the foreign pharmaceutical majors thus making life saving drugs accessible as well as

[69] This was implemented by the Patents and Trade Marks (WTO) Regulation 1999(SI 1999/1899).
[70] See Canada-Patent Protection of Pharmaceutical Products (WT/DS114/R), [7.91]
[71] Supra note 60 at 409-414.
[72] *Natco Pharma Ltd.* vs *Bayer Corporation*, C.L.A. No. 1 of 2011.

affordable for common man. Herein, The Controller of Patents held that the clause "*being worked in the territory of India"*[73] does not means mere importation of the drug and that it should be interpreted in a sense that drugs should be manufactured to a reasonable extent in India. This judgement no doubt is commendable but at the same time it lets open the door for domestic pharmaceutical companies in India to derive undue benefits as almost 90% of the patented life saving drugs are imported into India.

Section 83[74] lays down general principles applicable to working of patented inventions in India. Section 83(b),[75] 83(d),[76] 83(e)[77] and 83(g)[78] are of considerable importance in setting the backdrop of compulsory license in India. These provisions indicate the intention of the legislature is to give precedence to larger interest of public over the enjoyment by private bodies in the form of monopoly. Use of the word 'merely' suggests that commercial advantage are not the only philosophy behind the grant of patent rights. Specific mention of public health and nutrition is also mentioned in section 83(d), wherein, it is laid down that public health is not to be impeded by the grant of patent rather, they should act as an instrument to promote public welfare. A parallel can be drawn from paragraph 4 and article 8.1 of the TRIPS where sufficient scope for protection of public health is given. Further, section 83(e) makes it explicitly clear that intellectual property rights can never be an obstacle for promotion of right to health. Section 83(g) takes into account the concern for price regulation and makes it clear that that exclusive rights of patentee should not be used to price the product in an unreasonable and unaffordable manner. These general provisions pave the way for the provision of compulsory licensing, which is one of the most unique feature of the Indian Patent system.

A recent case of *Novartis v Cipla*[79] draws attention towards the various issues of infringement of patents and compulsory licensing. In this case the judgement was given in favour of

[73] As mentioned in Section 84(c) of the Indian Patents Act, 1970.
[74] Indian Patents Act, 1970.
[75] "That they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article."
[76]"That patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interest especially in sectors of vital importance for socio- economic and technological development of India."
[77]"That patents granted do not in any way prohibit Central Government in taking measures to protect public health."
[78]"That patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public."
[79] MIPR 2015(1) 108.(Decided by Delhi High Court)

plaintiff and it was said that the defendant could not infringe the right of the patent holder under the garb of public health. The defendant in this case demands the right to manufacture the drug on which the plaintiff had been granted a patent contending that public health is of larger importance and as the availability of drugs in not fulfilled by the plaintiff thereby the defendant must be given permission to manufacture and sell the same drugs. An attempt has been made to analyse the case in detail in order to understand the approach adopted by the Court in interpreting the case in balancing the rights of private party and public at large.

In the present case, the plaintiff Novartis, a Switzerland based company had filed a case against Cipla, a generic drug producing company claiming an injunction over the infringement of Plaintiff's Indacaterol Maleate which was a drug quite useful and efficacious in curing Chronic obstructive pulmonary disease[80] and was patented on the name of Novartis. Indacaterol is ultra-long lasting as it provides up to 24-hour bronchodilatory effect unlike its other substitutes which only provide 12 hours bronchodilatory effect. The Indacaterol as well as its maleate salt, namely Indacaterol Maleate in which Indacaterol is the active moiety, are both protected as an invention under the suit patent in India. [81]

Indacaterol (as its Maleate salt) was launched under the brand ONBREZ in India in the year 2010. The said product has been marketed in India since 2010 by way of import by plaintiff No. 2[82] .The said product is now being distributed by Lupin Ltd. by way of purchase from plaintiff No. 2 under distribution and co-promotion agreement dated 22nd March, 2012. Indacaterol Maleate inhalation powder is manufactured and sold by wholly owned subsidiaries of the Plaintiff No. 1, being Novartis Pharma Stein A.G., and Novartis Pharma A.G., respectively, both located in Switzerland. The plaintiff No. 1 uses one manufacturing plant located in Switzerland, for manufacturing Indacaterol Maleate inhalation powder to be distributed globally. This centralized manufacturing plant which is a state of art technology ensures that the plaintiff is saved the cost of manufacturing units in different countries and also ensures that the quality of the drug being manufactured and sold globally is consistent and up to the required standards.

[80] Chronic obstructive pulmonary disease is a general term that describes progressive respiratory diseases including emphysema (gradual damage to air sacs) and chronic bronchitis, where it is characterized by decreased airflow over time and increased inflammation. Hereinafter referred to as COPD.
[81] Active moiety is defined as the part of the molecule that is responsible for the physiological or pharmacological action of the drug substance.
[82] An Indian subsidiary company of Novartis named Novartis Healthcare Pvt. Limited.

The suit patent was granted in India as of 5th August, 2008. The plaintiffs argued that it is a valid patent as no evidence contrary to its validity has been produced, therefore, the present suit is filed by the plaintiffs on account of the infringement of suit by the defendant as the inhalation powder in the Defendant's product contains Indacaterol which confirms infringement and therefore claiming protection for their patent keeping in mind the rights of the patentee [83] an order of injunction[84] be passed against the defendant who is infringing the suit patent.

It was contested by the plaintiff that the present patent suit is a valid one. The defendant relies upon Section 92(3) to revoke the patent which is an admission that the suit patent is otherwise valid and a valid patent alone could be subjected to compulsory license and hence any plea raised herein by the defendant based on Section 64[85] is liable to be rejected.

The Plaintiff's further pleaded that it took well over 10 years to develop, launch and commercialize Indacaterol in the market internationally as well as in India and the defendant has time and again admitted before the Government that the patented drug is an effective drug and it is convenient to the patients and when administered in combination with other drug, the same has proven to be quite beneficial. Moreover, the defendant has agreed to pay royalty to the patentee which prima facie establishes plaintiff's claim of holding a valid patent.

Moreover, the Controller of Patent was satisfied with the novelty, inventiveness and industrial application of the compounds claimed. And the patent was granted to the plaintiff after close examination and scrutiny, has not been challenged by anyone, and the defendant in the case knowingly infringes the old registered patent.

He further contested that there is no obligation in law that the plaintiff must manufacture the patented drug in India as long as the patent is working in India and patients are getting the said medicine in required amount and therefore the defendants must not be allowed to avail the benefit of Section 83[86] of the Act which lays down general principles applicable to

[83] Provided under Section 48 of the Indian Patent
[84] Under Section 108 of the Indian Patent Act, 1970.
[85] Revocation of patents.
[86] General principles applicable to working of patented inventions :
Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter regard shall be had to the following general considerations, namely,- (a) that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the

working of patented inventions and thus should not be permitted to manufacture the drug under the suit patent in order to infringe the same.

Plaintiffs denied the contention of the defendant manufacturing of drug in India would reduce its cost as the price of the drug depends on several factors including the quality, research and development, clinical trials, volume of demand and supply etc. which the plaintiffs had undergone and the defendant could sell its drug cheaply in absence of any research involved in producing the drug.

Further, the defendants had claimed the drug to be obvious but had failed to explain as to how the cited documents invalidated the suit patent on account of existence of prior art.

Thus the plaintiffs thereby pleaded that the defendant was trying to infringe the suit patent of the plaintiffs under the garb of public interest which should not be allowed by the Court and hence brought a suit before the Court for infringement of Patent.

Defendant in his reply had claimed revocation of the patent of Novartis on the ground of: (a) unavailability of drugs to patients or to doctors to prescribe; (b) price of the drugs were very high and defendant can make those drugs at almost one-fifth of price of Novartis; (c) the drugs were not being made in India and there are no justification for not doing so and hence it is a clear violation of section 83 (a) of the Act which provides that *patents are granted to encourage inventions and to secure that the inventions are "worked in India" on a commercial scale and to the fullest extent that is reasonably practicable without undue delay.*

The defendant further elaborated the inadequacy of drugs by saying that about 1.5 crore unit/month is requirement of India and hence 1.5 X 12 months will be its yearly requirement but instead only 55,000 unit is supplied which is only 0.03% of the required quantity. Therefore, the percentage of the inadequacy in the requirement per year is a staggering figure of approximately 99.97%. The patent is 'non-working patent' and there is a hindrance since the demand is not met by the plaintiffs to an adequate extent, the commercial activities in India are prejudiced of an existing trade and industries. Defendant cited the case of *Bayer Corporation* vs *Union of India*[87] where it was held that *the patent holder would nevertheless have to satisfy the authorities under the Act as to why the patented invention was not being*

fullest extent that is reasonably practicable without undue delay; and (b) that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article.

[87] AIR 2014 Bom 178.

manufactured in India keeping in view Section 83 of the Act. This could be for diverse reasons but it would be for the patent holder to establish those reasons which makes it impossible/prohibitive for it to manufacture the patented drug in India.

The defendant contested that not making drugs available to general public at large and at the same time preventing other party which with *bona fide* intention trying to make drugs available to the general public is against the spirit of law and is impermissible too. It further stated that the purpose for granting patent is disclosure of invention to general public and used for the benefit of the same. Defendant goes on and stated that importance of access to medicines has been repeatedly reiterated even at the international level i.e. TRIPS agreement itself in Article 7 affirms the importance of Patents being a tool for technological dissemination and technology transfer as well as the Doha Declaration on the TRIPS Agreement and Public Health about the *obligation of member states to provide adequately for life saving medicines*. Therefore, being a patentee it is the duty of plaintiff to make the drug available to the general public which it had failed to perform.

The defendant had drawn the attention of court towards Article 21 of Constitution of India which provides the 'Right to life' to its people. This Right to Life enshrined in the Constitution is not merely a monotonous statement but an obligation that no person shall be deprived of his life of personal liberty except by procedure established by law.[88] This solemn obligation has been interpreted by the Supreme Court to include the 'Right to Health'. The statutory right granted to a patentee under patent law is always to be exercised in a manner which protects preserves and promotes the Constitutional intent to promote the right to life and not in a manner contrary thereto.

Defendant, in light of above arguments, prayed that injunction on production of drugs by defendant should not be permitted as it is for the benefit of the public.

On the basis of above arguments, the Court held that the plaintiffs be granted injunction as the defendant's act amounted to the infringement of a valid patent of the plaintiff and that it could not step into the rights of others under the shield of public interest. For the defendants' plea of the patent being not worked in territory of India, a wider approach was adopted by the court by holding that importation would amount to patent working in India as long as it sufficiently satisfies the need of drug in the domestic market.

[88] Constitution of India, Article 21.

Thus, in the light of the decision made above, it is quite clear that the judiciary's approach has evolved in a manner so as to harmonize with the rights of patentee and general public. At the same time public health should be given priority over individual rights and an attempt must be made to maintain a balancing of rights approach wherein the domestic companies do not receive undue benefits from the investment of the foreign companies in the garb of compulsory licenses. In furtherance of this, Compulsory licenses should be granted only after a strict assessment of whether the conditions in Section 84 have been adequately satisfied and a suitable compensation in the form of royalty must be provided to the patent holder so as to derive reasonable return on its investment. The clause "patented invention being worked in India" must be interpreted such that it does not palpably discard importation of life saving drugs when the importation is sufficient to meet the demand of drugs in domestic markets.

Thus, keeping in mind the rights of the parties involved, an amicable agreement must be reached upon which while promoting public health does not disturbs or infringes the right of the private parties concerned.

IV. CONCLUSION

"*That he, the inventor, ought to be both Compensated and rewarded...will not be denied...it would be a gross immorality of the law to set everybody free to see or use a person's work without his consent and without giving him an equivalent*."[89]

It is a natural human tendency to expect a reward for the work done for the society. A patentee needs to be provided with incentives so as to encourage the quest for innovation and invention. In order to attain this there must be a balance of interests of both the public and private parties. Public interest being vital it should not be at the cost of an individual's right over his invention. Thus compulsory licensing should only be granted upon genuine necessity to promote the public cause. A carefully crafted addition of compulsory licensing in patent law would enhance the public interest while still maintaining incentive to develop new inventions.

While at the same time there is a slight contrast to Mill's view as proposed by Jeremy Bentham's principle of Utilitarianism, according to which, 'pain' and 'pleasure' are the

[89] John Stuart Mill (1848).

sovereign masters under which every human being is bound.[90] Legislations are made for the people and utility of legislation is judged on its capability of maximizing the pleasure and minimizing the pain of the subject.

"India is a welfare state governed by a Constitution which holds the pride of place in the hearts of its citizens. It lays special emphasis on the protection and well-being of the weaker sections of society and seeks to improve their economic and social status on the basis of constitutional guarantees spelled out in its provisions."[91] The Benthamite perspective, instead of focusing on 'whose rights' or 'who deserves', thinks of the welfare of the largest number of people.

In light of the above mentioned principle, the Doha Declaration was passed which aims to protect the right to health by allowing developing countries to take certain measures circumventing TRIPS agreement, for public good, but it can be done only in case of "extreme urgency." The newly discovered uses and improved version of existing drug is entitled to get patent if it turns out to be beneficial for the patient, but at the same time there exists a need to determine differences between the innovations which improve the industrial ability to produce drugs and those which are designed only for extending of existing patent.

Finding new use of an existing drug or enhancing the efficacy of the drug are certain examples which need to be patented again and this is called "incremental innovation" which is to be distinguished from "evergreening" which is done only to get the monopoly extended for another 20 years.

In developing countries, the use of generic version has not been started yet, when drug from developed countries get another patent on newly discovered form or for its new use, limiting the access of the drugs in these countries at low prices. Whereas, it is necessary to encourage the incremental innovation, there should be a proper mechanism to do this. Despite the controversy over section 3(d) of the Act, it is a very efficient mechanism to balance the right to health and the right of patentee. In *F. Hoffmann-La Roche Ltd* vs *Cipla Ltd., Mumbai Central*[92] the court had observed that "Undoubtedly, India entered into the TRIPS regime, and amended her laws to fulfill her international obligations, yet the court has to proceed and

[90] Bentham, J., *An Introduction to the Principles of Morals and Legislations*, 1, Dover Publications (2007).
[91] *Vikram Deo Singh Tomar* vs *State of Bihar*, AIR 1988 SC 1782
[92] *F. Hoffmann-La Roche Ltd* vs *Cipla Ltd., Mumbai Central* MIPR 2008 (2) 35.

apply the laws of this country, which oblige it to weigh all relevant factors. In this background the Court cannot be unmindful of the right of the general public to access lifesaving drugs which are available and for which such access would be denied if the injunction were granted.

Thus, we see that the International standards governing the patent laws allow to accommodate certain flexibilities by the help of which developing countries could deviate from the general terms and conditions laid down in International agreements in order to give precedence to public interest over the rights of private parties. In India too, the judicial approach in this regard proceeds in the same direction, wherein the Supreme Court has denied the patent on the drug in *Novartis AG* vs *Union of India*, while the Delhi High Court has decided in favour of the patentee in *Novartis* vs *Cipla.* Therefore, the Courts while delivering various judgements have succeeded in upholding public interest and respecting the rights of the patent holder at the same time.

EXAMINE EXCLUSION IN PATENT LAW: HARMONIZING COMPREHENSION*

ABSTRACT

This research paper analyses the development of research exemption as doctrine for fair use under the Patent Laws its nature, scope and purpose and whether experimental use exemption is successful in maintaining the internal balance of patent system with special reference to the pharmaceutical industry particularly, to Indian legal scenario. TRIPS consistency of such exception, opinion that it is likely to be confirmed if the issue were specifically raised in a WTO dispute, consistency can be predicated with regard to exceptions that encompass only scientific, non-profit research or experimentation, as well as in cases where research with commercial intent is included, provided that research or experimentation is conducted on and not with the patented subject matter. The analysis of the legislation in developing countries and economies in transition indicates that the research experimentation exception has been widely recognized in patent law both before and after the TRIPS Agreement. An experimental use to promote innovation and competition, protect patent quality and avoid inefficient barriers to trade and avoid anti-commons is inevitable. Narrow experimental use will allow immunity only experiments for mere delight in spite of of whether experiment was performed for profit or nonprofit organisation. This narrow interpretation will result in retardation of innovation, competition and consumer welfare and contradiction between such a narrow exception and patent monopolies.

Keywords: research exemption, TRIPS Agreement, experiment, patent system, intellectual property.

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Intellectual property is a key aspect for economic development.[93]

Craig Venter

I. INTRODUCTION

Intellectual property rights are believed to be the catalysts for development of any science, art, architecture and a wide variety of goods and services. The funding and recognition of this monopoly right given to the patent holder is considered as a must have right and concomitant factor for the development of any economy based on private investment.[94] The history of origin and explanation of this right establishes this fact.[95] Most intellectual products are easily replicated these days and the enjoyment of them by one person does not prevent enjoyment by other persons. This creates the danger for the creators of such products that they will not be able to earn back their costs of expression that is the time and effort they have dedicated in creation of that intellectual property, because they will be undercut by people who copy their work thereby representation low costs of production to the person who is copying and thus, can offer consumers identical products at very low prices. To avoid this economically inefficient outcome all the creators for limited times is vested with certain exclusive monopolistic rights.[96] Along with this, unlike physical property, intellectual property is not having well-defined physical boundaries. Because of the inherent nature of monopoly creation in the intellectual property rights, it's more imperative that we define the contours of the law more extensively.

Grant of monopoly helps in having a return on the investment for the labour invested by the person creating the intellectual property. However, it needs to be balanced with access to information which in itself is the basic inevitability of the society at large. Therefore to balance these conflicting demands there has always been limitations built into the intellectual property legislation of that country that forms part of the relative amount [97] Intellectual property is a compromise between the interests of right holders and users, in other words, society at large. It represents a balance between the interests at stake. The system does not

[93] http://www.brainyquote.com/quotes/keywords/intellectual_property.html
[94]W.R Cornish, Intellectual Property, Sweet & Maxwell, London, 3rd Ed (1996), p.5.
[95]David I Bainbridge, Intellectual Property, Pitman Publishing, London, 4th Ed (1999), p.3.
[96]The Nature of a Patent Right, Thomas Reed Powell, Columbia Law Review, Vol. 17, No. 8. (December, 1917), pp. 663-686.
[97]Ruth Towse and Rudi Holzauer, The Economics of Intellectual Property, vol-1, Edward Elgar Publishing Limited, UK, (2002), p. ix

depend on the author or inventor alone; if society grants exclusive rights, it must be to its advantage to do so, and it is through exceptions and limitations that this balance is achieved Intellectual property rights are not ends in themselves. Their goal is to give as a decentralized system of innovation in science and culture. Thus, exceptions and limitations formed a sacrosanct and unique feature of intellectual property laws.[98]Patents such exemptions include use for research, prior-use exception, pharmacy exception, regulatory review exception etc.[99]

I. WHAT IS RESEARCH EXEMPTION?

In patent, the research exemption or safe harbour exemption is an exemption to the rights conferred by patents, which is especially relevant to drugs. According to this exemption, despite the patent rights, experimental use exception allows researchers to use patented inventions for carrying out experiments and research without taking the license from the patent holder. We can classify research exemption into two, on the basis of the nature of research work and purpose of research.[100] They are experimentation and research on the patented subject matter, and academic or non-commercial research with the patented invention.

People recognize intellectual property the same way they recognize real estate. People understand what property is. But it's a new kind of property, and so the understanding uses new control surfaces. It uses a new way of defining the property.[101]

Michael Nesmith

II. THEORIES FOR RESEARCH PROTECTION

The patent system stands on its ground by the twin theories namely incentive to invent and incentive to disclose.

[98] Peter Drahos, A Philosophy of Intellectual Property, (Ashgate Publishing Limited, England, 2005), p.23.
[99]Leon E. Seltzer, Exemptions and Fair Use in Intellectual Property, Harvard University press, London, (1978), p.4
[100] Robert P. Merges, As Many As Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform, 14 Berkeley Tech. L.J. 577, 587 (199).
[101] http://www.brainyquote.com/quotes/keywords/intellectual_property.html

- The incentive to invent theory is a free-rid
- E market theory is based upon the assumption that investments in the new ideas, unlike investments in capital equipment or materials, are appropriable by competitors at very little expense.[102] Thus, patents are awarded lest would be inventors be disinclined to make the investments necessary to develop.

- The incentive to disclose theory, on the other hand, is based on the notion that a patent is something in which an inventor teaches her invention to the public in exchange for a limited period of exclusive rights.[103]

The disclosure *quid pro quo* has little relevance to self-disclosing inventions. Because a self-disclosing invention is disclosed and enabled by its mere commercialization, the patent disclosure adds little to society's store of technical knowledge. The incentive to disclose is quite germane, on the other hand, inventions for which trade secret protection is a viable option.[104] For such non-self-disclosing inventions, the disclosure of the invention in the patent specification is valuable because it adds information that might have been kept secret to the store of public technical knowledge.[105]

III. NON SELF-DISCLOSING INVENTIONS

Examples of such non-self-disclosing inventions include industrial processes or complex software programs. The free-rider incentive to invent theory does not apply to non-self-disclosing inventions. Because these inventions could have been maintained as trade secrets, an exclusive patent grant is not necessary to stimulate invention.[106] Public benefit from patents on non-self-disclosing inventions must be secured instead through the patent system's disclosure requirements. The role of the patent system for non-self-disclosing inventions is to enable more rapid follow-on invention by disclosing new technical discoveries that can be

[102]Richard Jahn, "Experimental Use Exceptions: Changes in Research Tool Patent Protection in United States and A Comparison to Japan", 2005 (Vol 30) Delaware journal of Corporate Law, 925-948
[103]Simon A. Rose, "Patent Monopolyphobia: A Means of Extinguishing The Fountain Head", IPLR, 2000, 32, 3-51.
[104]Janusz A. Ordover, "A Patent System for both Diffusion and Exclusion", 5 J. Econ. Persp. (1991) at 43.
[105]Gerald T. Welch, "Patent Laws Ephemeral Experimental Use Doctrine: Judicial Lip Service to Judicial Misnomer or The Experimental Stage Doctrine", 13 IPLR 1981, 235-262.
[106]Christopher May, A Global Political Economy of Intellectual Property Rights: The new Enclosures? Routledge Publications, (2000) p. 45.

used as building blocks.[107] Patent exclusivity can also slow technical progress if the best follow-on inventors are prevented from building upon the inventive idea during the patent term.[108] When patents restrict research, the tension between incentives for initial invention and the progress that comes from building upon the available store of knowledge is palpable. On the other hand, a properly designed research exemption promises to relieve some of this tension. Because no license is required for exempted research, refusals to license motivated by private attempts to obtain unwarranted control over future innovation are avoided.[109]

IV. ADVERSE EFFECTS OF PATENTS RESEARCH EXEMPTIONS

Advocates of research exemptions highlight the adverse effects of patents, which fall into a number of categories-deadweight losses, transaction costs and fundamental uncertainty. They contend that the patent system is a necessary evil; not that it should be abandoned, just that its negative effects be attenuated. Exemptions assist in this regard by acting like a subsidy, in that they provide relief from the imposition of monopoly prices.[110] Proponents of research exemptions argue that since much research is cumulative in nature, there may be multiple licensing arrangements that need to be negotiated separately before any actual research can take place. These will probably involve significant transaction costs. These payments are deadweight losses from society's point of view and do not augment the incentive to invest for either party.[111] As a consequence, research will only be conducted up until the point where the transaction costs imposed are less than the total expected value of the research itself. This is of particular relevance with regard to an upstream market, enabling invention which has little or no commercial value yet provides the potential for considerable commercial opportunities downstream. In this case, it is likely that important research projects will not be undertaken at all.[112]

[107]Maureen A. O'Rourke, "Toward a doctrine of fair use in Patent Law", 100 Colum.L.rev.1177 [2000]
[108]J.H Reichman,"Legal Hybrids Between the Patent and Copyright Paradigms", 94 Colum. L.rev. 2432 (1994)
[109]Rebecca S. Eisenberg,"Property Rights and Norms in Biotechnology Research"97 Yale L.J. 177,220-226.
[110]Kenneth W. Dam, "The Economic Underpinnings of Patent Law" 27 IPLR 1995.
[111]William F Baxter, "Legal Restrictions On The Exploitation of Patent Monopoly: An Economic Analysis", L.Q.R 1911, Vol.27, p.60-74.
[112]William F Baxter, "Legal Restrictions On The Exploitation of Patent Monopoly: An Economic Analysis", L.Q.R 1911, Vol.27, p.60-74.

Another issue to contend with is that most research is, by its very nature, subject to fundamental uncertainty. Fundamental uncertainty occurs when information from past events cannot be used to form statistical probabilities over the outcomes of future events, since each event is so distinctive and novel. This concept plays an important role in understanding scientific progress since many important scientific breakthroughs have occurred purely by chance,[113] it cannot be known ex ante which scientific pathways will bear fruit, the greater the user and transactions costs associated with each pathway, the greater is the possibility that some important but not as yet known as being important research will not be undertaken. There is ample evidence which suggest that patent owners blocks research pathways.[114] The belief that uncertainty is pervasive within research has caused concern that the patent system is creating anti-commons over knowledge. As universities push for greater commercialization of output there is greater pressure on university researchers to keep their research a secret in order to fulfill the patenting criteria and to turn research output into proprietary knowledge. This has increasingly resulted in the privatization of the scientific commons and the creation of anti-commons, where knowledge is underused relative to the social optimum. Such a strategy may temper the rate of technological progress.[115] Moreover, it may change the direction of technological progress since if science is guided by the hand of commercial interests, it will focus primarily on puzzles that have commercial significance, rather than puzzles which are intrinsically interesting to scientists.[116]

If it can be demonstrated that the concerns about the adverse effects of patents are valid then there is a strong case for government intervention to remedy the situation. Working and re-working existing knowledge rather than creating new knowledge through research is a predominant activity in innovation. Although not widespread, cases of restricted access to patented inventions and delays in conducting or publishing research, indicate that governments must remain vigilant in ensuring that patenting does not unnecessarily hinder access to knowledge, reduce incentives to disseminate knowledge, or impede follow-on

[113]Walton Hamilton, "Patents and Free enterprise", 16 J.PAT.OFF.SOCY, 35.
[114]Carlos A. Primo Braga and Carsten Fink, The Economic Justification for the Grant of Intellectual Property Rights: Patterns of Convergence and Conflict, 72 Chi.-Kent L. Rev. 439, 440 (1996)
27. Robert P. Merges & Richard R. Nelson, On the Complex Economics of Patent Scope, 90 Colum. L. Rev. 839, 854 (1990).
[115]Steven J. Grossman, Experimental Use or Fair Use as A Defense to Patent Infringement, 30 IDEA 243, 255 (1990)
[116]Kenneth W.Dam, The Economic Underpinnings of Patent Law, 23 J. Legal Stud. 247, 253-54 (1994)

innovation.[117]IPR regimes need to protect researchers' access to fundamental inventions, such as through exemptions for research use of patented inventions.

Experimental use exemption has special relevance to the research of genetic material. The breadth of patents granted for genetic material has raised economic concerns. In particular, concerns have been raised that patents are being granted for genetic material even though the patent owner has not identified any specific use for the material, or that, having identified just one use, rights will be granted that cover all uses to which the genetic material might be put.[118] A consequence of this is that other researchers, who wish to use the patented genetic material in order to identify a use, or further uses, must then pay a license fee to do so.[119] This may discourage such research, which could mean that potentially valuable clinical applications of genetic material will not be developed, or that development of such applications will be delayed until the patent expires.[120] There is also concern that patents of such breadth may unnecessarily raise the cost of health care. When a research exemption exists, proprietary knowledge and technology can be used freely in others' research programs aimed at developing a new product or process which, if achieved, would in principle still be subject to patentability and infringement standards.[121] On research exemption is not envisioned, the mere act of trying to improve on an existing product may be infringing.

V. RELEVANCE OF RESEARCH EXEMPTION TO PHARMACEUTICAL INDUSTRY WITH REFERENCE TO INDIAN SCENARIO

Pharmaceuticals are self-disclosing inventions. They are only brought to market because of the patent regime, and the public benefit gained from the patent is market access to the product. Therefore, it would seem prejudicial to the Patentee's rights to create a research exemption in the field of pharmaceuticals as against the public.[122] Even though R & D costs

[117]Peter Drahos& Ruth Mayne, Global Intellectual Property Rights, Knowledge Access and Development,Macmillan Publishers, New York(2002)p90.
[118]Rochelle Dreyfuss, Diane L Zimmerman & Harry First, Expanding the Boundaries of Intellectual Property, Oxford, New York, (2001) p.57.
[119]PrabhudhaGanguly, Gearing up for Patents: The Indian scenario, Universities Press India ltd, Hyderabad, (1995) p.11.
[120]NunoPires De Carvalho, The TRIPs Regime of Patent Rights, Kluwer Law International, London (2002), p.67
[121]Alfred B. Engelberg, "Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?," 39 IDEA: Journal of Law and Technology
[122] Philip W. Grubb, Patents for Chemicals, Pharmaceuticals, Biotechnology: Fundamentals Global Law, Practice And Strategy, Claredon Press, Oxford, London, (1999) p.12.

for pharmaceuticals are exceptionally high, there needs to be a balance maintained between R & D costs and providing medicines to ensure public health.[123]

In order to instill this balance, price regulation, compulsory and research exemptions are being used. Generic drugs have an enormous impact on the price of brand name medicines.[124] To ensure that upon expiration of patent on the brand name drug, there is no unnecessary holdup and de facto extension of the brand name drug's domination while the generic drug manufacturer goes through the regulatory approval process; generic manufacturers are allowed to conduct preparatory work on patented drugs.[125] This exemption for generic drug manufacturers can either form a part of a broader experimental use exemption or can be contained in an industry specific experimental use exemption.[126]

Whether during the duration period of protection of a pharmaceutical patent, pre-clinical and/or clinical tests may be conducted. Ideally, two different types of testing can be done during the subsistence of a patent provided that a certain substance is protected as a pharmaceutical for a particular indication-

- First, tests with the aim of finding new indications of pharmaceutical substances that have been patented only for one indication.
- Second, tests for market approval of a patented substance for an already patented indication during the protection of a pharmaceutical patent.
- If the latter kind of test is permitted, a competitor of a Patentee can prepare for market approval well ahead of the expiration of the respective patent."[127]

The Experimental use Exception has been accepted in all other technical fields in courts.[128] Financial consequences of earlier or later market entry, particularly in the case of blockbuster pharmaceuticals have problems been experienced in experiments in Pharmaceuticals.[129]

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[123]Elizabeth A. Rowe, The Experimental Use Exception to Patent Infringement: Do Universities Deserve Special Treatment?, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=831044
[124]Janet A. Gongola, Prescriptions for Change: The Hatch-Waxman Act and New Legislation to Increase the Availability of Generic Drugs to Consumers, 36 Indiana Law Review (2003), 787.
[125]Alfred B. Engelberg, Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?, 39 IDEA: Journal of Law and Technology.
[126]PrabhudhaGanguly, Gearing up for Patents: The Indian scenario, Universities Press India ltd, Hyderabad, (1995) p.11.
[127]Edward T. Lentz, Pharmaceutical and Biotechnology Research After Integra and Madey, 23 Biotechnology Law Report (2004), 265 available at http://researchspace.auckland.ac.nz/bitstream/2292/202/1/260.pdf.
[128] Andrew J. Caruso, The Experimental Use Exception: An Experimentalist's View, 14 Albany Journal of Law, Science & Technology (2003), 217.

The trend of denying medicines to growing numbers of people worldwide cannot continue forever, since ultimately, without consumers/clients, the industry cannot survive either. It furthermore seems unlikely that the industry will disappear given its financial clout.[130] The only change that can occur is a change in the industry's modus operandi or a take-over of some of its functions by other parties.[131] This problem is therefore not limited to the Indian Pharma scenario. Keeping in mind the international pressure, we have to design policies on an international framework fulfilling the international obligations and satisfying the domestic demands as opposed to framing a regime purely domestic market oriented.[132]

VI. IMPORTANCE OF RESEARCH EXEMPTION FOR TECHNOLOGICAL DEVELOPMENT AND R&D ESPECIALLY FOR THE PHARMACEUTICAL INDUSTRY

Indian Patent Act, 1970 under Section 47(3) has provided that the research exemption includes the use of any machine, apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted, may be made or used, and any process in respect of which the patent is granted may be used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils. This provision is not much liberal as the section uses the expression merely for research and educational purpose. Comparing this with other national legislations it stands with countries that provide for limited exception. Liberal interpretation to this section since it has simply stated scientific or research purpose without limiting the scope of experimentation with reference to the field of research or nature of research. Liberal interpretation provided by Japan or Germany keeping in view the urgent demands of research in pharmaceutical industry, to make drugs at affordable prices to the public at large.

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[129]Heather Hamme Ramirez, Defending the Privatization of Research Tools: An Examination of the Tragedy of the Anticommons in Biotechnology Research and Development, 53 Emory Law Journal (2004), 362.
[130]Andrew Webster &Kathryn Packer, Innovation And Intellectual Property System, Kluwer Law International, London, (1996) p.65.
[131] Peter Drahos& Ruth Mayne, Global Intellectual Property Rights, Knowledge Access and Development,Macmillan Publishers, New York(2002), p90.
[132] Rochelle Dreyfuss, Diane L Zimmerman & Harry First, Expanding the Boundaries of Intellectual Property, Oxford, New York, (2001) p.57.

VII. CONCLUSION & SUGGESTIONS

In order for patent law to secure a sustainable process of innovation, a research or experimental use exemption needs to be recognized. Such an exception is especially justified in areas where cumulative innovation is crucial, since the flow of innovation resolutely depends on the absence of barriers to the use of already protected knowledge. The exception is also essential in fields of radical innovation, since research and experimentation on existing technologies determines ensuing technological progress and, in particular, the development of new applications. Narrow research exceptions as well as the lack of use of permitted exceptions may slow down important research by restricting or delaying access to patented technologies that may be necessary and for which licenses are sometimes not available or are too expensive to obtain. An exception for research or experimentation fulfils without difficulty the three-step test established by Article 30 of the TRIPS Agreement. TRIPS consistency of such exception, opinion that it is likely to be confirmed if the issue were specifically raised in a WTO dispute, consistency can be predicated with regard to exceptions that encompass only scientific, non-profit research or experimentation, as well as in cases where research with commercial intent is included, provided that research or experimentation is conducted on and not with the patented subject matter. The analysis of the legislation in developing countries and economies in transition indicates that the research/ experimentation exception has been widely recognized in patent law both before and after the TRIPS Agreement. Many countries including the most technologically advanced have not used, however, the full room for man composition left by the Agreement to legislate on this matter.

An experimental use requires difficult compromise between the right of patentees, the rights of patentee competitor and right of public. An experimental use to promote innovation and competition, protect patent quality and avoid inefficient barriers to trade and avoid anti-commons is inevitable. Narrow experimental use will allow immunity only experiments for mere delight in spite of of whether experiment was performed for profit or nonprofit organisation. This narrow interpretation will result in retardation of innovation, competition and consumer welfare and contradiction between such a narrow exception and patent monopolies. On the other hand a broad experimental use will exempt any use of patent by any without regard of its commercial or non- commercial nature. So what we need is an asymmetric experimental use provides differential access asymmetric access to patent subject matter for corporations, small business and non-profit research organisation. Otherwise we

can formulate a statutory experimental use exemption similar to the fair use provision of copyright. Before determining infringement of a patent right, the Court will have to solve the following issues:

- Whether the experimentation is on a patented invention and/ or is research involving the use of a patented invention.
- The purpose or intention of experimentation or research, in terms of its technical, scientific or commercial motivations.
- The technical, scientific or commercial outcomes of experimentation or research; and
- The nature of the organisation conducting the experimentation or research, for example whether the organisation is a commercial or not-for-profit entity.

Such a fair use experimental use provision will be successful in solving the conflict between different affected parties and also in attaining a compromise between various conflicting interests of the patent system and will ensure R&D to the economy by maintaining the internal balance of the patent system. Such a provision will give the flexibility for interpreting the exemption as per the needs of the time and also in accordance with the exigencies of the situation. Such provision can create uncertainty and broadens the exemption; it will stand the legal crisis as it has established clearly in the copyright arena.

IS REGISTRATION OF COPYRIGHT COMPULSARY?*

ABSTRACT

The article focuses about the general rules relating to copyright registration. It is summary as to what copyright is, what rights are associated with it and how registration helps in confirmation of those rights and what are the limitations of those rights. It also focuses on the authorities relating to copyright registration

Keywords: Copyright, rights granted after registration, limitation and expectation, is copyright rights mandatory.

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Is Registration of Copyright Compulsory?

I. GENERAL INTRODUCTION ABOUT INTELLECTUAL PROPERTY

Property according to the traditional classification is either *moveable* or *immoveable property*. Moveable properties are also known as *personal property* whereas immoveable property is known as *real property*. However, both moveable and immoveable property falls under the category of corporeal property which can be touched, sensed, or perceived. The other category is incorporeal property which cannot be physically touched, sensed or perceived. **Intellectual property is such an example of incorporeal property.**

Copyright, Patent, Industrial Designs, Geographical indication, Trademark are types of Intellectual Property.

II. WHAT IS COPYRIGHT? WHAT ARE THE WORKS PROTECTED UNDER COPYRIGHT?

Copyright is a unique kind of intellectual property, the importance of which is increasing day by day. Copyright is the first intellectual property which receives legal recognition in the world. Copyright is a legal term used to describe the rights that creators have over their literary and artistic works. Works covered by copyright range from books, music, paintings, sculpture and films, to computer programs, databases, advertisements, maps and technical drawings. The law of Copyright aims at protecting the fruit of a man's work, labour, skill from annexation by other people.

Copyright is a legal term used to describe the rights that creators have over their literary and artistic works. Works covered by copyright range from books, music, paintings, sculpture and films, to computer programs, databases, advertisements, maps and technical drawings.

Generally, Copyright protection subsists in original works expressed in tangible medium (eg: paper) or with the aid of electronic medium or device (eg: typing in computer or typewriter) intending to communicate, perceive or reproduce the work directly or through any other electronic medium (eg: internet).

Works commonly protected by copyright throughout the world include:

1. Literary works such as novels, poems, plays, reference works, newspaper articles;
2. Computer programs, databases;
3. Films, musical compositions, and choreography;
4. Artistic works such as paintings, drawings, photographs, and sculpture;
5. Architecture; and
6. Advertisements, maps, and technical drawings.

III. AUTHOR AND OWNER OF COPYRIGHT

According to S.17 of the Copyright Act, author of the work shall be the 1st owner of the copyright. "Author'' in Section 2(d) of this Act means,

(i) **In relation to a literary or dramatic work**: the author of the work;

(ii) **In relation to the musical work:** the composer;

(iii) **In relation to an artistic work other than a photograph**: the artist;

(iv) **In relation to a photograph:** the person taking the photograph;

(v) **In relation to a cinematograph film or sound recording**: the producer;

(vi) **In relation to any literary, dramatic, musical or artistic work which is computer-generated:** the person who causes the work to be created

(vii) **In cinematographic film**: producer

(viii) **Newspaper report**: the person who writes

IV. RIGHTS OF THE OWNER:

There are two types of rights under copyright: **economic rights**, which allow the rights owner to derive financial reward from the use of his works by others; and **moral rights**, which protect the non-economic interests of the author.

Is Registration of Copyright Compulsory?

The economic rights owner of a work can prohibit or authorize:

- its reproduction in various forms, such as printed publication or sound recording;
- its public performance, such as in a play or musical work;
- its recording, for example, in the form of compact discs or DVDs;
- its broadcasting, by radio, cable or satellite;
- its translation into other languages; and
- its adaptation, such as a novel into a film screenplay.

Copyright infringement is the use of works protected by **copyright** law without permission, **infringing** certain exclusive rights granted to the **copyright** holder, such as the right to reproduce, distribute, display or perform the protected work, or to make derivative works.

V. LIMITATIONS AND EXCEPTIONS

In order to maintain an appropriate balance between the interests of right holders and users of protected works, copyright laws allow certain limitations on economic rights, that is, cases in which protected works may be used without the authorization of the right holder and with or without payment of compensation.

Limitations and exceptions to copyright and related rights vary from country to country due to particular social, economic and historical conditions. International treaties[133] acknowledge this diversity by providing general conditions for the application of exceptions and limitations and leaving to national legislators to decide if a particular exception or limitation is to be applied and, if it is the case, to determine its exact scope. Due to the development of new technologies and the ever-increasing worldwide use of the Internet, it has been considered that the above balance between various stakeholders' interests needs to be recalibrated.

[133] To see Copyright-related treaties administered by WIPO - http://www.wipo.int/copyright/en/index.html#laws

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In the Copyright Act however, there are some expectations to the general rule laid down in Section 17 of the Act, they are:

1. Dramatic or artistic work made by the author in the course of his employment by the proprietor of a newspaper, magazine or similar periodical under a contract of service or apprenticeship, for the purpose of publication in a newspaper, magazine or similar periodical, the said proprietor shall, in the absence of any agreement to the contrary, be the first owner of the copyright in the work

2. In the case of a photograph taken, or a painting or portrait drawn, or an engraving or a cinematograph film made, for valuable consideration at the instance of any person, such person shall, in the absence of any agreement to the contrary, be the first owner of the copyright therein;

3. In the case of any address or speech delivered in public, the person who has delivered such address or speech or if such person has delivered such address or speech on behalf of any other person, such other person shall be the first owner of the copyright

4. In the case of a Government work, Government shall, in the absence of any agreement to the contrary, be the first owner of the copyright therein;

5. In the case of a work made or first published by or under the direction or control of any public undertaking, such public undertaking shall, in the absence of any agreement to the contrary, be the first owner of the copyright therein;

Limitations and exceptions is an issue considered in the agenda of the WIPO Standing Committee for Copyright and Related Rights[134] (SCCR) and, recently, its debate has been focused mainly on three groups of beneficiaries or activities in relation to exceptions and limitations – on educational activities, on libraries and archives and on disabled persons, particularly visually impaired persons.

[134] To see Standing Committee on Copyright and Related Rights (SCCR) - http://www.wipo.int/policy/en/sccr/

Is Registration of Copyright Compulsory?

VI. FAIR DEALING OF COPYRIGHT

Copyright infringement is the use of works protected by **copyright** law without permission, **infringing** certain exclusive rights granted to the **copyright** holder, such as the right to reproduce, distribute, display or perform the protected work, or to make derivative works.

Fair dealing is a limitation and exception to the exclusive right granted by copyright law to the author of a creative work. It permits reproduction or use of copyrighted work in a manner, which, but for the exception carved out would have amounted to infringement of copyright. The defense of "fair dealing" initially originated and emanated as a doctrine of equity which allows the use of certain copyrightable works, which would otherwise have been prohibited and would have amounted to infringement of copyright. This doctrine is one of the most important aspects of Copyright Law which draws a line between a legitimate, bona fide fair use of a work from a malafide blatant copy of the work. This is the reason why this doctrine was explicitly enshrined in Article 13 of the Trade Related Aspects of Intellectual Property Rights.

The laws relating to fair dealing have been incorporated in Section 52 of The Copyrights Act, 1957. As the Indian Copyright Act does not defines the term "fair dealing" .But apparently, the Indian courts have also started paying attention to the same.

The exceptions to the general rules of infringement of copyright as laid down in Section 52 are:

1. a fair dealing with a literary, dramatic, musical or artistic work not being a computer programme for the purposes of private use including research.

2. the performance of a literary, dramatic or musical work or the communication to the public of such work or of a sound recording in the course of any bona fide religious ceremony or an official ceremony held by the Central Government or the State Government or any local authority before a non-paying audience.

3. in relation to a literary, dramatic or musical work recorded or reproduced in any cinematograph film, the exhibition of such film after the expiration of the term of copyright therein.

4. the reconstruction of a building or structure in accordance with the architectural drawings or plans by reference to which the building or structure was originally constructed: Provided that the original construction was made with the consent or license of the owner of the copyright in such drawings and plans

5. the making of copies or adaption of the computer programme from a personally legally obtained copy for non-commercial personal use.

6. the reproduction or publication of a literary, dramatic, musical or artistic work in any work prepared by the Secretariat of a Legislature or, where the Legislature consists of two Houses, by the Secretariat of either House of the Legislature, exclusively for the use of the members of that Legislature.

7. the reproduction of a literary, dramatic, musical or artistic work—by a teacher or a pupil in the course of instruction; or as part of the questions to be answered in an examination; or in answers, to such questions;

8. the performance, in the course of the activities of an educational institution, of a literary, dramatic or musical work by the staff and student of the institution, or of a cinematograph film or a sound recording, if the audience is limited to such staff and students, the parents and guardians of the students and persons directly connected with the activities of the institution.

9. sound recordings of that work have been made by or with the licence or consent of the owner of the right in the work.

VII. REGISTRATION OF THE COPYRIGHT

The question is whether copyright registration is compulsory or not?

Is Registration of Copyright Compulsory?

Registration of copyright is **optional** and not mandatory. It is not a pre- requisite condition for claiming copyright in a work. Copyright subsists as soon as the work created is communicated or published.

Copyright Act, 1957 facilitates the registration of copyright in Section 44- Section 50A.

Section 44 of the Act provides that a Register of Copyright shall be maintained, in which the names or titles of the works and the names and addresses of owners of copyright and such other particulars may be entered. Section 48 provides that the register of the copyrights would be deemed as prima facie evidence of the particulars entered therein.

The persons applying for registration has to file an application in the prescribed form accompanied by the prescribed fee to the Registrar of the Copyright.

The applicant should give notice of his application to every person who claims or has any interest in the subject-matter of copyright. In case of joint authorship, when one of the authors makes an application for registration, the notice of such application is to be given to other author or authors.

If no objection to such registration is received by the Examiner of the Copyright within 30 days of the receipt of the application, he will be finding if there is any discrepancy relating to the correctness of the particulars given in the application. If no discrepancy is found, the copyright is sent for the approval of the Registrar. The Registrar shall enter the particulars in the Register of Copyright if he approves it.

If any discrepancy arises, the Examiner shall issue discrepancy letter to the applicant and hereafter, the applicant will be heard by the Registrar. After hearing of the applicant, the Registrar either approves or disapproves the copyright.

If the copyright is approved the Registrar will send a copy of the entries made in the Register to the party concerned.

If disapproved the Registrar will send a letter of rejection to the applicant.

If the Examiner receives any objection relating to such registration within 30 days of the receipt of such application, a letter to appear before the Registrar is send to both the parties. After hearing, the application is either accepted or rejected.

If accepted it will be send to the Examiner to see whether there is any discrepancy and further send for the approval of the Registrar.

A person aggrieved by the decision or order of the Registrar may within 3 months of the date of such order or decision appeal to Copyright Board.

VIII. CONTENTS OF THE COPYRIGHT APPLICATION

Every application for registration of copyright shall be in respect of only one work and every application shall specify:

- Name of the applicant.
- Address of the applicant.
- Nationality of the applicant.
- Nature of the applicant's interest in the copyright work.
- Class and description of the work.
- Title of the work.
- Language of the work.
- If the author is deceased, the date of his death.
- Whether work is published or unpublished
- If published, 1. Year of publication 2. Country where it was 1st published 3. Name, address, nationality of the publisher.

IX. WHO IS REGISTRAR OF COPYRIGHT? AND WHAT IS HIS POWER?

Section 9 of the Act provides for the establishment of the copyright office under the immediate control of the Registrar of the Copyright. The Registrar functions under the superintendence and directions of the Central Government. The Central Government appoints the Registrar and may appoint one or more "Deputy Registrars" of Copyright.

A Deputy Registrar discharges his functions or duties under the superintendence of the Registrar of Copyright.

Is Registration of Copyright Compulsory?

The function of a Registrar or Deputy Registrar is restricted to administrative matters only.

The Registrar cannot be a member of Copyright Board but can act as his secretary.

The Registrar enjoys same powers of the Civil Court while trying a suit. It can:

1. Summon and enforce attendance of any person.
2. Examine any person on oath.
3. Require the discovery and production of any document.
4. Receive evidence on affidavits.
5. Issue commission for examination of witness and documents.
6. Requisition any public record or copy thereof from any court or office and
7. Deal with any matter which may be prescribed.

A person aggrieved by the decision or order of the Registrar may within 3 months of the date of such order or decision appeal to Copyright Board.

X. WHAT IS COPYRIGHT BOARD? AND WHAT ARE IT'S POWERS?

The Copyright Board as mentioned in Section 11 of the Act, is quasi-judicial body constituted by the Central Government consisting of a Chairman and not less than two members. The Chairman and the members are appointed for a period not exceeding 5 years. They are eligible for reappointment.

The Central Board ordinarily hear the proceedings instituted before it.

The Copyright Board enjoys same powers of the Civil Court while trying a suit. It can:

1. Summon and enforce attendance of any person.
2. Examine any person on oath.
3. Require the discovery and production of any document.
4. Receive evidence on affidavits.
5. Issue commission for examination of witness and documents.
6. Requisition any public record or copy thereof from any court or office and
7. Deal with any matter which may be prescribed.

Any person aggrieved by the final decision or order of the Copyright Board may within 3 months of the date of such order or decision may appeal to the High Court.

XI. CONCLUSION

If the owner gets the copyright in his work registered with the Register of Copyright, certain rights emerge from such registration which is exclusive rights to reproduce, publish, perform and expose the work to the public. The registration of the work under the Copyright Act,1957 confers a property right over the Copyright work.

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