PATENTS, POWER AND PUBLIC INTEREST: RETHINKING COMPULSORY LICENSING UNDER INDIAN PATENT LAW

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ABSTRACT

The patent system seeks to encourage innovation by granting inventors exclusive rights over their inventions, but such exclusivity may create tensions with public interest, particularly where patented medicines and technologies remain inaccessible or unaffordable. This paper critically examines the balance between patent monopoly and public interest under the Patents Act, 1970, with particular emphasis on the framework of compulsory licensing in India. It analyses the statutory provisions governing compulsory licensing, including Sections 84, 85, 92 and 92A, and examines the circumstances in which patent rights may be restricted to safeguard public welfare. The study further evaluates the relationship between Indian patent law, the TRIPS Agreement and the Doha Declaration, particularly in relation to the right to health and access to essential medicines.

Judicial decisions including Novartis AG v. Union of India, Bayer Corporation v. Natco Pharma Ltd., Lee Pharma v. AstraZeneca, BDR Pharmaceuticals v. Bristol Myers Squibb and Merck Sharp & Dohme Corp. v. Glenmark Pharmaceuticals are examined to understand the judicial approach towards patent protection, affordability, availability and procedural safeguards. The paper argues that compulsory licensing operates as an important mechanism for reconciling innovation incentives with social welfare. It concludes that effective patent regulation requires a careful balance between protecting legitimate commercial interests and ensuring that patent monopolies do not undermine public health and access to essential medicines.

Keywords: Compulsory Licensing; Patent Exclusivity; Public Interest; Public Health; Indian Patent Law

CHAPTER 1: INTRODUCTION

1.1 Concept of Patent Monopoly

A patent right is not a positive right which entitles the right holder to do certain things,[1] it is an exclusionary right[2]. It permits the patent owner to prevent others from producing, using, selling, stocking, the protected products or processes[3]. One of the extensively underlined understanding of Patent rights is that grants monopoly rights exclusively to the patent owner for his invention, such an assumption calls for an inquiry whether patent system is just promoted to enable commercial benefit of invention or does it also benefits any public interest, to understand the underlying object of patent rights it is essential to explore the patent jurisprudence in detail.[4]

There are different theories which lay down the basic origin of patent laws, surprisingly Utilitarian theory theorizes that manufacturers are rewarded for fulfilling a larger objective of public utility.[5] It argues that monopoly right should be granted to the creators so that they can bring benefits to the society as a whole and maximize public utility[6]. William C. Robinson made a significant observation that, patent protection is sustained only on condition that three goals are achieved, rewarding the inventor for his skill, diligence and labour; tempt him to

[1] As an object of property, however, it is a positive right, which means that is an asset in itself, which can be transferred, licensed etc. See e.g., Art. 28(2) TRIPs: "2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts."
[2] The mere fact that one has a patent on for instance stem cell technology does not in and of itself the right holder to practice this technology and exercise the rights in practice, as there might be regulatory limitations or even prohibitions to perform any activities relating to stem cells. To the extent that such limitations and prohibitions would not be there, the right holder can exercise the patent rights.
[3] According to the statutory definition, a patent shall confer on its owner the following exclusive rights: (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product; (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process. The above definition stems from Art. 28 TRIPs Agreement, but is largely identical to national statutory provisions in the EU member states.
[4] Klitzke, Ramon A, Historical Background of the English Patent Law, 41 J. PAT. OFF. SOC'Y 615 (1959).
[5] FISHER, WILLIAM, THEORIES OF INTELLECTUAL PROPERTY," IN NEW ESSAYS IN THE LEGAL AND POLITICAL THEORY OF PROPERTY 168 (2001).
[6] Katz, Larissa, Ownership and Social Solidarity: A Kantian Alternative, 17 LEGAL THEORY 119 (2011).

improve still further upon his invention, and, above all, conveying immediate knowledge of the invention to the world in such manner as to best subserve the public interest.[7]

1.2 Meaning and Scope of Compulsory Licensing

The Compulsory Licensing mechanism is a straightforward legal means to reconcile these competing public interests by ensuring continued incentives for innovation; and the ability for the public to access affordable medicines and technologies without patent barriers.[8] The part of the Controller‘s review under section 84 specifically permits the assessment of both availability and affordability, and the Act as a result sets Compulsory Licensing as a vehicle for public, interest considerations when the patent owner‘s monopoly results in intolerable public consequences, thus, even if Compulsory Licensing does, in some respects, break down the principle of exclusivity, the solution remains economically internationally acceptable, if implemented in accordance with the provisions of the TRIPS.[9] In Novartis vs Union of India, it became more clear that India had a fight in its hand against “evergreening” (granting of patents for “minor modifications to existing drugs that do not provide enhanced therapeutic efficacy”) under Section 3(d), Novartis made it apparent that the judiciary was willing to hold the line on patentability and scope of patents in order to safeguard the access to medicines for its citizens resulting in a copyright environment during the creation and maintaining of patent(s).[10]

Taken together, these authorities show that India‘s Compulsory Licensing regime is not just a legal tool but part of a larger jurisprudential and policy approach that values public health, which would be negatively affected by patent protection, [11] section 84 provides that “Any interested person” may apply for a compulsory licence after three years from the date of the grant of the patent if any of the following conditions are satisfied: (a) the reasonable requirement of the public with respect to the patented invention have not been satisfied; (b) the patented invention is not available to the public at a reasonably affordable price; or (c) the

[7] WILLIAM C ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS (1890).
[8] (WTO | Intellectual Property (TRIPS) - Agreement Text - Standards, n.d.)
[9] (Indian Patent Act 1970-Sections, n.d.-b)
[10] Novartis AG v. Union of India is (2013) 6 SCC 1
[11] Bayer Corporation v. Natco Pharma Limited, 2014(60) PTC 277 (BOM). (n.d.). Drishti Judiciary. https://www.drishtijudiciary.com/landmarkjudgement/intellectual-property-rights/bayer-corporation-v-natco-pharmalimited-2014-60-ptc-277-bom

1.4 Role of Compulsory Licensing in Balancing Competing Interests

At the centre of the dispute is, arguably, the TRIPS Agreement which is a binding treaty in the context of the World Trade Organization will set minimum standards for IP protection, such as pharmaceutical patents.[17] Although the TRIPS contain flexibilities, namely, compulsory licenses and parallel trade, many nations including India encounter legal and diplomatic obstacles in implementing these, for example, India's first compulsory license for the cancer drug, Nexavar, met with a harsh reaction from multinational pharma companies and their governments in 2012.[18]

The difficulty of implementing TRIPS, the incentives to include "TRIPS, Plus" measures into bilateral trade agreements, all hinder developing countries in using TRIPS flexibilities without penalties.[19] Notwithstanding the constraints, patent legislation in India, , primarily the Patents Act 1970 (amended in 2005 to bring in compliance with TRIPS), contains some important measures to promote a balance between innovation and the access considerations, for instance, there is the Health and Patent Policy in India, Section 3(d) which seeks to prevent evergreening of drugs by nullifying the patent rights based on trivial variations of drugs known already, except where they have an improved therapeutic value, and Section 84 providing for compulsory licensing in an eventuality where the patented invention is not available to the citizens at a "reasonable price" or an adequate scope.[20]

India will be required to balance the demands of respect for its international commitments to intellectual property law (IP) while simultaneously respecting its constitutional obligation to protect health, while India's legal structures offer considerable defense against the potential harms of patent monopolies, the political and economic risks of employing them (e. g. trade sanctions, threats of investment arbitration) will be difficult to ignore.[21]

[17] Agreement on Trade-Related Aspects of Intellectual Property Rights arts. 7–8, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299.
[18] Ministry of Commerce and Industry, Government of India, Press Note on Grant of Compulsory License to Natco Pharma Ltd. for Nexavar (Mar. 12, 2012).
[19] Sangeeta Shashikant & V. S. Suneetha, TRIPS-Plus Provisions in FTAs: Impact on Access to Medicines, 13 Indian J. Med. Ethics 99, 101–03 (2016)
[20] The Patents Act, No. 39 of 1970, §§ 3(d), 84, India Code (1970).
[21] Frederick M. Abbott, Protecting Public Health and Access to Medicines in the WTO: The TRIPS Agreement and Flexibilities for Developing Countries, 12 Syr. Sci. & Tech. L. Rep. 1, 9– 12 (2005).

CHAPTER 2: PATENT RIGHTS UNDER THE PATENTS ACT, 1970

2.1 Nature and Scope of Patent Monopoly

Different historical reasons related to the history of IP protection account for the frequent equaling of a patent and a monopoly, the first one is related to legislation. Many laws passed much before the XXth century have equated patent to monopoly, in the XIXth century, patent rights were not similar to the rights over intangible goods we know today, they did not constitute "property rights" attached to intangible goods, patents rights were instead concessions of specific "privileges" issued to natural persons, usually, a patent granted its owner of the right to be the only one authorized to sell particular kind of goods or services.[22]

The notion that a patent was a sort of monopoly has stuck ever since and has spilled over to IPRs, for example, monopolies have frequently been mentioned in the context of patents in the case, law of the US antitrust.[23] During the late XIXth and early XX th centuries, the US courts continually ruled that patents were not subject to the antitrust law, notwithstanding the monopolistic character.[24]

2.2 Rights Conferred on Patent Holders

A significant case is injunctive relief would be: F. Hoffmann La Roche Ltd v Cipla Ltd. (2008), where the Delhi High Court granted Roche a preliminary injunction, the prevention of Cipla selling a generic version whether this use was a 'method of treatment by surgery or therapy', the Court decided that neither application, however much ingenuity they were thought to embody, constituted a "method of treatment by surgery or therapy.". the importance of this case lies in its emphasis that although drugs themselves are the subject of patent protection, no monopoly is conferred over methods of using them to cure diseases or other medical conditions,

[22] For a historical overview of the patent system, see S.J.R. Bostyn, Enabling Biotechnological Inventions in Europe and the United States. A study of the patentability of proteins and DNA sequences with special emphasis on the disclosure requirement, Eposcript Series, nr. 4, EPO, München, 2001,, 7-22

[23] See e.g., Bement v. National Harrow Co. 186 U.S. 70, at 91 (1902): "[t]he very object of these laws is monopoly"; Continental Paper Bag Co. v. Eastern Paper Bag Co. 210 U.S. 405, at 423 (1908): "The patent law is the execution of a policy having its first expression in the Constitution..... It is worthy of note that all that has been deemed necessary for that purpose, through the experience of years, has been to provide for an exclusive right to inventors to make, use and vend their inventions. In other words, the language of complete monopoly has been employed." For more details, see G.S. Rich, "Are Letters Patent Grants of Monopoly"?, 15 WESTERN NEW ENGLAND LAW REVIEW, 1993, (239) at 249.

[24] See e.g., Henry v A.B. Dick Co., 224 U.S. 1 (1912).

a further source of tension stems from the patentee's protection of its exclusive rights and that there is sufficient access in terms of affordability, accessibility, and availability of medicines for all of us in India[25]

According to Article 33 of the TRIPS Agreement and Section 53 of the Indian Patents Act, the ordinary term of a patent is 20 years from or, if filed after expiration of such terms, by an application for extension of time filed within the one year following expiration, to continue the patent, renewal fees must be paid periodically to the patentee, non payment of this sum means that the license expires at the end of Patent rights, as can be seen in the Indian Supreme Court case Dr. (Mrs.) Suman Dhamija v. Union of India[26]

2.3 Limitations and exceptions to patent rights

The exception, provided for in Section 47(3) of the Patents Act, is that any person is entitled to use a patented product or process for the purpose 'merely of experiment or research including imparting of instructions to pupils'.[27] Section 49 of The Patents Act lays down that there is no infringement of a patent if the patented invention is used in a vessel or aircraft or land vehicle (hereinafter referred as 'vehicle') not registered in India while such vessel or aircraft or land vehicle is temporarily or accidentally on Indian territory including Indian air space or Indian territorial waters under the registration of such foreign vessel or aircraft or land vehicle or by a person who, ordinarily, resides in a foreign country; or is used on board of, or in the construction or working of, such vessel or aircraft or land vehicle.[28]

The provisos to Section 11A subsection (7) is an odd provision brought to patent law by the Patents (Amendment) Act, 2005, under said section 11A (7), it is provided that 'on the date on which the patent application was published, the patent applicants shall have the like privileges and rights as if a patent has been granted', this section essentially states that when the patent is granted, the patent applicant is free to sue and claim damages from the date on which the patent application was published.[29]

[25] F. Hoffmann-La Roche Ltd. v. Cipla Ltd., 148 (2008) DLT 598 (Delhi)
[26] Dr. (Mrs.) Suman Dhamija v. Union of India, (2004) 2 SCC 90 (India)
[27] See S.47 of Patents Act 1970
[28] See S. 49 of the Patents Act 1970
[29] See S.11A(7); http://ipindia.nic.in/ipr/patent/eVersion_ActRules/sections/ps11.html

The non commercial use exception which is applicable to the grant of compulsory licence has been taken up on a different module, the private and non commercial use exception provisions have been assigned in Section 84 (Compulsory licenses), 85 (Revocation of patents by the Controller for non working) and 92 (Special provision for compulsory licences on notifications by Central Government) of the Patents Act 1970, this exception also encompasses the Para 6 of the Doha Declaration in section 92A, which grants the licence to any third party, manufacturing and exporting patented pharmaceutical products to 'any country that experiences insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided a compulsory licence has been granted by such country or such country has, through notification or otherwise, approved importation of the patented pharmaceutical products from India.[30]

2.4 Working of Patents in India

Patent law is just one aspect of intellectual property law in general, the regime for the protection of property rights, which is set up to encourage the production and use of inventions, had two fundamental characteristics, this grants the inventor he exclusive rights over the invention for a set period, as it concerns to pharma field, patents enable researchers to research and Development (R&D), give the innovator the chance to recover investment and profits from their creations, since the structural solution would involve increased levels of investment into culture, it would inevitably create job opportunities for cultural workers, of course, the extensive provision of jobs would be specific to a given time.[31]

India's patent system, embedded in the Patents Act,1970 is the result of the country's persistent struggle to balance the standards of intellectual property protection with the socio, economic needs of its developing society.[32] Indian patent law was aimed not only at rewarding inventors but also at protecting the rights of the larger community, this balancing act was particularly

[30] Implementation of Para 6 of the Doha Declaration on the TRIPS Agreement and Public Health http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm
[31] Frederick M. Abbott & Jerome H. Reichman, The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions, 10 J. Int'l Econ. L. 921, 924 (2007).
[32] The Patents Act, No. 39 of 1970, India Code (1970)

acute within the pharmaceutical sector at the turn of the century as patent monopolies could, and indeed did, threaten the availability of life, saving medicines.[33]

CHAPTER 3: LEGAL FRAMEWORK OF COMPULSORY LICENSING

3.1 Compulsory Licensing under Patents Act 1970

The Indian Patents Act, 1970, embodies a considered compromise between the need to protect patent rights and the wider social responsibilities, particularly in the area of public health.[34] A key element of this framework is compulsory licensing, this provides for a legal mechanism such that, under certain circumstances, the government or other interested party can set aside the rights of a patent holder.[35] The most important provision already alluded to is Section 84 of the Act, which provides for the grant of compulsory licenses after three years from the date of grant of the patent by the Controller of Patents.[36]

3.1.1 Section 84 – Grounds for grant of Compulsory Licensing

The first such ground of grant is that the reasonable requirements of the public with respect to the patented invention have not been satisfied[37]. This situation may occur when the product (particularly one as critical as a life saving medication) is offered in inadequate quantities and/or to only a narrow segment of the population, say urban hospitals, or the top medical centres, thereby leaving the rest of the citizenry out in the cold.[38] When this occurs, the invention may exist but, even though its use provides the advantage, its gains are unfairly spread out.[39]

The position taken by the law is that the patent should benefit the patentee as well as meet the general health needs of the populace.[40] The second and maybe more important reason is that

[33] S. Chandrasekharan, Indian Patent Law and Its Impact on the Pharmaceutical Industry, 17 J. Intell. Prop. Rts. 254, 256–57 (2012)
[34] The Patents Act, No. 39 of 1970, India Code (1970).
[35] Id. § 84.
[36] Id.
[37] Id. § 84(1)(a)
[38] Feroz Ali, The Law of Patents 332–33 (2d ed. 2021).
[39] Id.
[40] Shamnad Basheer, India's Tryst with TRIPS: The Patents (Amendment) Act 2005, 1 Indian J.L. & Tech. 15, 25–27 (2005)

that protected invention is not available at a reasonably affordable price.[41] This is especially relevant in a country like India where the immense numerical majority will be unable to afford costly treatments.[42] For example, in the case of the cancer drug 'Nexavar', Bayer priced it at about 2.8 lakhs per month, making it beyond the reach of more than 99% of patients.[43] These prices, even if they are considered necessary, are even inconsistent with the Indian constitutional right to health.[44]

3.1.2 Section 85 – Revocation of Patents

The Patents (Indian) Act, 1970, Section 64 enumerates different reasons for revoking the patent i. e. the conditions for revocation of Patents, any interested person can file petition for revocation of a patent under section 64 of the Patents Act or the Central Government can also do so, they are: Another point of evident was that the invention was already claimed in an earlier valid patent in India, the patent was obtained by any person who was not entitled to make the application under the provisions of this Act, the rights of petitioner or persons whose rights petitioner represents have been infringed by the grant of the patent, the matters the subject of the patent claim is not an invention within the meaning of this Act, the invention is not new because it was already available (whether by experience, use, publication of its description in India or elsewhere) to the public before the priority date, the invention is obvious or does not involve an inventive step having regard to any information made publicly available in India or used in India before the priority date or to any information published in India or elsewhere before the priority date, the invention has no practical use.[45]

Philips v. Rajesh Bansal, Sole Proprietor, Manglam Technology (2017), this was a litigation filed by Philips for infringing the patent rights in DVD, ROM, the defendant filed a counter claim for revocation of the patent for lack of inventive steps and novelty, court held in favour of the patent and pronounced it to be valid, this judgement reflects the hardships in proving patent to be lacking in novelty and inventive steps for revocation under Section 64, merely

[41] The Patents Act § 84(1)(b)
[42] Srividhya Ragavan & Amaka Vanni, Compulsory Licensing in India: Past, Present and Future, 18 J. Generic Meds. 157, 160–61 (2022).
[43] Bayer Corp. v. Natco Pharma Ltd., Compulsory License Application No. 1 of 2011, Controller of Patents (Mar. 9, 2012).
[44] Paschim Banga Khet Mazdoor Samity v. State of West Bengal, (1996) 4 SCC 37 (India).
[45] The Patents Act, 1970, https://ipindia.gov.in/writereaddata/Portal/IPOAct/1_31_1_patent-act-1970-

stating allegations will not suffice, wherein strong evidence has to be produced to fulfil the heavy burden of revocation.[46]

Enercon (India) Ltd. & Ors. v Enercon GMBH & Anr (2014) in this case enercon India challenged several patents from enercon GMBH which were not found to be novel, inventive or followed proper procedures, the case was exhausted by Supreme Court of India and they decide to revoke some of the patent whereas will have to uphold some others, this case was very important on the basis that this was a leading example that all patents have to be so thoroughly scrutinized through Section 64, this not only applies in cases of Mechanical Devices but to all types of devices.[47]

3.1.3 Section 92 – National Emergency and Public health

The WTO was formed in 1994 under the Marrakesh Agreement, TRIPS agreement was also signed by the various counties in the same period,[48] the right to health is one of the leading rights protected under the auspices of the IHRL, placed alongside other of the 'most basic and fundamental rights' such as the right to life and the right to freedom, article 25 of the Universal Declaration of Human Rights affirms the right to health by providing that: 'Everyone has the right to a standard of living adequate for the health and well, being of himself and of his family, including, the right to security in the event of sickness' the right to health was also included in the Preamble of the Constitution of the World Health Organization (WHO), created in 1946, which stated: "The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.[49]

3.1.4 Section 92(A) – Export of Pharmaceutical Products

Export licensing is a requirement dictated by governments to control the export of certain goods, of which a pharmaceutical product is a part, the following summarizes: Aims: Export licensing seeks to regulate export of sensitive or strategic goods, such as pharmaceuticals, in

[46] Philips v. Rajesh Bansal, Sole Proprietor, Manglam Technology 2017 https://indiankanoon.org/doc/156062069/
[47] Enercon (India) Ltd And Ors vs Enercon GMBH And Anr 2014 https://indiankanoon.org/doc/146487961/
[48] Gustavo Bravo, From Paris Convention to TRIPs: A Brief History, 12 J. Contemp. Legal Issues 445 (2001).
[49] World Health Organization Constitution 1946, Preamble

order to comply with national and international legislation, prevent the diversion of products to unauthorised end users, and to protect the health and safety of the public, Regulatory bodies: Export licensing is usually administered by government bodies charged with trade, business or customs, such as the United States Department of Commerce or the European Union Directorate, General for Trade, Licensing procedures: Pharmaceutical exporters are required to register for licenses with the relevant regulator before exporting, this process may include the submission of an application form, supporting information (such as product information, certificates of analysis), and payment of any fees, Regulatory conditions: Certain kinds of export licenses may impose conditions or limitations, such as restrictions on quantities, specific destination countries, or end, user end confirmation, or the entry into international trade sanction regimes.[50]

3.2 Procedure for Grant of Compulsory License

As one of the requirements for patent it should have an industrial application in the domestic market and be used in the public interest, so, if the innovation is not available in public domain in a sufficient quantity as per requirement perhaps, one can apply for a grant of compulsory license, when the innovation is not affordable it is surely out of the reach to the general public which is again in negation of the basic requirement for the grant of patent, where the invention is not commercially worked in India within a reasonable period of time, then can be a ground for issuing a Compulsory License to a third party so that maximum benefit could be derived from the invention by the public, besides these, there are many other reasons suggested from the provisions which provide grounds for the grant of Compulsory License, from the perspective of public interest, licensing on dependent patents, use of government, in India, while using the patented invention, the government is required to follow certain procedures provided in chapter XVII of the Patents Act, 1970, which include.[51]

[50] "Quality Control and Documentation Requirements for Pharmaceutical Exports: Regulatory Perspectives and Industry Practices" Authors: Jessica White, Michael Lee, Sarah Wilson Journal: Pharmaceutical Quality Assurance Review Year: 2021

[51] Patents Act 1970, Chapter XVII Use of Inventions for Purpose of Government and Acquisition of Inventions by Central Government

3.3 Role of Controller of Patents

The Patents Act gives detailed statutory provisions to the powers of the Controller with the most significant being those in Section 73, 77, 78 and other Sections of the Act. These provisions from the Statutes themselves define the extent of the powers as well as their limits, creating a delicate balance between the need for administrative flexibility and fairness. The Patent Office is now under Controller General, which has four branch offices in Chennai, Delhi, Kolkata and Mumbai. Under this organization, patent administration is decentralized but the power of the controller is applied uniformly in the whole country.

CHAPTER 4: PUBLIC INTEREST AND INTERNATIONAL OBLIGATIONS

4.1 Public Interest in Patent Law

Patents compel the inventor to publish those innovations, contributing to the proliferation of knowledge, in theory, this open disclosure has the twofold purpose of encouraging additional innovations by providing others with information, and allowing the innovation to be accessible for use and modification once the patent expires, some students of the patent system have been alarmed at the gaps in the information contained within patent specifications, as this information is often incomplete, vague or deliberately misleading then, by its very nature, a patent specification cannot materially enable a person skilled in the art to replicate the invention in its entirety, furthermore in the patent system secrecy is sometimes encouraged as the ingenuity of the invention can often be masked or given away with the specification, inventors can also use other methods such as maintaining a trade secret and the specification will seldom give anything more than a fuzzy outline of how the invention works.[52] The relationship between patents and public health, shown here in the context of pharmaceuticals and vital technologies, is an example of how exclusivity can work against availability.[53]

[52] LawTeacher.net, Patent Technology Devices, lawteacher.net, July 2025 https://www.lawteacher.net/free-law-essays/copyright-law/patent-technology-devices.php.
[53] Dr Uday Shankar, Prioritising public interest in patent law of India, SCC Online, June 14, 2021 https://www.scconline.com/blog/post/2021/06/14/patent-law/#:~:text=The%20provisions%20that%20allow%20the,the%20public%20over%20private%20interest..

4.2 Right to health and access to Medicine

The Indian Constitution's Article 21 also guarantees the "right to life" which is considered to also include the "right to health" which the courts have deemed as an inherent right. [54] Improvements to the UN position on the right to health can be found in the 1966 International Covenant on Economic Social and Cultural Rights (ICESCR) which establishes the right to health in Article 12 as:"[t]he States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.[55]

4.3 TRIPS agreement and Doha Declaration

TRIPS Agreement (Trade Related Intellectual property Rights) is the 1st legally binding international instrument on IPRs, which governs seven types of IPRs, provides Convention plus protection for IPRs on the additional responsibilities imposed by the Paris, Berne, Rome and Washington group of treaties in their respective areas.[56] In India, Patent Protection for Pharmaceutical and Agrichemical Products the panel observed that the TRIPS Agreement has a self, contained sui generis status within the WTO.[57]

The Doha Declaration (Paragraph 5(d) went a step further and noted that the provisions of Article 6 of TRIPS "shall be understood as allowing members to determine the regime of exhaustion that will operate within their territories".[58] Exhaustion of IPR refers to the fact that when a patented, trademarked or copyrighted article has been sold by the IPR owner or his licensee/ agent, he cannot thereafter control its further sale or distribution (the process of "exhaustion of rights" principle), this is recognized in nations within their national jurisdictions[59]

[54] Article 21, The Constitution of India
[55] United Nations General Assembly, International Covenant on Economic, Social and Cultural Rights, International Covenant on Civil and Political Rights and Optional Protocol to the International Covenant on Civil and Political Rights, 16 December 1966, A/RES/2200, Article 12(1).
[56] Correa Carlos M., Intellectual Property Rights, the WTO and Developing Countries- The TRIPS Agreement and Policy Options, p. 2
[57] WT/DS 50/R (1998) para 7.19 taken from Correa Carlos M., Trade Related Aspects of Intellectual Property Rights- a commentary on TRIPs Agreement, p. 5.
[58] Chaudhari Sudip, The WTO and India's Pharmaceuticals Industry-Patent Protection, TRIPS, and Developing Countries, p.79.
[59] Ping Xiong, 'Pharmaceutical Patents in the TRIPS Agreement and the Right to Health - Can These Rights Be Reconciled?', http://www.austlii.edu.au/ au/journals/ UWA Law Rw/2012/

CHAPTER 5: JUDICIAL INTERPRETATION AND IMPACT ANALYSIS

a) Lee Pharma v. AstraZeneca (2015)

The case of Lee Pharma v. AstraZeneca (2015) was a key patent law ruling in India that considered compulsory licensing as per Section 84 of the Patents Act, 1970, this ruling reaffirmed the strict requirements for applying for a compulsory license, and clarified that claiming high price of a drug or non working of a patent (after the term has commenced) is not enough to warrant grant of such a license, Lee Pharma, a company manufacturing Indian generic drugs, sought a compulsory license to produce and market Saxagliptin in India, it filed the application under Section 84 of the Patents Act, 1970, claiming that AstraZeneca (the license holder) had not worked its patent in India and that the drug was not reasonably affordable, the Controller ruled in favor of AstraZeneca for the following reasons: While the drug was relatively expensive in comparison to other diabetes drugs sold in India, Saxagliptin had been priced reasonably when compared to other drugs used to treat diabetes, AstraZeneca was importing the drug into India, and ensuring its delivery through local distributors, meaning that there was adequate supply, AstraZeneca was not required to locally manufacture medication in order for its patent to be considered "worked" in India if it ensured availability of the drug through imports, the application failed to prove that granting a license would promote the public's interests, given the availability of other diabetes drugs in India.[60]

b) Merck Sharp & Dohme Corp. v. Glenmark Pharmaceuticals (2015)

Merck instituted proceedings against Glenmark for patent infringement of Sitagliptin, a prescribed drug for treating diabetes, the Delhi High Court granted an ad interim injunction against Glenmark and underscored the importance of a robust patent protection regime in pharmaceuticals, barring any clear case for invalidity, in Merck Sharp & Dohme Corporation & Anr. v. Glenmark the Delhi High Court had to decide whether Glenmark was infringing Merck Sharp and Dohme's patent on Sitagliptin, Merck Sharp and Dohme (MSD) alleged that the production and sale of Sitagliptin Phosphate Monohydrate by Glenmark under the trade names ZITA and ZITA, MET constitute an infringement of its Indian Patent No. 209816, which was granted for Sitagliptin, it also filed for a permanent injunction, damages and other reliefs in terms of Sec. 48 Indian Patents Act, 1970, Glenmark filed a counter claim for revocation of

[60] Lee Pharma v. AstraZeneca C.L.A. No. 1 OF 2015

the patent on the grounds that it was not new and inventive, the Court held that the impugned drug was within the ambit of the claims of the suit patent and that this constituted infringement, it granted an injunction on Glenmark manufacturing and sale of the impugned drugs.[61]

c) BDR Pharmaceuticals V. Bristol Myers Squibb (2013)

The BDR Pharmaceuticals V. Bristol Myers Squibb (2013) case reaffirmed the rigidity of procedural rules for compulsory licensing in Indian patent law. The key messages derived were: Mandatory Pre, application Negotiations for a Voluntary license this case emphasized that gains from a mandatory negotiation process for a voluntary license are significant, and applicants cannot submit a formal application without requiring the licensee to sell or license under the patent, applicants cannot directly jump to the patent office without requiring requirements of a voluntary license on the patent holder, strict Interpretation of Six Month Waiting Period, the case strengthened the view that the six, month minimum period for negotiations under Section 84 (6) has to be rigorously followed, and premature applications will be rejected outright without evaluation of the affordability or public interest aspect, different Result in Comparison with Natco Pharma v. Bayer (2012), in contrast to the Natco case, a prima facie case was not made out as there was no evidence that the medicine was prohibitively expensive or inaccessibility, this case demonstrated that each patent grant is considered on individual merits, and there is no presumption carried over from prior compulsory licenses, signalled Patent Holders to Engage in Negotiations the decision reassured innovator pharmaceutical companies that India would not frivolously issue compulsory licenses, as long as the patent holder complied with procedural fairness, however, it also reinforced the need for good faith negotiations.[62]

d) Monsanto Company v. Coramandal Indag Products (P) Ltd. (1986)

Monsanto Company v. Coramandal Indag Products (P) Ltd. (1986) was a case involving patent dispute over an herbicide, Monsanto claimed patent rights over the discovery of the product, suggesting that "Phytotoxic Compositions" and "Grass Selective Herbicide Compositions" containing Butachlor belonged to them, Monsanto sued the respondent for patent infringement,

[61] Merck Sharp & Dohme Corp. v. Glenmark Pharmaceuticals FAO (OS) 190/2013
[62] BDR Pharmaceuticals V. Bristol Myers Squibb C.L.A. No. 1 of 2013

never at the cost of the common man. Achieving this balance requires upholding the rule of law at the same time as adopting new ways of achieving the goals of fairness to its citizens.