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BALANCING PATENT LAW AND PUBLIC WELFARE

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"Jeremy Bentham argued that the role of patent rights was to provide the creator with incentive to use their invention for public good"[1]. He also highlighted the fact that said right over intellectual property was not absolute and that these rights could be taken away for the sake of public good. However, in recent times these laws have been manipulated to such an extent that instead of protecting intellectual property rights, they have become enablers of restrictive trade practices and monopolies in the pharmaceutical industry. Commenting on the same, Joeseph M Gabriel writes that the "interdisciplinary exploration of patent law, the pharmaceutical industry, and the medical profession serves to at least partially explain how United States' healthcare system became the most expensive in the world."[2]

In this paper we will be comparing the Patent protection systems of Australia, United States of America, Sub Saharan Africa and India to see how provisions for intellectual property rights of each country influence the health care system and structure of the pharmaceutical industry. For the same this paper will be relying on the Patent legislations of each of the above-mentioned countries along with relevant case laws, articles, legislative debates, podcasts and other academic literature which sheds light on the above mentioned predicament.

Evolution of patent rights:

Patent rights can be traced back to the middle ages In the Medieval Era, exclusive monopolies were granted by the sovereign for a sum of money. This was a common method for raising money without resorting to taxation.

"Such grants were common in many European countries. Some of these, for example, in mining regions or textile production, seem to have had a relation to innovations….

[1] John M Kraft and Robert Hovden, 'Natural Rights, Scarcity & Intellectual Property' (2013) 7 NYU JL & Liberty 467
[2] Joseph M. Gabriel, Medical Monopoly: Intellectual Property Rights and the Origins of the Modern Pharmaceutical Industry.

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Towards the end of Elizabeth's reign, the English courts, probably at least to some extent noting developments on the Continent, started to restrict the rights of the sovereign to grant monopolies, unless they were for the introduction of a new industry to the country"[3]

"Every useful discovery is, in Kant's words "the presentation of a service rendered to Society." It is, therefore, just that he who has rendered this service should be compensated by Society that received it. This is an equitable result, a veritable contract or exchange that operates between the authors of a new discovery and Society. The former supply the noble products of their intelligence and Society grants to them in return the advantages of an exclusive exploitation of their discovery for a limited period."[4]

United States of America

As Abraham Lincoln once put it, "The Patent System added the fuel of interest to the fire of genius." [5]The United States Constitution, on which U.S. Patent Law depends, was drafted at the height of the Industrial Revolution at a time when the impact of patents was first being seriously felt in England. Interestingly, while the Constitution was being drafted in Philadelphia, the Constitutional Convention apparently adjourned one afternoon to watch John Fitch's steamboat undergo trials on the Delaware River. A pro-patent climate endured in the United States through much of the nineteenth century leading to the comments by President Lincoln and Mark Twain noted above. However, the last two decades of the nineteenth century and the twentieth century have seen a number of climate changes.

"The history of patent law can be stretched back to 1790 when the first patent act of the United States was enacted."[6]The drafting of the Patent laws in the United States was heavily dependent on the industrial revolution which was gaining momentum in the late eighteenth and early 19th century. however it was not till the late nineteenth century ie the time of the 1st depression, wherein patent laws were seriously debated to ensure that the 'big businesses" did not usurp the inventions of small establishments or individuals."[7] It was in 1871 when the Patent and Trademark Resource Centre Program was established under 35 USC 12 provided for the

[3] A BRIEF HISTORY OF THE PATENT LAW OF THE UNITED STATES < https://ladas.com/education-center/a-brief-history-of-the-patent-law-of-the-united-states-2/>
[4] ibid
[5]ibid
[6]] Jamie Crook, 'Balancing Intellectual Property Protection with the Human Right to Health' (2005) 23 Berkeley J Int'l L 524
[7] ibid

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distribution of printed patents to libraries for use by the public.

However, it was the early twentieth century which saw a stimulation of patent legislation as the depression had run its course and the economy was slowly recovering. The first marker in the development was the relationship between patent and antitrust laws. This was marked by the Sherman Act of 1890 which prohibits (1) anticompetitive agreements and (2) unilateral conduct that monopolizes or attempts to monopolize the relevant market. However, it was not until the 1930s that patent laws started attracting criticisms for enabling monopolies in various industrial sectors.

Drugs and money in the United States have been intertwined since the writing of the American Constitution wherein the congress was given the right "to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries"[8]

In the United States, Issues regarding patents and trademarks are handled by the United States Patent and Trademarks Office (USPTO) established under "section one (establishment clause) of the Manual of Patent examining Manual" The manual further provides information about the criteria for grant of patents and for extension of the aforementioned patents. The issue that exists here is the system of lobbying which leads to evergreening of patents.

"The patent system exists to protect the intellectual property of innovators. Too often, however, some brand-name drug companies attempt to patent features of drugs that do not represent true innovation. Some attempt to bury competition from generic and biosimilar drugs indefinitely by finding ways to repackage existing inventions in later patents. These "patent thickets" chill competition by discouraging competitors from entering a market because of the exorbitant cost of litigating meritless patents."[9]

It has been noted that:

- "There are 125 patent applications filed and 71 granted patents per drug.
- Branded drug prices have increased by 68 percent since 2012, and only one of the top 12 drugs has actually decreased in price.

[8] ibid

[9] Abuse of the patent system is keeping drug prices high for patients <https://accessiblemeds.org/campaign/abuse-patent-system-keeping-drug-prices-high-patients>

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- There are 38 years of attempted patent protection blocking generic competition sought by drugmakers for each of these top grossing drugs – or nearly double the 20-year monopoly intended under U.S. patent law.
- These top-grossing drugs have already been on the U.S. market for 15 years.
- Over half of the top 12 drugs in America have more than 100 attempted patents per drug"[10]

"It was further observed in the study that AbbVie Inc.'s rheumatoid arthritis drug HUMIRA® (adalimumab) is the best-selling prescription drug in the world, with over $12 billion in U.S. sales per year. Humira was approved in 2002, and it now makes more money annually than all of the NFL teams, combined. The initial patent on the product expired in 2016, but within the three years before expiration, the company applied for and obtained over 75 patents that would extend its monopoly to 2034 – and keep this enormously expensive treatment inaccessible to many patients."[11]

"In the early 1980s, the thinking of the Chicago School of economists came to the fore, and with the election of President Reagan, enthusiasm for antitrust enforcement went out of fashion. During the same period, the Court of Appeals for the Federal Circuit were created to remedy a scandalous disarray between the regional circuit Courts of Appeal in dealing with patent cases. The new court was initially pro-patent in its attitude, which resulted in a generally more favorable attitude to the value of patents throughout American business.[7] One manifestation of this change has been the court's assertion that the patent statute means what it says when stating that "[a] patent shall be presumed valid."[8] The court has held that anyone challenging the validity of a patent needs "clear and convincing" evidence to succeed.[9] This contrasts with the normal standard of proof in civil cases in which a party asserting a cause need only establish his case on the balance of probabilities. On the other hand, more recently, decisions of the court have cautioned against giving too wide an interpretation to patents and reiterated the importance of the public having a clear understanding of what does or does not fall within the ambit of any given patent.[*See, for example, Nautilus, Inc. v. Biosig Instruments, Inc. 134 S.Ct. 2120 (2014) *] Thus, over the past two decades patents have been back in favor, but the pendulum will probably swing again."[12]

[10] ibid
[11] ibid
[12] supra <3>

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The model of the united states has affected people globally.

"In 1995, as mandated by the Uruguay Round Agreements Act, patent terms in the United States were changed from 17 years from the date the patent was granted to 20 years from the date the patent application was filed. This extended patent terms for many products, including pharmaceuticals. In 1996, Congress enacted a statutory mandatory compulsory license for products brought to market prior to patent expiration, provided that a generic manufacturer had previously made "substantial investment" toward bringing a product to market in anticipation of the pre-1995 patent expiration. The mandatory compulsory license applied to over 100 brand name pharmaceutical products. However, the benefits of these compulsory licenses were undermined because drug registration issues were not addressed in the GATT implementation legislation."[13]

There have been multiple cases in the same sphere in the States since well before that.

Cases involving government use under 28 USC 1498

"In 2001, DHHS Secretary Tommy Thompson used the threat to use 28 USC 1498 to authorize imports of generic ciprofloxacin, for stockpiles against a possible anthrax attack."[14] "In 2005, the US Department of Justice cited its right to use patents in 28 USC 1498 when it opposed injunctive relief for infringement of the patents relating to the Blackberry email services supplied to both the government and private firms that used the Blackberry device to communicate with the government."[15] "In a November 2005 Congressional Hearing, DHHS Secretary Michael Levitt testified before the House of Representatives that he had effectively required the patent owners for Tamiflu (Roche/Giliead) to invest in US manufacturing facilities for the product, so that the United States government would have access to Tamiflu if confronted with an avian flu pandemic."[16] "In 2007, the US Supreme Court was petitioned to hear an appeal of Zoltek Corp. v. U.S.[6] Zoltek has a US patent on a process for making material used in F-22 fighter jets, but the U.S. imports the product from an unlicensed foreign manufacturer without paying royalties to Zoltek. The United States argues that it may, in effect,

[13] KEI RN 2007:2 Recent examples of compulsory licensing of patents
[14] http://www.cptech.org/ip/health/cl/cipro/
[15] The United States' Statement Of Interest, November 2005., NTP, INC., Plaintiffs, V. RESEARCH IN MOTION, LTD., Defendant., Civil Action No. 3:01CV767.
[16] See video excerpts from November 8, 2005 Hearings of the Subcommittee on Health of the House Committee on Energy and Commerce, http://www.cptech.org/ip/health/tamiflu/hearingexcerpts11082005.html

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has a royalty-free compulsory license for government use of the product because the patented process is carried out in a foreign country, meaning that the patent holder is not entitled to "reasonable and entire compensation" under 28 USC 1498."[17]

Cases involving Bayh-Dole Act

"In 1997, a March-In rights petition by Cell-pro was denied, and ultimately their infringing device was pulled from the market despite its clinical advantages and lack of a licensed alternative."[18]

"In 2001, DHHS used its authority to exercise March-In rights for patents on stem cell lines resulting from publicly funded research and held by the Wisconsin Alumni Foundation (WARF) as leverage to secure an open license on those patents."[19]

"In 2004, DHHS and NIH refused to grant March-In rights in a case brought by Essential Inventions involving patents on the AIDS drug ritonavir/Norvir." [20] "Abbott Laboratories had increased their U.S. price of the drug by 400% in one day to promote sales of their new combination therapy and undermine sales of competitors' drugs. A similar request by Essential Inventions for march-in rights to patents involving the glaucoma drug latanoprost (Xalatan) was also denied."[21]

"In May 2006, the U.S. Supreme Court issued an opinion in eBay v MercExchange, which set the standards under which a court should evaluate requests for injunctions to enforce a patent owners' exclusive right to authorize the use of a patented invention. To get an injunction, a patent owner must show the court:

1. That it has suffered an irreparable injury;
2. That other possible legal remedies, including the payment of royalties, are inadequate to compensate for that injury;
3. That considering the balance of hardships between the plaintiff
4. and defendant, a remedy in equity is warranted; and
5. That the public interest would not be disserved by a permanent injunction.

[17] Petition available at: http://www.scotusblog.com/movabletype/archives/Zoltek.pdf
[18] supra <13>
[19] September 5, 2001, "National Institutes of Health and WiCell Research Institute, Inc., Sign Stem Cell Research Agreement," http://www.nih.gov/news/pr/sep2001/od-05.htm. Memorandum of Understanding between WiCell Research Institute, Inc. and Public Health Service: http://stemcells.nih.gov/staticresources/research/registry/MTAs/Wicell_MOU.pdf
[20] http://www.essentialinventions.org/drug/ritonavir.html
[21] http://www.essentialinventions.org/drug/latanoprost.html

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Under this standard, a court can choose to issue a compulsory license to use the patent, rather than enforce the exclusive right, a path that has been taken several times since May 2006."[22] The evolving doctrine under eBay v. MercExchange places the U.S. closer to legal traditions in Europe and Japan, where governments and courts have the authority to issue compulsory licenses in a wide range of cases, including those involving uses of dependent patents, refusals to license (such as the three recent Italian cases on pharmaceutical patents), and to more generally protect the public interest.

Cases involving merger reviews

"In 2002, the US Federal Trade Commission (FTC) ordered[12] a compulsory cross-license of the Immunex tumor necrosis factor ("TNF") patent, to Serono, including the "freedom to practice in the research, development, manufacture, use, import, export, distribution and sale of TNFbp-I Products and certain glycosylated and nonglycosylated fragments, derivatives and analogs thereof in the United States." Note the permission to export, which is anticipated by Article 31.k of the TRIPS. In this case, the compulsory cross-license allows a Swiss firm to compete with the US patent owner."[23]

"In 2005, the FTC ordered a compulsory license of Guidant's intellectual property surrounding the RX delivery system for Drug-Eluting Stents (DES) as a condition of Guidant's acquisition by either Johnson & Johnson or Boston Scientific Boston Scientific, which eventually won the bidding to acquire Guidant, was required to license DES patents to a potential entrant, Abbott."[24]

Cases involving non-merger remedies to anticompetitive practices

"In 2002, the US Department of Justice required Microsoft to license on reasonable and non-discriminatory terms intellectual property rights in a number of different protocols needed to create products that were interoperable with Microsoft Windows."[25]

[22] Supra <13>
[23] http://www.ftc.gov/opa/2002/07/amgen.htm
[24] http://www.ftc.gov/opa/2006/04/bostonscigui.htm
[25] United States Of America, Plaintiff V. Microsoft Corporation, Defendant. Civil Action No. 98-1232 (CKK), Final Judgment, (November 12, 2002), available at: http://www.usdoj.gov/atr/cases/f200400/200457.htm. For a detailed account of work to implement the order, see: Interim Joint Status Report On Microsoft's Compliance With The Final Judgments, available at: http://www.usdoj.gov/atr/cases/f201300/201386.htm.

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"In February 2007, in a case involving a failure to disclose patents on the standard, an FTC antitrust remedial order compelled memory chipmaker Rambus to license its patented technology on certain specified terms and limited the maximum royalty rates that Rambus can collect for use of its patents to 0.25 percent for SDRAM products; 0.5 percent for DDR SDRAM products, as well as SDRAM memory controllers or other non-memory chip components; and 1 percent for DDR SDRAM memory controllers, or other non-memory chip components. After three years, the royalty rate will be zero percent."[26]

Balancing Public Welfare and Patent Laws:

The TRIPS agreement of 1994 clearly states in "Articles 7 and 8 to provide some flexibility in the form of allowing compulsory licensing and also allow for certain restrictions on patents for pharmaceuticals, the same is undercut by the TRIPS requirement (Doha Agreement,2001) that such measures be consistent with the patent-protection provisions of the agreement".[27] "Furthermore, most FTAs which have been signed by the United States over the past decade have included provisions that curb governments' ability to use the health safeguards in TRIPS and have mandated higher levels of IP protection. These provisions block or delay the onset of generic competition, keeping medicine prices high."[28]

Therefore"[i]n South Africa, tens of thousands of people are dying every year because excessive prices are charged for life-saving anti-retroviral medicines."[29]South Africa's battle with Aids provides a representative picture of the ill effects of the combination of poverty and patent protection. While the "generic version of anti-retroviral drug therapy can be purchased for as little as USD $140, the landscape provided by the high rates of poverty and excessive patent protection has led to a situation where 80% of the people afflicted with HIV in South Africa cannot afford the required healthcare facilities. This is in stark contrast to the situation in Brazil where multiple generic versions of the same drug are available making it easier to control the AIDS epidemic in Latin America."[30]

It is under situations as mentioned above that debates with regards to individual rights and public welfare are triggered. Traditional capitalists would argue that not providing adequate

[26] http://www.ftc.gov/os/adjpro/d9302/070205opinion.pdf and http://www.ftc.gov/os/adjpro/d9302/070205finalorder.pdf
[27] Jamie Crook, 'Balancing Intellectual Property Protection with the Human Right to Health' (2005) 23 Berkeley J Int'l L 524
[28] ibid
[29] ibid
[30] ibid

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protection to the pharma industry in terms of patents and copyrights would lead to the disastrous consequence of a halt in innovation in the pharma industry. While on the other hand we have policies which are more aligned with Jeremy Bentham's school of thought which argues that while the rights of the inventor have to be acknowledged, the main idea of innovation is to ensure better quality of human life which require that IP rights not be absolute and also overlooked to ensure mass benefit.

Classic liberals and libertarians lean on Locke's argument "since mixing labour with the natural world creates property rights, mixing labour with thought similarly gives rise to a property interest in what is created thereby."[31] The same has been translated in a modern context with reference to pharmaceuticals especially where they say Drug-patent supporters argue that patents guarantee profit returns, which in turn enable continuing research and development.

Another argument which works in favour of patents is the international setup itself. "Since 1995, TRIPS has transformed the nature of patents from a national prerogative to an internationally enforceable to institution through rigid treaty terms and a compulsory, binding dispute resolution procedure."[32] In certain countries TRIPS has a tendency to impose patent obligations in the country which are stricter than those in the United States.

"While Articles 7 and 8 of TRIPS provide some flexibility in the form of allowing compulsory licensing and also allow for certain restrictions on patents for pharmaceuticals, the same is undercut by the TRIPS requirement that such measures be consistent with the patent-protection provisions of the agreement. Furthermore, TRIPS has created confusion as to what constitutes a "national emergency" under Article 3 1(b), whether individual members have the right to define such an emergency, and how much discretion developing states enjoy to utilize any patent-related flexibilities TRIPS appears to grant."[33]

The final argument used in favour of patent laws for pharma is the concept of shifting the burden. The poverty not patent model propagates that the limited public health resources of these countries to argue that domestic poverty levels alone explain the lack of access to treatment. "Surely poverty and under-resourced public health infrastructure are major barriers

[31] John M Kraft and Robert Hovden, 'Natural Rights, Scarcity & Intellectual Property' (2013) 7 NYU JL & Liberty 467
[32] Supra <2>
[33] ibid

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to access to costly medications."[34]

Arguments against Patents:

The Lockean view is undercut by "Jeremy Bentham who talks about the need to improve human life and how the sole purpose of inventions is to make human life easier instead of merely giving monetary incentives to inventors. The same is seen in the TRIPS agreement which under article 8 gives states the power to issue compulsory licensing for pharmaceuticals under public welfare policy."[35]

A broad interpretation of the right to life arguably the most basic human right, to which some international tribunals have granted jus cogens standing-should include access to life-saving medication if withholding such treatment would otherwise deprive life. The Universal Declaration of Human Rights (UDHR) establishes "the right to a standard of living adequate for [] health and well-being... including ... medical care and necessary social services."[36]

"More than 60% of new cases occur in Africa, Asia, and Latin America, and these regions account for 70% of the world's cancer deaths. The burden of cancer in LMICs also significantly impacts the economy of these regions, yet only 6% of global resources for cancer are spent in the developing world."[37]

As far as shifting the burden is concerned, "public health advocates counter that the unfolding AIDS catastrophe requires a more immediate palliative than the distant hope of discovering a cure or treatment, neither of which would likely be any more accessible to infected populations than current patented drug therapies."[38] Furthermore, as is the case in most underdeveloped countries a prime example being with reference to the Aids crisis in Africa "*With as little as $8 to spend on health care per person annually, the governments of most sub-Saharan states cannot afford the $10,000 price tag for a year's supply of name-brand anti-retrovirals*."[39]

While underfunded health infrastructure and abject poverty are barriers to access to adequate

[34] ibid
[35] John M Kraft and Robert Hovden, 'Natural Rights, Scarcity & Intellectual Property' (2013) 7 NYU JL & Liberty 467
[36] Universal Declaration of Human Rights, pmbl.,
[37] Compulsory Licenses for Cancer Drugs: Does Circumventing Patent Rights Improve Access to Oncology Medications?
[38] Jamie Crook, 'Balancing Intellectual Property Protection with the Human Right to Health' (2005) 23 Berkeley J Int'l L 524
[39] ibid

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medical help, one cannot deny the fact that the situation is worsened by the heft price tags which essential drugs such as anti-retrovirals and cancer medication have, which stems from excessive patent protection being provided to pharmaceutical conglomerates.

"Many sub-Saharan states ravaged by HIV/AIDS stand to lose substantial portions of their populations to early AIDS-related deaths. USAID has predicted that average life expectancy in eleven sub-saharan countries by the year 2010 will be thirty. Alex De Waal, director of Justice Africa and member of the United Nations Commission on HIV/AIDS has observed this phenomenon of a shrinking life expectancy and coined the term 'death roll tax'"[40] which poses the risk of hyperinflation and collapse of the national economy as the workforce keeps getting depleted at an unstable rate.

Therefore, one cannot merely shift the burden of providing health facilities on the government and ignore the impact that excessive patent regulations and drug prices play in regulation the population growth rate of a country. Since as can be seen in Africa with reference to the Aids epidemic it poses the threat of bankrupting a country and causing the country to collapse on account of a depleting population.

The Indian Scenario

India saw it's first patent act come up in 1856, it was based on the British Patent Law of 1852. It granted privileges to a manufacturer or inventor for 14 years. In 1859 the act was modified as XV Patent act which granted monopolies called exclusive privileges (making. Selling and using inventions in India and authorizing others to do so for 14 years from date of filing specification). "In 1872, the Act of 1859 was consolidated to provide protection relating to designs. It was renamed as "The Patterns and Designs Protection Act" under Act XIII of 1872. The Act of 1872 was further amended in 1883 (XVI of 1883) to introduce a provision to protect novelty of the invention, which prior to making application for their protection were disclosed in the Exhibition of India. A grace period of 6 months was provided for filing such applications after the date of the opening of such Exhibition."[41]

The act remained in force for thirty years but in the year 1883, certain modifications in the patent law were made in United Kingdom and it was believed that the Indian laws should mirror the same. In 1888, an Act was introduced to consolidate and amend the law relating to invention

[40] UNAIDS - WHO, AIDS Epidemic Report 3 (Dec. 2003),
[41] http://www.ipindia.nic.in/history-of-indian-patent-system.htm

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and designs in conformity with the amendments made in the U.K. law.

The Indian Patent and design act replaced all the previously existing acts. "This Act brought patent administration under the management of Controller of Patents for the first time. This Act was further amended in 1920 to enter into reciprocal arrangements with UK and other countries for securing priority. In 1930, further amendments were made to incorporate, inter-alia, provisions relating to grant of secret patents, patent of addition, use of invention by Government, powers of the Controller to rectify register of patent and increase of term of the patent from 14 years to 16 years. In 1945, an amendment was made to provide for filing of provisional specification and submission of complete specification within nine months"[42]
Post-Independence it was observed that the 1911 act was not adequate and subsequently a new legislation was fashioned. Accordingly, a committee was constituted under the chairmanship of Justice (Dr.) Bakshi Tek Chand, a retired Judge of Lahore High Court, in 1949 to review the patent law in India in order to ensure that the patent system is conducive to the national interest. The committee made the following recommendations:

- "To survey and report on the working of the patent system in India
- To examine the existing patent legislation in India and to make recommendations for improving it, particularly with reference to the provisions concerned with the prevention of abuse of patent rights;
- To consider whether any special restrictions should be imposed on patent regarding food and medicine;
- To suggest steps for ensuring effective publicity to the patent system and to patent literature, particularly as regards patents obtained by Indian inventors;
- To consider the necessity and feasibility of setting up a National Patents Trust;
- To consider the desirability or otherwise of regulating the profession of patent agents
- To examine the working of the Patent Office and the services rendered by it to the public and make suitable recommendations for improvement; and
- To report generally on any improvement that the Committee thinks fit to recommend for enabling the Indian Patent System to be more conducive to national interest by encouraging invention and the commercial development and use of inventions."[43]

[42] ibid
[43] ibid

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The committee submitted its report on 4th August 1949 with recommendations to prevent the abuse of the 1911 act. "It further suggested amendments to sections 22, 23 & 23A of the Patents & Designs Act, 1911 on the lines of the United Kingdom Acts 1919 and 1949. The committee also observed that the Patents Act should contain clear indication to ensure that food and medicine and surgical and curative devices are made available to the public at the cheapest price commensurate with giving reasonable compensation to the patentee."[44]

Based on the recommendations of the report the 1911 act was amended in 1950 for working of inventions and compulsory licence/revocation. Other provisions were about license of right by application of the government so that the controller could grant licences. The 1952 amendment provided for "compulsory licence in relation to patents in respect of food and medicines, insecticide, germicide or fungicide and a process for producing substance or any invention relating to surgical or curative devices. The compulsory licence was also available on notification by the Central Government. Based on the recommendations of the Committee, a bill was introduced in the Parliament in 1953 (Bill No.59 of 1953). However, the Government did not press for the consideration of the bill and it was allowed to lapse."[45]

"In 1957, the Government of India appointed Justice N. Rajagopala Ayyangar Committee to examine the question of revision of the Patent Law and advise government accordingly. The report of the Committee, which comprised of two parts, was submitted in September, 1959. The first part dealt with general aspects of the Patent Law and the second part gave detailed note on the several clauses of the lapsed bills 1953. The first part also dealt with evils of the patent system and solution with recommendations in regards to the law. The committee recommended retention of the Patent System, despite its shortcomings. This report recommended major changes in the law which formed the basis of the introduction of the Patents Bill, 1965. This bill was introduced in the Lok Sabha on 21st September, 1965, which however lapsed. In 1967, again an amended bill was introduced which was referred to a Joint Parliamentary Committee and on the final recommendation of the Committee, the Patents Act, 1970 was passed. This Act repealed and replaced the 1911 Act so far as the patents law was concerned. However, the 1911 Act continued to be applicable to designs. Most of the provisions of the 1970 Act were brought into force on 20th April 1972 with publication of the

[44] ibid
[45] ibid

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Patent Rules, 1972."[46]

The act remined in force for the next 24 years without any changes till 1994. "An ordinance effecting certain changes in the Act was issued on 31 st December 1994, which ceased to operate after six months. Subsequently, another ordinance was issued in 1999. This ordinance was subsequently replaced by the Patents (Amendment) Act, 1999 that was brought into force retrospectively from 1st January, 1995. The amended Act provided for filing of applications for product patents in the areas of drugs, pharmaceuticals and agro chemicals though such patents were not allowed. However, such applications were to be examined only after 31-12-2004. Meanwhile, the applicants could be allowed Exclusive Marketing Rights (EMR) to sell or distribute these products in India, subject to fulfilment of certain conditions."[47]

The second amendment to the 1970 act was brought in Patents (Amendment) Act (Act 38 of 2002). This Act came into force on 20th May 2003 with the introduction of the new Patent Rules, 2003 by replacing the earlier Patents Rules, 1972

The final amendment was brought in the Patents (Amendment) Ordinance, 2004 w.e.f. 1 st January, 2005. This Ordinance was later replaced by the Patents (Amendment) Act 2005 (Act 15 Of 2005) on 4 th April, 2005 which was brought into force from 1-1-2005.

India to has faced certain amount of arm twisting with regards to relaxing norms for application of patents on account of the TRIPS Agreement however India has held on to the policy of controlling patents on medicines.

"Being a signatory to TRIPS, India was under a contractual obligation to amend its Patents Act to comply with its provisions. India had to meet the first set of requirements on 1st January 1995 to give a pipeline protection till the country starts granting product patent. However, India retained its view on Public welfare by not allowing patents for drugs and medication prior to the 2005 amendment."[48]

[46] ibid
[47] ibid
[48] Jaya Bhatnagar and Vidisha Garg, India: Patent Law in India
< http://www.mondaq.com/india/x/54494/Patent/Patent+Law+in+India>

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"The Act was amended in 1999 and some of the significant changes which were brought around were:

- *Section 5(2) was introduced which provides for filing of applications for patent in the field of drugs, medicines and agro-chemicals. These applications were kept pending in the mailbox or black box. This mailbox was to be opened on 1st January 2005.*
- *Provision of Exclusive Marketing Rights (EMR) was brought in by way of Chapter IV A. Thus, pipeline protection was provided for pharmaceutical and agro-chemical manufacturers whose applications for product were lying in black box.*
- *Section 39 was omitted from the Act, thereby enabling the Indian residents to file the applications for in an outside India simultaneously.*
- *Chapter II (A) was inserted in the Indian Patent Rules dealing with International Applications under PCT.*

The second phase of amendments came about in the Patents Act 2002, which came into force in 2003. The significant changes it brought around were:

- *Term of patent was extended from 14 to 20 years, wherein the date of patent was the date of filing of complete specification. Also, the difference in term of a drug/food patent and other patent was removed.*
- *The definition of "invention" was made in conformity with the provisions of TRIPS Agreement by introducing the concept of inventive step, thereby enlarging the scope of invention.*
- *Deferred examination system was introduced.*
- *Introduction of the provision of publication of application after 18 months from the date of filing thereby bringing India at par with the rest of the world.*
- *Microorganisms became patentable, whereas inventions relating to traditional knowledge were included in the list of "what are not inventions".*
- *The concept of unity of invention in accordance with EPC and PCT.*
- *Section 39 was reintroduced thereby prohibiting the Indian residents to apply abroad without prior permission or first filing in India.*
- *Provisions of Appellate Board were brought in by inserting section 116. All appeals to the decision of the Controller would be appealable before the Appellate Board. The Head Quarter of the Appeallate Board is to be in Chennai.*

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The third and final amendment to the Patents Act, 1970 came by way of Patents (Amendment) Ordinance, 2004, which was later replaced by The Patent (Amendment) Act, 2005, and Patents (Amendment) Rules, 2006 with retrospective effect from 1st January, 2005. With the third amendment India met with the international obligations under the TRIPS. Significant achievements of this amendment were:

- *Deletion of section 5, opening of mailbox and grant of product patents. Thus this amendment led to the dawn of the "product patent regime" in India.*
- *Abolition of Exclusive Marketing Rights (EMR).''*[49]

While TRIPS required that India allow stringent patent protection in accordance with TRIPS, the Indian Act has put constraints on the same through section 47 on account of public Welfare. Section 47 (4) of the act which states that:

"in the case of a patent in respect of any medicine or drug, the medicine or drug may be imported by the Government for the purpose merely of its own use or for distribution in any dispensary, hospital or other medical institution maintained by or on behalf of the Government or any other dispensary, hospital or other medical institution which the Central Government may, having regard to the public service that such dispensary, hospital or medical institution renders, specify in this behalf by notification in the Official Gazette"[50]

By virtue of this provision, the government has reserved the right to provide medication at a subsidized rate for the sake of its public welfare program, even if it undercuts certain rights of the Patentee.

Furthermore, under the Novelty Rule[51], evergreening of patents is prohibited by requiring a new and unknown invention being required for patent i.e. mere changes in the form of the invention irrespective of how significant the change is, are not sufficient grounds for providing a new patent. The same can be interpreted from section 3(d) if the Act.

Section 3(d):
"the mere discovery of a new form of a known substance which does not result in the

[49] ibid
[50] Section 47(4)
[51] Supra <15>

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

Explanation-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;"[52]

However, the most important example of giving importance to public welfare comes form the case of Novartis A.G. v Union of India. The facts of the case are as follows:

"Novartis had filed for a patent on the anticancer drug Glivec which is used to treat Chronic Myeloid Leukemia (CML) and Gastrointestinal Stromal Tumours (GIST) on the basis that it invented the beta crystalline salt form (imatinib mesylate) of the free base, imatinib.. It is a critical drug which is patented in about 35 countries of the world However, India did not provide patents for drugs prior to 2005 and when the patent request came up in 2006, the same was denied on the grounds that it was prohibited under section 3(d) since it had already existed in the free base form. On account of this rejection Novartis filed a writ petition in the Madras High Court under Article 226 of the Indian Constitution, the matter was further taken on appeal in the Supreme Court."[53]

While commenting on the above-mentioned issue the apex court had said that:

(1) Whether the invention is in consistent with Section 3(d) of the patent act?
"the product was one of the new forms of the substance and not the whole substance. It has always existed in the original amorphous form. The product thus has to qualify the test laid down in Section 3(d) of the Patent Act."[54]

(2) Interpretation of Section 3(d) of the patent act?
An invention is not patentable unless it shows enhanced efficacy

(3) Whether the invention qualifies for the test of novelty and inventive for the alleged product?

[52] Section 3(d), Patents Act 1970
[53] Novartis AG v UOI, Civil Appeal No. 2706-2716 of 2013
[54] ibid

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> "Novartis contended that the physico-chemical properties of the polymorph form of the imatinib molecule, i.e. better flow properties, better thermodynamic stability and lower hygroscopicity, resulted in improved efficacy and hence is patentable under Indian law.
>
> The Apex Court rejected this contention stating that in the case of medicines, efficacy means "therapeutic efficacy" and these properties while they may be beneficial to some patients do not meet this standard. The Supreme Court also held that patent applicants must prove the increase in therapeutic efficacy based on research data in vivo in animals."[55]

The judgement's view on public welfare:

"The judgement cited Article (7) of the TRIPS Agreement which states that:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."[56]

The court while expanding on the same said that the patent could not be extended because if the drug were to be prohibited from entering the public domain and restrict creation of a generic version of the medicine which would be accessible to a larger section of the society. The court relied on section 83(c) of the Patent Act, which echoes the sentiments of Article 7 of the TRIPS Agreement, i.e.

"that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations;"[57]

Australia

While the Australian Patent Office was formed in 1904, government involvement in the protection of Australia's innovation began well before the previous century with individual state registers of trade marks, patents and copyright.

[55] ibid
[56] ibid
[57] ibid

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The federation of these registers and the introduction of the Patents Act 1903 saw the first patent filed at the new Australian Patent Office in Melbourne, on 13 February 1904. The Australian Patent Office formed to become the Australian Government agency responsible for patent registration and rights. In the years to follow, the office also took responsibility for trademarks and designs systems.

By 1933 the office had moved a small number of staff to the newly formed federal capital, Canberra, and had taken responsibility for patent, trade mark and design registrations. The 1903 Act was re-enacted with substantial changes in 1952 and again in 1990. The *Patents Act 1990* (Cth) (*Patents Act*) provides the current legislative framework governing the grant and administration of patents in Australia,

"Section 133(2)(a) of the Patents Act provides that the court may make an order for the grant of a compulsory licence in favour of an applicant, where: (a) The applicant has tried for a reasonable period, without success, to obtain authorisation from the patentee to work the invention on reasonable terms and conditions; and (b) The "reasonable requirements of the public" are not being met with respect to a patented invention; and (c) The patentee has given no satisfactory reason for failing to exploit the patent. Section 133(2)(b) provides that the court may make the order if the patentee has contravened or is contravening Part IV of the Competition and Consumer Act 2010 (Cth) (CCA). Section 135 sets out the circumstances in which the "reasonable requirements of the public" are taken not to have been satisfied. Additional provisions apply where the patent in question is a 'dependent patent'; that is, an invention that cannot be worked without infringing another patent. [58]"Under the same generic medicines have been allowed in Australia. Generic medicines can only be sold in Australia if they meet the same strict standards of quality, safety and effectiveness as the original.

"Under Australian Patent law a compulsory licence must not grant the exclusive right to work the patented invention.[11] The patent holder is entitled to be paid for use of the patent at an agreed rate or, failing agreement, 'such amount as is determined by a prescribed court to be just and reasonable having regard to the economic value of the licence'.[12] A compulsory licence may be revoked where the circumstances that justified its grant have ceased to exist and are unlikely to recur, and the legitimate interests of the licensee are not likely to be

[58] https://www.alrc.gov.au/publication/genes-and-ingenuity-gene-patenting-and-human-health-alrc-report-99/2-the-patent-system/an-outline-of-the-patent-system/#:~:text=In%201901%2C%20the%20Australian%20Constitution,Patents%20Act%201903%20(Cth).

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adversely affected by the revocation."[59]

Sub Saharan Africa:

The situation in sub Saharan countries is quite pitiable. Due to their dependence on the IMF, World Bank and America for financial aid, there is excessive patent protection and patent abuse in these countries. The Aids crisis in Africa is so grave that "With as little as $8 to spend on health care per person annually, the governments of most sub-Saharan states cannot afford the $10,000 price tag for a year's supply of name-brand anti-retrovirals." Furthermore, "while Articles 7 and 8 of TRIPS provide some flexibility in the form of allowing compulsory licensing and also allow for certain restrictions on patents for pharmaceuticals, the same is undercut by the TRIPS requirement that such measures be consistent with the patent-protection provisions of the agreement. Furthermore, TRIPS has created confusion as to what constitutes a "national emergency" under Article 3 1(b), whether individual members have the right to define such an emergency, and how much discretion developing states enjoy to utilize any patent-related flexibilities TRIPS appears to grant."[60]

In Cameroon "On January 2005, the nonprofit corporation Essential Inventions requested the Minister of Public Health to grant ex officio licenses for the patents relevant for importation, manufacture or sale of generic versions of the following medicines used in the treatment of HIV/AIDS: Nevirapine/Viramune®, Lamivudine/3TC®, and Fixed dose combinations of Lamivudine and Zidovudine/Combivir®. The request is still pending."[61]

While there have been some attempts to curb evergreening of patents in Africa, they haven't been of much success. For instance, in Guinee "On April 18, 2005, the Ministry of Health issued compulsory licenses for importation on patents on drugs to treat HIV-AIDS."[62]

Similarly, in Eretria "On June 5 2005, the Minister of Health issued compulsory licenses for importation into Eritrea of generic HIV-AIDS medicines." However, the same has not been of much benefit as there is still a severe Aids crisis in Africa. Infact "Many sub-Saharan states ravaged by HIV/AIDS stand to lose substantial portions of their populations to early AIDS-related deaths. USAID has predicted that average life expectancy in eleven sub-saharan countries by the year 2010 will be thirty. Alex De Waal, director of Justice Africa and member of the United Nations Commission on HIV/AIDS has observed this phenomenon of a shrinking

[59] ibid
[60] Supra <33>
[61] http://www.essentialinventions.org/docs/cameroon/
[62] Supra <13>

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life expectancy and coined the term 'death roll tax'"[63]

Post Corona World

"As the novel coronavirus pandemic (COVID-19) accelerates and continues to claim lives all over the globe, governments are ramping up efforts to find a cure. This includes developing a vaccine to prevent the illness from spreading further, testing kits and most importantly, formulating the right kind of drugs to treat those who are already victims of this disease."[64]

"Under normal circumstances, most pharmaceutical companies would try ti enforce their patents and restrain unauthorized use, thus minting money; "however, in a global crisis like this, there is pressure on these companies to waive off any proprietary rights they may have ordinarily claimed to facilitate universal distribution of drugs that may aid the fight against this widespread disease"[65]

Given the gravity of the situation it is no surprise that governments all over the world are taking pre-emotive measures to ensure that any monopolistic structure is not established. "In March, the parliament of Chile unanimously passed a resolution justifying the use of compulsory licensing to facilitate access to vaccines, drugs, diagnostics, devices, supplies, and other technologies for surveillance, prevention, detection, diagnosis and treatment of people infected by the virus. Since then, governments world over have made concerted efforts to hone their regulatory regimes relating to compulsory licensing."[66]

In Germany a law was passed called, "'Prevention and Control of Infectious Diseases in Humans Act' which came into force on March 28, 2020. By this Act, the Federal Ministry of Health has been, inter alia, granted the power to issue a compulsory licence under the existing provisions of the German Patent Act. The government can circumvent patent rights "in the interest of public welfare or in the interest of public security" Albeit it has an obligation to inform the patent holder about the grant of compulsory licence and pay an appropriate fee for the patented drugs."[67]

Similarly, in Israel "the Health Minister of Israel issued a permit allowing the State to import a generic version of the drug Kaletra (an HIV drug currently being tested for effectiveness in the treatment of COVID-19) from India. This move of the government of Israel is significant since the State is not required to consult with the patent holder prior to grant of the license.

[63] Supra <40>
[64] Ira Law
[65] ibid
[66] ibid
[67] Supra<64>

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Moreover, the patent holder does not have a right of judicial review."[68]

In France "More sweeping measures have been taken in France, where a new law (No 2020-290) was enacted in March. The government of France sought to introduce a new article to the country's public health code, allowing the government to order seizure of all goods and services necessary to fight against sanitary disaster, temporarily control the prices of products, and to take any measures necessary to make relevant medicines available to patients. From a practical perspective, this would mean that the government would be able to permit seizure of drugs and to direct launch of generic drugs on the French territory before the expiry of patents, if necessary. This is being seen as a move that goes beyond the compulsory licensing measures adopted elsewhere in the world."[69]

Conclusion:

The conclusion of this paper is a grey area. It is neither pro patent nor is it anti patent. It is an acknowledged fact that for innovation there needs to be some incentive so if we completely scrap the patent system, it would be catastrophic in nature because in the absence of incentives there would be no innovation. However, one needs to draw a lin=e in the sand and weigh the benefits and consequences of upholding this right unconditionally. In certain life sustaining cases as in medicines, state intervention and curtailment of the right of the inventor in necessary however it does not mean that the inventor needs to be at a disadvantage. One solution that is there is that the government can compensate the inventor by paying a fair price to the inventor for the technology and right of manufacture. Then it can license the product to make it available to the masses at an affordable price. For example, as the doctrine of Crown use Works in the UK. "Interestingly in the UK, compulsory licensing is not the only way out for the government to ensure supply of essential drugs to its citizens in times of an emergency. Under the UK Patent Act, 1977, there exists a concept of 'Crown Use' which entitles the government to sell, or offer to sell, a patented product without the consent of the proprietor and carry out acts which would otherwise infringe a patent, such as the production, supply, or use of specific drugs, medicines etc. The Act also provides for grant of compulsory licenses under certain circumstances -, this, however, is a more restrictive route compared to the Crown Use exception."[70]

[68] ibid
[69] ibid
[70] Ibid