PATENTING OF DRUGS DURING PANDEMIC/EPIDEMIC.

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ABSTRACT:

This paper talks about the Pandemic Scenario and the instances in past when the drugs in those situations were patented and related provision in the Indian Patent Laws. This paper deals with the issue Pharmaceutical industry faces and related International laws from WTO and WIPO, special emphasis is to be given to the time when Tamiflu was being patented. Further, TRIPS and Doha Declaration pays specific attention to the medicines and its outreach and how Patent regime can be made flexible for the Least Developed Countries and how they can benefit from this effort. Thereafter, this paper talks about right to health in context of Indian Constitution and other Legislations.

The issues and challenges faced thereunder, are related to the Market against Competition in setting of abusive dominant markets, with regards to the Compulsory licensing and how regulation and combination can have adverse effects on the patenting of drugs. Further, ambiguities in the current Patent Act, Proliferation of patents and issues faced by the government as well as the stakeholders are also discussed in depth.

Changes in the Patentability criteria and Suggestions from the other countries have been recommended.

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[I] INTRODUCTION

Intellectual Property law regulates the creation, use and exploitation of mental as well as the creative labor.[2] Drug patenting is the grant of negative right to the holder which excludes others from right of manufacturing of that drug. Monopoly rights granted by IPRs were regarded as crucial to prevent the developing countries from further undergoing the "catching-up" process towards industrialisation based on imitating and copying technologies, as the developed countries themselves had done. In other words, IPR protection was a tool to guarantee the comparative advantage that had so far ensured the developed countries technological supremacy.
The international treaties have created contours for international patent system, nonetheless there still does not exist world patent. The international framework has brought about certain synergies in law and practice and is the basis for considerable cooperation on patent administration, yet a patent remains strictly a *territorial right* in both grant and enforcement. That is why, where no patent is in force, even if patent protected in other countries, is free for use by anybody.
In the wake of the public health crisis afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics, the ministerial conference of WTO adopted 'The Doha declaration on TRIPS and Public Health' (2001). The Doha declaration provided a mechanism for compulsory licensing to supply medicines to countries with insufficient or no-manufacturing capacities. The declaration also explicitly stressed that the TRIPs Agreement can and should be interpreted and implemented in a manner supportive of WTO members right to protect public health and, in particular, to promote access to medicines for all. Consequently, a provision (Section 92A) was introduced in the Patents Act for Compulsory Licensing for the purpose of export of pharmaceuticals products to any country having insufficient or no manufacturing capacity.

Pharmaceutical patenting in India is of utmost concern not only to the people of India, but also for the world community as India has emerged as "the pharmacy of the world", especially in the wake of national emergency like situation during epidemics/ pandemics.

[2] Bishwanath Prasad Radhey Shayam v. Hindustan Metal Industries, (1979) 2 SCC 511.

[II] DURING PANDEMICS

A. PHARMACEUTICAL ASPECT

The world has faced 3 pandemics in the 20th century, the most catastrophic was Spanish Flu (1918-19), which killed 50 million people (approximately) worldwide and leaving one-third of the world's population to be infected.[3]

During the H5N1 influenza, there was a rapid increase in patenting activity, not only in context of vaccines but relating to diagnosis and treatment as well. The difficulty arose in making definitive judgements about the impact of those patent activities on vaccine production and pandemic preparedness: -

i) it takes several years to examine a patent application and to take a decision on whether or not to grant a patent; in that time, the application may be withdrawn or rejected, or the scope of its claim narrowed.

ii) An international patent application[4] only renders into patents with direct effects under the national law if and when the patentee chooses to seek protection in a specific country, meaning thereby, the existence of a PCT application does not imply that protection will be actively sought in all PCT countries.[5]

Further, the technological aspect has another role to play, since the technology in vaccine production methods are patented in some countries while the case differs in many other countries.

The general patenting mechanism requires a considerable amount of investment of both private and public resources, for the purpose of an effective response against the public health threats.

B. Obligation under International Organisations

[3] https://www.cdc.gov/flu/pandemic-resources/1918-pandemic-h1n1.html
[4] The Patent Cooperation Treaty (PCT) is a mechanism for administering international applications that may mature into actual patents in some or all of the countries adhering to the PCT.
[5] World Health Organisation: Working Paper on *Patent issues related to influenza viruses and their genes.* *https://apps.who.int/medicinedocs/documents/s21417en/s21417en.pdf*

World Health Organisation (hereinafter referred as 'WHO') and World Intellectual Property Organisation (hereinafter referred as 'WIPO') have collaborated several times in history to provide an effective solution against the catastrophic widespread of Pandemics. One such collaboration took place when world was scrambling to defend against H5N1 Avian influenza strains (Bird Flu) and recently by H1N1 influenza.

A series of WIPO and WHO reports[6] were based on PCT application searches. The resultant quantitative analysis showed that there had been a rapid increase in the early 2000s in patenting activity broadly referring to H5N1 subtype of the influenza virus, in context of vaccines, with slight increase in patenting activities related to diagnosis and few therapeutics.

As a consequence, a list of 1024 documents for H5N1 and 76 for H1N1 was generated, out of which most of them fell outside the specific objective of the study.[7]

27 (H5N1) and 4 (H1N1) patent families were scored as relevant and withing the clear scope of the request, mainly pertaining to the origin and chemical composition of the virus. Also, among these families, 73% were vaccines, 24% were diagnostics and the rest 3 % were therapeutics. Further, 35 (H5N1 and 8 (H1N1) were counted as relevant but, subject to interpretation, which claimed sequences as one part or element of claimed invention. Rest of the patent families did not fall within the scope of study. [8]

Therapeutic is of relating to the treatment of disease or disorders by remedial agents or methods[9], the two classes of antiviral medicines used for pandemic influenza are

i. Neuraminidase inhibitors, including oseltamivir (known by the brand name of Tamiflu) and zanamivir (e.g. Relenza)
ii. M2 inhibitors, including amantadine and rimantadine.

[6] WIPO (2006). Working Paper: Patent issues related to influenza viruses and their genes - An overview. WIPO: Geneva. http://tiny.cc/6xa2t and WHO (2007). Patent Landscape for the H5 virus: Interim Report. http://tiny.cc/xf6l4 and WHO (2007). Mapping of Intellectual Property Related to the Production of Pandemic Influenza Vaccines. WHO: Geneva. http://tiny.cc/dnt37

[7] World Intellectual Property Organisation: WIPO PATENT SEARCH REPORT ON PANDEMIC INFLUENZA PREPAREDNESS (PIP)-RELATED PATENTS AND PATENT APPLICATIONS, April 1st, 2011. https://apps.who.int/medicinedocs/documents/s21426en/s21426en.pdf

[8] Ibid.

[9] Merriam Webster Dictionary.

Another class of approved antiviral drugs known as M2 inhibitors (amantadine and rimantadine) can be effective for treating seasonal influenza. However, the pandemic (H1N1) 2009 virus has been shown to be resistant to these particular antiviral drugs.[10]

i. Tamiflu:

Avian influenza, or "bird flu" or "avian flu" is an infection caused by avian (bird) influenza (flu) viruses. These flu viruses occur naturally among birds. Wild birds worldwide carry the viruses in their intestines, but usually do not get sick from them. However, bird flu is very contagious among birds and can make some domesticated birds, including chickens and ducks, very sick and kill them.[11]

Due to non- availability of any other effective vaccine, Oseltamivir (commonly known by its brand name as Tamiflu) emerged as the first line of defence against the Bird flu, and was used in both prevention as well as for treatment of the influenza.

The patents covering the invention of Oseltamivir are owned by Gilead Sciences, who opted to license certain exclusive rights to Roche in 1996.[12] Subsequently, Roche sublicensed Tamiflu by permitting more companies to manufacture and sell it, issuing sublicenses to Shanghai Pharmaceuticals Group in China and to Hetero Drugs in India and although these companies did not get a sublicence to produce the drug independently, but got integrated into Roche's own supply chain network, taking over specific production steps.[13]

ii. Doha Declaration

Apart from these strict licensing policies, Article 31 of the World Trade Organization's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and Doha Declaration on TRIPS and Public Health, provides flexibilities regarding compulsory licenses for the supply of drugs to countries with limited manufacturing capacities.[14] The Least Developed

[10] World Health Organisation: Frequently asked question https://www.who.int/csr/disease/swineflu/frequently_asked_questions/antivirals/definitions_use/en/
[11] Avian Influenza: Frequently Asked Question https://www.aiims.edu/aiims/bird-flu/FAQ_Bird_flu.htm
[12] World Intellectual Property Organisation: WIPO Magazine, AVIAN FLU DRUGS: PATENT QUESTIONS, Issue 2/2006. https://www.wipo.int/wipo_magazine/en/2006/02/article_0005.html
[13] https://www.wipo.int/wipo_magazine/en/2006/02/article_0005.html
[14] For WTO's TRIPS Fact Sheet (Last Updated in March 2018) see: http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm

Countries (LDC) have benefited the provision of special treatment under Paragraph 7 of the Doha Declaration, which provides a special extension of the TRIPS transitional period for pharmaceutical products. This came to be known as *TRIPS flexibilities*. LDCs did not have to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or enforce rights provided for under these Sections until 1 January 2016. In LDCs therefore, neither patents nor data protection was a barrier to purchasing or producing generic versions of medicines.[15] Thus, government authorities are also empowered to issue compulsory licenses in certain situations to issue a compulsory license, or a government use authorization, for production of the patented product without the consent of the patentee.

India under its Patents Act, 1970, [16] provides for issuance of compulsory license for manufacturing and exporting of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical industry to address the public health problems. Provided such country has granted compulsory license or allowed the importation of patented pharmaceutical products from India.[17] The sole purpose of this provision to adhere with the decision of the TRIPS Council on Paragraph 6 of the Doha Declaration.

Some laws provide for the possibility of compulsory licenses specifically on the grounds of "national emergency" or "circumstance of extreme urgency". In India and Hong Kong, the examples of such circumstances may include public health problems resulting from "HIV/AIDS, tuberculosis, malaria and other epidemics".[18] The Indian law provides the following meaning of "use of invention for the purpose of the Government": "…an invention is said to be used for the purposes of Government if it is made, used, exercised or vended for the purposes of the Central Government, a State Government or a Government undertaking".[19]

A. Compulsory licensing and government use

[15] See MSF Report *Determining the Patent status of essential medicines in Developing Countries (2004) [Health Economics and Drugs EDM Series No. 17]*.
[16] Section 92A of the Patents Act, 1970.
[17] Natco Pharma Ltd., India v. Bayer Corporation, USA. C.L.A No. 1 of 2011. March 9, 2012. P. H. Kurian, Controller of Patents, Mumbai.
[18] Section 92(3) of the Indian Patents Act, 1970.
[19] Section 99 of the Indian Patents Act, 1970.

An important tool for developing country governments and their procurement authorities in dealing with potential obstacles presented by patents is a "compulsory licensing" or "government use" authorization.

A patent is a government grant that permits its holder to exclude third parties from the market for a product. A *Compulsory license* is an authorization by the government to itself or to a third party to use the patented invention without the permission of the patent holder. This enable the compulsory licensee to use, manufacture, import, sell and export (with some limitations) the product under patent. Most countries allow the government to make use of patented inventions for public purposes with fewer bureaucratic obstacles than those applied to the private sector. A compulsory license authorizing the government to use the patent for its own purposes is also referred to as a *government use* authorization. An obligation remains with the government to pay the patent holder an adequate amount of remuneration by taking into account the economic value of such authorization.

Article 31 of the TRIPS Agreement authorizes governments to grant compulsory licenses without restriction as to purpose or grounds. This authority was confirmed in Paragraph 5(b) of the Doha Declaration.

The TRIPS Agreement establishes certain procedural requirements for granting a compulsory license. However, these requirements can be significantly minimized. Prior negotiations with the patent holder before granting of compulsory licenses are not required in the case of a national emergency, other circumstances of extreme urgency or when the license is intended for public non-commercial use. Countries are free to determine what they consider a national emergency. TRIPS Agreement does not prescribe any procedure for using the emergency safeguard; for example, a declaration of emergency is not required. Countries are also free to define what is "public non-commercial use" and hence this can be defined as procurement or production of health care products for use in the public sector.[20]

i. Parallel Importation

It refers to the import and resale in a country, without the consent of the patent holder, of a patented product that ahs been legitimately put on the market of the exporting country. The sale

[20] Ibid.

of the patented medicine in the exporting country is deemed to "exhaust" the patent holder's right in the importing country. It denotes the import of the branded product and can be useful when the patent holder has put the product on the market elsewhere at a lower price. A country that allows parallel importation from any other country has an "international exhaustion regime". A country adopting a "regional exhaustion regime" would only allow parallel importation from other countries that are members of the same regional trade agreement or arrangement. An international exhaustion regime will be more helpful than a regional exhaustion regime in the respect, as prices within a region will probably be similar. Paragraph 5(d) of the Doha Declaration illuminates the fact that countries are free to determine their exhaustion regimes. There are no procedural or remuneration requirements in the case of parallel importation. The extent to which parallel importation is possible depends upon the regime of exhaustion adopted in the national legislation. [21]

B. Ensuring Right to health in Indian Context

i. Indian Constitution

It is pertinent to note that Article 21 of our Constitution guarantees right of life, which further includes right to good health. The courts through judicial pronouncements concluded that right to life includes right to health and "access to medical treatment" as well.[22] The Government must make every effort to provide access to the life-saving drugs to its citizens.[23]The State is under constitutional obligation to see that there is no violation of fundamental right of any person.[24] The Preamble and the Directive Principles of State Policy (DPSP) of our Constitution need policies in order to balance social and economic rights. Hence, while formulating patent legislations the balance must be made between public health and the economic interests of pharmaceutical industries.

According to the Ayyangar Committee Report[25], India being a developing nation, grant of patent confers monopolistic rights which will deny major population of our nation from access to medicines. Therefore, policies which grant monopolistic rights violate the Preamble and also the

[21] Ibid.
[22] L.M. Singhvi and Jagadish Swarup (2006), Constitution of India, Vol. 1, Modern Law Publications, (2nd Edn. p. 1100).
[23] *All India Drug Action Network* v. *Union of India*, (2011) 14 SCC 479.
[24] *People's Union for Democratic Rights* v. *Union of India*, (1982) 3 SCC 235.
[25] Report on the revision of the patent law, Rajagopal Ayyangar Committee, September 1959.

fundamental rights guaranteed under Article 21 of our Constitution. Meeting the needs of its population came before meeting the needs of foreign innovators.

ii. Indian Legislation

Provisions related to the grant of compulsory licence in India are prescribed under Sections 82-94 (Chapter XVI) of the Patents Act, 1970, and Rules 96-102 (Chapter XIII) of the Patents Rules, 2003.[26] The Controller of Patents can issue compulsory licence under the following situations: compulsory licence under Section 84; licensing of related patents under Section 91; special provision for compulsory licences on notifications by Central Government under Section 92; and, compulsory licence for export of patented pharmaceutical products in certain exceptional circumstances under Section 92-A.

It is to be noted that *Natco case*[27] has pioneered a revolution in Indian pharmaceutical industry on working of patents and established a consonance between TRIPS and domestic laws. It has showcased that all the developing countries including India can use the TRIPS flexibility effectively to provide healthcare to public and also fulfil the constitutional obligation of right to life as envisaged under Article 21. Further, even the Bombay High Court agreed with the findings of the Controller General of Patents and the Tribunal regarding compulsory licensing under Section 84 of the Patents Act.

Other applications for compulsory licensing have also been filed, however, they were rejected by the Controller. One such application was filed by BDR Pharmaceuticals to manufacture the generic version of anti-cancer drug Dasatinib, patented by Bristol-Myers Squibb in India.[28] Further, in 2015, Lee Pharma filed an application for seeking the grant of a compulsory licence for manufacturing and selling the drug Saxagliptin used in the treatment of type II diabetes mellitus. Both applications were rejected as they failed to convince the Controller of Patents to make a prima facie case for the grant of compulsory licensing.[29]

Although the comparative study[30] concludes that compulsory licensing provisions in India are fully TRIPS compliant. However, compulsory licences are conceptually

[26] Patents (Amendment) Act, 2005 .
[27] *Bayer Corpn.* v. *Union of India*, 2014 SCC OnLine Bom 963.
[28] *BDR Pharmaceuticals International Pvt. Ltd. v. Bristol-Myers Squibb Company. CLA No. 1 of 2013.*
[29] *Lee Pharma Ltd. v. AstraZeneca AB, CLA No. 1 of 2015.*
[30] Compulsory Licensing of Pharmaceutical Patents in India: A Research Study, European Journal of Pharmaceutical and Medical Research, 2016, 538.

oxymoronic and fundamentally problematic.[31] Till date, only one compulsory licence has been granted in India. The prime reason that can be attributed for such restricted usage of flexibilities is the procedural complexities. The paper version of the concept is very overwhelming but the actual construction is in the hands of the patent office. To further strengthen the compulsory licensing provisions in India, there is a need of policy formulations. A detailed guideline must be issued by Indian Patent office.

[III] ISSUES AND CHALLENGES

A. Monopolistic market against Competition

Competition is the essence of any market[32] and pharmaceutical sector is no exception. For the purpose of an inclusive growth and economic development of any nation, competition ensures a fair and healthy competition in its market. The vital role of allocation of resources is done in order to preserve and promote competition in any country, for the betterment of the nation by achieving better quality of products in lower prices and to achieve the ultimate goal of maximum social welfare.

In 1982, the then Indian Prime Minister, Indira Gandhi, told the World Health Assembly that

> *"the idea of a better-ordered world is one in which medical discoveries will be free of patents and there will be no profiteering from life and death".*[33]

The statement is still an interesting one, because it highlights so clearly the tension between the way things should be, the ethical basis on which we would expect the world to be organized and the way things are diametrically opposed to the ethical notion that monopolistic proprietary rights in the form of patents should not be granted for pharmaceutical products. Not only are there medical patents, and not only is there profiteering from life and death, but patents form the

[31] Daniel R. Cahoy, Breaking Patents, 32 Mich. J. Int'l L. 461, 462 (2010).
[32] Ashwini Siwal, IPR and Competition Law regime: towards a common goal, The Lex-Warrier: Online Law Journal, ISSN: 2319-8338, LW (2012) Nov. 27.
[33] Carlos Braga, *The Economics of Intellectual Property Rights and the GATT*: *A View from the South, in* TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY 253 (Connie T. Brown & Eric A. Szweda eds., 1990).

entire basis of the research and development strategy of the major US and European pharmaceutical companies.

The product patents were not eligible of protection prior to 2005 amendment in the Indian Patent Act. This resulted into the rapid growth of pharmaceutical industry in India which caused the development of cheaper versions of a number of drugs patented for the domestic market and eventually moved ahead into the international market with generic drugs once the international patents expired[34]. It was after India became a signatory of WTO TRIPS Agreement that Indian Parliament introduced Patents (Amendment) Act, 2005, which reintroduced the product patent system in India.

i. Patent Law and Competition Policy in India

Since the Patent laws provide its right holder, the exclusive right on such invention i.e., it excludes others from the use of his monopoly right, absolutely or on terms, the conspiracy in price control and distribution is not within the purview of the Patent laws.

Article 40 of TRIPS focuses upon intersection of Intellectual Property standards and Competition law.[35] A plain reading of Article 40 makes it evident that the protection of intellectual property rights must co-exist with competition law, and that competition law is necessary in arriving at a balance of rights and duties under TRIPS[36]. It provides that "*Nothing shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market."*

In India, after repealing MRTP Act, 1969 the competition policy was set out by enacting Competition Act, 2002. The purpose of the new act is to prevent all practices which are having adverse effect on the competition thereby upholding the spirit of healthy competition in Indian markets.

[34] Ibid.
[35] UNCTAD, the TRIPS Agreement and Developing Countries, UNCTAD/ITE/1, Geneva (1997).
[36] C.M. Correa, Review of the Trips Agreement: Fostering the Transfer of Technology to Developing Countries, available at http://www.twnside.org.sg/title/foster.htm

Section 3 of the Competition Act, 2002 prohibits the anti-competitive agreements, nonetheless it recognizes the importance of Intellectual Property Rights and nothing shall prevent the right of any person to restrain any infringement of, or to impose reasonable conditions, as may be necessary for protecting any of his right enjoyed under the statues relating to respective intellectual property rights[37].

Regardless of many similarities between Indian patent laws with US and that of UK standards, Section 3(d) [38] talks about an additional statutory requirement of showing an increased therapeutic efficacy for pharmaceutical compounds that are structurally related to previously known compounds.

ii. Competition issues in the Indian Pharmaceutical Industry

A broad classification of practices, which appears to be anti-competitive in pharmaceutical industry, can be done primarily into three classes: intellectual property rights related breaches, abuse of competition norms arising from mergers and acquisition and collusive, and other anti-competitive practices[39].

However, public health being a sensitive issue, government often fluctuates the price of the medicines or drugs. This is to be understood as a practice required to control the price of essential drugs and not to be termed as an anti-competitive[40].

The issues of concern in Indian pharmaceutical industry pertaining to the competition are: -

a. Abuse of dominance

Dominant position means[41] a position of strength enjoyed by an enterprise, in the relevant market, which enable it to:

a. Operate independently of competitive forces prevailing in the relevant market; or

[37] Subsection (5) of Section 3, Competition Act, 2002.
[38] Patents (Amendment) Act, 2005.
[39] Options for Using Competition Law/Policy Tools in Dealing with Anti-Competitive Practices in the Pharmaceutical Industry and the Health Delivery System, Report Prepared For World Health Organization Office of the WHO Representative to India & Ministry of Health and Family Welfare, Government of India (Prepared by Cuts Centre for Competition, Investment and Economic Regulation, Jaipur (2006).
[40] Article 47, Constitution of India.
[41] Explanation to Section 4, Competition Act, 2002.

b. Affect its competitors or consumers or relevant market in its favour.

Dominance has its significance only in the relevant market and thereby, it is the abuse of dominance which is considered as bad and not the dominance itself.

When a patent right provides its inventor a monopoly over the exploitation of their invention for a limited period of time, that doesn't necessarily constitute a dominant position. However, many patent holders attempt to abuse their position in numerous ways such as ever-greening of patents.

Ever-greening of patents provide the patent holders the chance to retain their monopoly over its product after patent period is expired by bringing small changes in the same product and claiming a new patent right for another twenty years on it, thereby expanding the patent life beyond twenty years.

The Indian Patents Act eliminates, a mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant, from the ambit of an invention. [42]

The constitutional validity of Section 3(d) of Indian Patent Act, 1970 was challenged by Novartis claiming immunity for their drug *Gleevic*[43]. In applying 3(d) of the Act, the division bench of Supreme Court decided to interpret "efficacy" as "therapeutic efficacy" because the subject matter of the patent is a compound of medicinal value and that all the properties of a drug are not relevant, the properties which directly relate to efficacy in case of medicine is its therapeutic efficacy. Further, Court stated that 30% increase in bioavailability qualifies as increase in therapeutic efficacy under Section 3(d). In order to discourage *evergreening* of patents, the Court upheld the view that under Indian Patent Act, what is necessary for the grant of pharmaceutical patents is the new test of enhanced therapeutic efficacy for claims that cover incremental changes to existing drugs along with the traditional tests of proving the novelty, inventive step and application.

[42] Section 3(d) of Patents Act, 1970.
[43] Novartis AG v. Union of India & Ors. (2013) 6 SCC 1.

On a similar case Cipla won the right to manufacture and market the generic version of the anticancer drug *Tarceva* originally patented by the Swiss pharma company Hoffman La Roche[44]. It was a case where the plaintiff has filed the suit for permanent injunction restraining infringement of patent, rendition of accounts and damages.

b. Compulsory Licensing

The main objective of compulsory licensing is to ensure that public is not denied of drugs because of high price. Nevertheless, in India, compulsory licensing is a good way of misusing the monopoly by large pharmaceutical companies.

Mumbai High Court rejected Bayer AG's contention to stop a local company from manufacturing and selling a generic version of its cancer drug *Nexavar*[45]. This petition ascended from the orders granting a compulsory license of the patented drug owned by the petitioner to NATCO on application of the provision of Section 84 of the Patent Act, 1970. While rejecting the contention of Bayer AG, it was observed by the court that, "*public interest is and should always be fundamental in deciding a lis between the parties while granting a compulsory licence for medicines/drugs*".

c. Regulation of Combination

Section 6 (1) of the Competition Act, 2002 prohibits any person or enterprise form entering into a combination which could cause or is likely to cause an appreciable adverse effect on competition in India. Thus, combination including mergers, amalgamations, acquisitions and acquisitions of control, which are above a certain threshold are restricted to safeguard the interest of market.

The Competition Commission of India is empowered to review any combination as an outcome of mergers, amalgamations, acquisitions and acquisitions beyond the permissible level of assets or turnover, as prescribed by the Commission.

Though the Act made the pre-notification of combinations voluntary for the parties concerned and if, the parties to the combination chose not to notify the Competition Commission of India,

[44] F. Hoffmann-La Roche Ltd. and Anr. v. Cipla Limited, MIPR 2008 (2) 35.
[45] Bayer Corporation v. Union of India, AIR (2014) Bom 178.

they run the risk of a post-combination action by the Competition Commission of India, if it is discovered, subsequently, that the combination has an appreciable adverse effect on competition. In such circumstances role of competition law is very significant otherwise such combinations could have adverse implications in the market.[46]

B. Patent policies

The TRIPS Agreement sets out the minimum standards for patent protection with which all WTO Members must abide. After TRIPS, all inventions in the pharmaceutical sector fall within the scope of the patentability requirements of the TRIPS Agreement and national authorities must provide patent protection for a minimum term of 20 years provided that the invention is new, inventive and capable of industrial application.[47]

The criteria to ascertain an invention to be worthy of protection by a patent for exclusive rights, is commonly known as 'Patentability'. Although, this criterion depends upon the individual framework of National or Regional patent laws, but they are often shaped by general international standards.

The diagnostic, therapeutic and surgical methods for the treatment of humans or animals have been specifically mentioned as exceptions, along with others, under the TRIPS Agreement. WTO Members are to apply these exceptions as they deem necessary under their national laws. These exclusions are significant to some patenting scenarios relevant to flu virus. More specifically:

i. An inventive procedure which might make use of a flu virus might be considered diagnostic or therapeutic methods, and thus may fall under the exceptions;
ii. A legitimate invention making use of a flu virus might be prevented from being exploited in order to protect public order or morality, including human life and health.

Thus, these inventions would not qualify for patent and would be refused under National laws, as it would be considered contrary to public order, even if it were technically 'new' and 'inventive'.

The concept of *novelty* is an essential condition for eligibility of a patent. It mandates the invention to be new or novel and that it must not be existing prior to filing such application.

[46] Vishnu Warrier: Patent Law and Competiton issues in the Indian Pharmaceutical Industry, The Lex-Warrier Online Law Journal, ISSN 2321-4171.
[47] Article 27.1 of the TRIPS Agreement.

Another concern is in regard to the existence or derivation of such invention from a genetic material in a natural context. This issue has a long preceded modern gene technology: for instance, a patent when obtained a century ago on the first isolated and purified adrenaline, a naturally occurring hormone, even though adrenaline is already present in humans. When it was challenged, the Court upheld the patent since adrenaline as it occurred in its natural state was of no value as a treatment for heart disease. The novelty about the patent was not the existence of adrenalin as such, but it was rather the knowledge about how to isolate and apply it as a new therapeutic mechanism.[48]

In the quest of acquiring a patent, the most complex and debated criteria is of the requirement of an *inventive- step* i.e., it should be non-obvious to someone working in the relevant field to undertake what is claimed as the invention. This test has been the subject of considerable scrutiny by policymakers, and has frequently undergone review and recalibration by the courts.[49] In an European case, the obviousness of already existing background knowledge denied the inventiveness of the isolation of a gene: "the existence of additional 7TM receptors was predicted in the prior art and the procedure for the identification of said additional member of 7TM receptor family has been well established. Consequently, the disclosure of the primary structure of an additional 7TM protein which is arrived at by following the well stablished methods disclosed in the prior art is not considered inventive …."[50]. Obviousness does not require absolute predictability of success. All that is required is a reasonable expectation of success.[51]

The usefulness of an invention is determined by its *industrial application* under some laws. In order to establish its industrial utility, it has to be specific and credible in nature, to be used in an industry. In the field of biotechnology, namely in respect of inventions related to genes, the requirement of industrial application has been given much importance. Thus, if an inventor identified a naturally occurring substance and made it available for the first time, even if it would be considered patentable substance matter, inventive and huge scientific advance, it would still

[48] Parke-Davis & Co. v. H. K. Mulford & Co., 189 F. 95, 103 (S.D.N.Y.1911).
[49] KSR v. Teleflex, 550 U.S., 237 S. Ct. 1727 (2007).
[50] ICOS Corporation/ Seven transmembrane reception OJEPO 2002, 293 (EP-B-0630405).
[51] IPAB in Ajanta Pharma Limited vs Allergan Inc., ORA/20/2011/PT/KOL,ORDER (No.172 of 2013).

not be considered as patentable despite being unknown earlier. Thus, that substance could not be related to a disease or any other practical use like the production of a vaccine.

i. Ambiguities in the Indian Patents Act

The new amended act,[52] introduced few ambiguities. To address a few, the 2005 Act requires the generic drug maker to pay a "reasonable" amount of royalty to apply a for a copy of patented drug, only after the initial three years from the date of registration of the patented drug. Nowhere in the act, the term "reasonable" has been defined, this can result into unwarranted complications and needless litigation.

The act talks about the three-year time period before granting of compulsory license, this condition has not been mandated by the TRIPS Agreement.

Further, the act provides the Controller of Patents, a series of wide-ranging discretionary powers in determining the criteria like "reasonable affordability", "reasonable pricing" and "reasonable royalty".

Lastly, with the removal of Section 5 of the law, it is not clear if chemical processes continue to be defined to include biochemical, biotechnical and microbiological processes.[53]

C. Proliferation of Patents

An investigation carried out by the European Union (EU) about the conduct and practices of the pharmaceutical industry between 2000 and 2007 found that a single medicine can be protected by up to 1300 patents or pending patent applications.[54] The number of lawsuits between originator companies and generic companies has increased four-fold in the EU. These lawsuits delay the entry of the generic product by between six months and six years. The study estimates that the savings resulting from the entry of generics could have been approximately EUR 3 billion, if the entry had occurred immediately after the loss of exclusivity.[55]

[52] Patents (Amendment) Act, 2005.

[53] Section 5 of Th e Patent Act, 1970 states, inter alia, "In the cases of inventions - (a) claiming substances intended for use, or capable of being used, as food or as medicine or drug, or (b) relating to substances prepared or produced by chemical processes .... no patent shall be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture shall be patentable.

[54] Investigation by the European Union: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html.

[55] Investigation by the European Union, Op. cit.

A policy and strategy change at the patent office level could lead to significant changes. In Argentina, for example, after the introduction of new guidelines for the examination of pharmaceutical patents in 2012, the number of patents granted was 54, while in Mexico, a similar-sized market to Argentina, the number of patents granted in 2012 for pharmaceutical products was 2500.

D. Challenges Faced by the Member States in Implementing the Exception Regarding the Compulsory Licensing

The challenges relating to the implementation of patent flexibilities may be of dual nature:

i. The difficulties faced by the government in implementation of international law at national level; and
ii. Challenges encountered by individual stakeholders in using the national legal framework, resulting from the government's enactment of the national law.

i. The difficulties encountered by the governments

a. The Constructive ambiguity and vagueness of certain clauses in International Treaties can lead to different interpretations, thereby affecting the national implementation process. It gives rise to the possibility of interpreting texts which leads to a different understanding.
b. Generally, national implementation of international treaties includes not only the passing of legislation, but also execution and operation of the law by administrative bodies and courts. Therefore, where more than one administrative body is involved in the procedure of granting or refusing of compulsory license, the clarity of their responsibilities and mandates might be also importance for a clear decision-making process.
c. The insufficiency in local legal and technical expertise to incorporate the flexibilities contained in international treaties into the national law is one of the major challenges. For example, the Delegation of Algeria on behalf of the African Group stated that "[…] the majority of developing countries did not have the technical capacity to make use of those flexibilities, for example, compulsory licensing".[56]
d. The implementation of various provisions contained in international treaties into the national law, in particular, on compulsory licensing, requires the involvement of various

[56] WIPO: *Standing Committee on the Law of Patents*, Thirtieth Session Geneva, June 24 to 27, 2019.

government departments and ministries, such as patent offices, ministries of health and trade, and drug regulatory authorities. In some countries, reportedly, their activities are not necessarily coordinated in order to pursue common policy goals, creating tensions between, for example, ministries responsible for the promotion of trade and the protection and enforcement of intellectual property and those responsible for public health.[57]

ii. Challenges faced by various stakeholders

a. In many countries, there still exists ambiguity in the national procedures, such as the procedural aspects relating to such licenses are not spelled out in details under the national legal frameworks, or at least, are difficult to find. This issue was also highlighted in the submission of Costa Rica which stated that the challenge for the Industrial Property Registry is to establish the procedure to review the conditions under which the license may be granted, limitation of the scope of the license, its duration and the economic remuneration to be received by the right holder.[58]

b. In addition to a good knowledge of the legal norms concerning compulsory licensing by the users of the system, the technical and technological knowledge of the product concerned, and practical legal expertise in other disciplines can be indispensable in order to steer the process. Particularly, where a compulsory license is sought for importation of the medicine, not only the laws pertaining to health and intellectual property but also trade law would be involved.

c. In order to determine whether a compulsory license is necessary to legally manufacture or import a patented product, first, relevant patents covering that product should be identified, and then, the legal status of such patents should be determined. Particularly, in developing countries and LDCs, such information may not be easily accessible. In addition, even if legal status information is made available to the public by the respective national/regional patent office, the varied format of such information makes it difficult for the users to access the data. Furthermore, a good knowledge of patent procedures in a given country is necessary to fully understand the legal status of the patent concerned. The difficulty faced by those who

[57] The Report of the United National Secretary-General's High-Level Panel on Access to Medicines, Promoting Innovation and Access to Health Technologies, p.24. See also a paper by Patrick L. Osewe et al., which reports that in most developing countries in Africa, national coordination systems on IP issues are generally weak or non-existent. Patrick L. Osewe et al., Improving Access to HIV/AIDS Medicines in Africa, Trade-Related Aspects of Intellectual Property Rights Flexibilities, International Bank for Reconstruction and Development and World Bank 2008.

[58] See the submission of Costa Rica to the thirtieth session of the SCP.

do not have sufficient technical and IP expertise in unequivocally identifying patents covering a specific product has been fairly known.

d. The filing of patent application in a country is primarily an economic and business decision of the technology holder. Therefore, the patent applications on a specific product and process may be filed in some countries but not in others. In addition, since the patentability criteria are not exactly the same in all countries, a patent may be granted on a given invention in some countries, but not in others. The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) had stated that, in reality, most pharmaceutical companies either do not patent in developing countries and least developed countries (LDCs) or do not enforce their rights in those jurisdictions. [59]

Similarly, in relation to the implementation of the special export compulsory licensing system under the TRIPS Agreement, a study focusing on Africa reports that most countries in the region procure their first-line treatment for HIV/AIDS from India, where most of those medicines were not patented.[60] However, some WTO Members have expressed their concern that the implementation of full patent protection for pharmaceutical products in India, coupled with the expiry of the transition periods in LDCs, could make it more difficult in the future to procure generic versions of new medicines.[61]

[IV] RECOMMENDATIONS

A. Changes required in patentability criteria

[59] As regards pharmaceutical patents, the research conducted by the University of Ottawa on the WHO Model List of Essential Medicines (MLEM) found that, of the 375 items on the 2013 WHO MLEM, 95% are not under patent protection in most lower-income countries, meaning that patents with respect to these medicines have expired, or were not filed in the first place. Authors noted, however, that in the long-term, the proportion of patented products on the MLEM would likely increase. Reed F Beall and Amir Attaran, Global Challenges Report: Patent-based Analysis of the World Health Organization's 2013 Model List of Essential Medicines, WIPO, available at: http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=334437.

[60] Patrick L. Osewe et al., Improving Access to HIV/AIDS Medicines in Africa, Trade-Related Aspects of Intellectual Property Rights Flexibilities, The International Bank for Reconstruction and Development, The World Bank, 2008.

[61] WHO, WIPO, and WTO Study, Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade, 2012, p. 179, indicating observations made by the WTO members on whether the special export compulsory licensing system is fulfilling its intended function. Following a decision taken by the WTO General Council on November 30, 2015, the transitional period applies until January 1, 2033 (WTO document WT/L/971).

Definition of patentability requirements from a public health perspective

In April 2012, the WHO Consultative Expert Working Group on Research and Development (CEWG) recommended the start of international negotiations for a treaty on R&D for pharmaceutical products, within the scope of Article 19 of the WHO Constitution, which states:

> "The Health Assembly shall have authority to adopt conventions or agreements with respect to any matter within the competence of the Organization. A two thirds vote of the Health Assembly shall be required for the adoption of such conventions or agreements, which shall come into force for each Member when accepted by it in accordance with its constitutional processes."

The only precedent in the history of WHO of the use of this article in a substantive area was the Framework Convention on Tobacco Control (FCTC). New, effective and simultaneous mechanisms[62] that promote innovation and access to medicines are needed, particularly for diseases that chiefly affect developing countries. A binding international instrument or international treaty on R&D, negotiated under the auspices of WHO could provide an adequate framework to guarantee the establishment of priorities, coordination and sustainable financing for medicines at affordable prices for developing countries.

Develop a public health perspective in the examination of pharmaceutical patents

The Guidelines[63] for the examination of pharmaceutical patents developed by WHO are a guide for the drafting of internal procedure manuals of national intellectual property offices for the examination of patentability of chemical-pharmaceutical inventions. The purpose of the guidelines for the examination of pharmaceutical patents is to provide a series of general guidelines for the examination of some common types of pharmaceutical patents granted. They respond to the growing concerns emerging in different circles60 about the proliferation of patents that protect minor variants, and in some obvious cases, existing medicines and processes. The recommendations set forth under the guidelines, having relevance here are as follows: -

[62]World Health Assembly Global strategy and plan of action on public health, innovation and intellectual property point 13.

[63] World Health Organisation: GUIDELINES ON PATENTABILITY AND ACCESS TO MEDICINES, Research Paper 61, March, 2015.

Formulations and compositions

Recommendation: New formulations and compositions are generally considered to be obvious when a single active ingredient is claimed to be already known. Exceptionally, claims of this type could be patentable if a truly unexpected or surprising effect is obtained, for instance, when a really difficult problem or a long standing need, such as a noticeable reduction in side effects, is solved in a non-obvious way, or when the solution found leads to a tremendous advantage compared to the state of the art.

Selection patents

Recommendation: As a general rule, selection patents should not be granted if the selected components have already been disclosed or claimed and, hence, lack novelty. If an existing product were deemed patentable due to its unexpected advantages under the applicable law, the patentability of a selection could be considered when an inventive step is clearly present.

B. Suggestions from other countries

In 2003, via a World Health Assembly resolution,[64] the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) was established. In 2006, a report of CIPIH on Public Health, Innovation and Intellectual Property Rights, stated that "The TRIPS Agreement allows countries a considerable degree of freedom in how they implement their patent laws. Thus, developing countries may determine in their own ways the definition on an invention, patentability requirements, the rights conferred on patent owners and what exceptions to patentability are permitted."[65]

Following this principal, different countries have adopted different patentability criteria with a same contour of elements of *novelty, inventive step and industrial applicability (utility)* in their patent policies.

Given below are the suggestions which can be taken out from different countries to strengthen our own patent policies: -

[64] WHA Resolution, WHA56.26 Intellectual Property Rights, Innovation and Public Health.
[65] WHO, "Public Health, innovation and intellectual property" Geneva 2006, Op. cit. p. 21.

a. In terms of expenditure and funding on Research and Development (R&D), India spent just 0.7 % of its Gross Domestic Product (GDP) in 2016-17, whereas, Japan, the US and China spent 3.2 %, 2.8 % and 2.1 % respectively, in 2017.[66]
b. In India, the time period taken to grant a patent was of 84 months in 2015. In 2017, India on average took 64 months to grant a patent, compared with 22 months each in China and the European Patent Office and 24 months in the US.[67]

India ranked at 52nd position in the GII, 2019, gaining five positions since 2018. India has successfully remained at 1st position in Central and Southern Asia region and moves up to the 4th position among lower middle-income economies. India has also outperformed on innovation relative to its GDP per capita for nine consecutive years. [68]

The economy improves in four of the seven GII areas. Among the most notable gains, India improves its rankings in IP-related variables, notably Patent applications and PCT patent applications by origin, and Intellectual property receipts. It maintains its top positions in Information and Communication Technology (ICT) services exports, where it ranks 1st in the world, and in Labour productivity growth. It also improves in two important variables: Gross expenditure on R&D and Global R&D companies. In the former, despite improvement, India is still at rank 50th.[69]

From the abovementioned data, it is evident that India is improving in the arena of R&D. The R&D sector is the most crucial aspect for the growth of Intellectual Property regime in any country. With the help of financial and academic support in R&D area, India can supplement itself for better innovation input.

[V] CONCLUSION

The patent law in India, which has long served as the 'pharmacy of the developing world', is particularly influential. The Doha Declaration and the general awareness of the need for more health-sensitive patent policies has enabled India to implement a patent law containing a number

[66] The Organisation for Economic Co-operation and Development (OECD)
[67] World Intellectual Property Organisation.
[68] WIPO: Global Innovation Index, 2019, available at https://www.wipo.int/edocs/pubdocs/en/wipo_pub_gii_2019/in.pdf
[69] Ibid.

of very significant safeguards, including: strict patentability criteria to limit the number of patented products, automatic compulsory licensing for generic drugs brought to market between 1995 and 2005, and the possibility for anyone to oppose the granting of a patent. While this law was challenged – most significantly by Novartis after it was denied a patent on its cancer drug imatinib mesylate – thus far, it has been upheld and has set an important example for other countries wishing to build more flexibilities into their national patent laws.

The information available shows that the universalization of pharmaceutical patents will not lead to increased R&D on new drugs by large companies nor to the possibility that this will be carried out to any significant degree in developing countries. Neither will the developing countries receive increased flows of direct foreign investment or transfer of technology."[70]

Medicines are a fundamental tool for society to prevent, treat and cure diseases and access to them is a fundamental right of citizens, an integral part of the right to health care as established in some international treaties and the constitutions of many countries.[71]

Access to medicines has to be considered as a fundamental human right, with full international and constitutional recognition. The Universal Declaration of Human Rights (1948) refers to this in article 25:

> "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services (…)"

In 2018, India ranked at 36th position[72] in Market Sophistication, India has exhibited its strength particularly in the area of Trade, Competition and has been ranked at 16th position in Market scale. India held 2nd rank among middle-income economies (after China) in indicators that capture the quality of the innovation inputs and outputs. In 2018, India was celebrated as the

[70] C. Correa, «The Uruguay Round and Drugs » in Medicines and the new economic environment, edited by F. Lobo and G: Velasquez, Ed. Civitas, Madrid 1998.
[71] Seuba, X. "The protection of health in light of international regulation of pharmaceutical products" Doctoral thesis p. 92 onwards, Barcelona 2008.
[72] WIPO: Global Innovation Index, 2018, available at https://www.wipo.int/edocs/plnkdocs/en/wipo_pub_gii_2018_in.pdf

most innovative country in Central and Southern Asia by attaining the 1st position. In 2019, India ranked as 52nd country among the 129 economies featured in the GII 2019.[73]

As India is the leader in the global supply of affordable antiretroviral drugs and other essential medicines, we hope that the Indian government will take the necessary steps to continue to account for the needs of the poorest nations that urgently need access to anti-retroviral, without adopting unnecessary restrictions that are not required under the TRIPS Agreement and that would impede access to medicines.

[73] WIPO: Global Innovation Index, 2019, available at https://www.wipo.int/edocs/pubdocs/en/wipo_pub_gii_2019/in.pdf