PATENT REGIME AND DRUG PRICING REGULATIONS: AN INTERTWINING THREAD IN DETERMINING ACCESSIBILITY AND AFFORDABILITY OF ESSENTIAL MEDICINES IN INDIA

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Abstract — *Innovation in the area of pharmaceutical industry brings in hope to save human life. The development of drug is a cost-intensive process, thus the pricing of drugs becomes a contentious issues in every jurisdiction. The newly crafted legal regime on patent grants monopoly right to the inventor and assures the industry/individual to invest in the invention of new drug to cure the life-threatening disease. The grant of patent thwarts the accessibility and affordability of the medicine, which is an integral component of the right to healthcare, on account of the high-pricing or abuse of the monopoly right. Generally, the industry justifies the cost on the expenditure incurred to develop a new drug and the recovered cost to again invest in inventing a drug for newer kind of diseases. Under patent law, compulsory licensing or parallel imports are well known mechanism to guarantee the availability of the drug to the lower-strata of the population. Additionally, the countries adopt the regulatory measures to fix the price of essential drugs which is instrumental for the realisation of the right to healthcare, a right recognised in the national as well as international legal sphere. However, there is need to understand a paradigm of drug pricing and the relationship with the patent regime. Any attempt to over-regulate the pricing of drug would be fatal for the*

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innovation in healthcare industry. The paper traces the evolution drug pricing and builds the argument that how it relates to the affordability of the medicine. It attempts to draw the connection with the patent law and justifies the regulation of pricing. Lastly, it advocates for the innovative means to protect the innovation without compromising with the right to healthcare of an individual.

Keywords: Drug Pricing, Patents, Accessibility and Affordability, Drug Pricing Control Order, National List of Essential Medicines, Right to Healthcare.

I. INTRODUCTION

In recent years, healthcare has emerged as one of the largest sectors of India in terms of both revenue and employment.[1] The Indian healthcare sector is also cost competitive as compared to the other nations in Asia and Western countries.[2] The cost of surgery in India is about one-tenth of that in the US or Western Europe.[3] Medical tourism is a growing phenomenon in the Indian market and is growing at a rate of 18 percent year on year and is expected to reach US $9 billion by 2020.[4] Despite having such a cost-competitive environment that India provides, it ranks 145 among 195 countries in global healthcare access and quality (hereinafter HAQ) index.[5] The index shows that India's performance is worse than that of many poorer countries in Sub-Saharan Africa, and even that of conflict-prone Yemen performs better than India.[6] It also shows that the leadership shown by India is not bringing any benefit to the people of the country because the people are not in a position to afford the costly healthcare that is prevalent despite having a drug pricing mechanism

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1 IBEF, Indian Healthcare Industry Report (Feb. 8, 2020, 5.28 p.m.) <https://www.ibef.org/industry/healthcare-india.aspx>.

2 *Ibid.*

3 *Ibid.*

4 *Ibid.*

5 Swagata Yadavar, "World Health Day 2019: Access, Quality of Care Ranks India Among Lowest Globally", (May 9, 2020, 9.11 a.m.) <https://www.firstpost.com/india/world-health-day-2019-access-quality-of-care-ranks-india-among-lowest-globally-4480939.html>. *See* "Measuring Performance on the Healthcare Access and Quality Index for 195 Countries and Territories and Selected Subnational Locations: A Systematic Analysis from the Global Burden of Disease Study 2016", The Lancet, Vol. 391, Issue 10136, 2-8 June 2018, pp. 2236-2271 (May 9, 2020, 9.18 a.m.). <https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)30994-2/fulltext>.

6 *Ibid.*

that is more than a decade old. The major finding of the HAQ index[7] shows that the countries that are the top performers in the list employ more percent of their gross domestic production (GDP) on health per capita and have a quality healthcare system.[8] As per the WHO report, India is counted among the countries that spend less GDP percentage on healthcare.[9]

In a country like India, where a large proportion of the population resides in an ambiance where even the basic amenities are lacking, providing quality healthcare by the Government is still a challenge. In many of the Indian states, the accessibility of medicine is as poor as 35% or less.[10] New drugs have worst impact on accessibility of medicines in India. It was observed that many newer drugs that may be proved beneficial to the patients were launched very lately in India, in comparison with the time of global launch, and in worst case scenario, the launch never takes place in India.[11] Challenges in ensuring accessibility and affordability of quality drugs are numerous. Disproportionate healthcare services, ineffective medicine supply networks, insufficient allocation of funds for healthcare services, artificially low target levels of coverage, high prices for essential life-saving drugs, intricacies related with patented drugs and drugs that retain market exclusivity etc. complexes the matter to a great extent.

In the Indian scenario, about 89 percent of the total household expenses are spent on Out-of-Pocket (OOP) expenditure for healthcare and medicines.[12] This out of pocket expenditure is resulting in millions of people being dragged below the poverty line.[13] This also makes it difficult for the Government to percolate the benefits to the grassroot level. The patent system also has an important role to play in this regard. Patents are popularly known for promoting research and development, especially when it comes to pharmaceutical related research. Innovation in Pharmaceutical sectors must be

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7 The Healthcare Access and Quality (HAQ) Index is indexing of the countries based on 32 risk-standardized mortality rates or mortality-to-incidence ratios from causes that, in the presence of quality healthcare, should not result in death – also known as amenable mortality. HAQ Index performance is shown on a scale of 0 to 100, with 0 reflecting the worst observed levels across countries from 1990 to 2016 and 100 being the best observed during this time. *See* <https://www.thelancet.com/action/showPdf?pii=S0140-6736%2818%2930994-2>.

8 *Supra* note 6.

9 As per WHO, India ranks 184th out of 191 countries in terms of GDP percentage spend on healthcare. India spends just 1.4% of its total GDP on healthcare sector. *See* Vivek Tiwari, "Budget 2020 Expectations for India's Healthcare Sector" (Feb. 9, 2020, 1.11 p.m.) <https://www.financialexpress.com/budget/budget-2020-expectations-for-indias-healthcare-sector/1842519/>.

10 Nilanjan Banik and Philip Stevens, "Ayushman Bharat: Its Crucial to Ensure Easy Access to Life-Saving Foreign Medicines in Indian Markets", *The Financial Express*, Sep. 25, 2019.

11 *Ibid.*

12 G. Forgia and S. Nagpal, Government Sponsored Health Insurance in India: Are You Covered?, The World Bank, Washington D.C., 2012, p. 20.

13 Government of India, National Health Policy Draft, Ministry of Health and Family Welfare, Government of India, New Delhi, 2014.

a comprehensive one involving development at each sector of healthcare, providing it to reach to the end-users. The Commission on Intellectual Property Rights, Innovation, and Public Health of the World Health Organization (WHO)[14] has also pointed out, from time to time, the need for effective pharmaceutical policies that must be implemented in countries with poor access to quality drugs. This paper is an effort to analyze the relationship between the patent system and the drug pricing regime in determining the accessibility and affordability of the essential drugs. It dwells upon the mechanism adopted by the government to fix the price of the drugs under the category of essential medicines. Further, the paper further examines the impact of patent regime of pharmaceutical industry and the ways in which accessibility of essential drugs be provided at affordable prices. In conclusion, it suggests the way to improve the measures for the affordability of the drugs under these two legal regimes.

II. DRUG PRICING SYSTEM AND AFFORDABILITY OF ESSENTIAL DRUGS

Generally, the price fixation of a product is the sole prerogative of the market. Pharmaceutical industry falls in exceptional category and the government wants to closely monitor the pricing mechanism due to the role it plays in the life of an individual. For larger justification of the regulation of the price, the drugs are categorized into non-essential and essential. Market-based interest governs the former whereas the later warrants the intervention of the government. Essential drugs, as defined by WHO, are "those that satisfy the priority healthcare needs of the population".[15] The WHO maintains a list of Essential Medicine List (EML), which is used by the countries as guidance in making of their National list of Essential Medicines and to treat common health issues. The WHO bases its work on an "access framework" for essential medicines. This framework uses four criteria that must be fulfilled simultaneously in order to improve sustainable access to medicines.[16] These criteria are: rational selection and use of medicines, affordable prices, sustainable financing, and reliable health and supply systems.[17] Essential medicines are thus vital, fundamental and indispensable for a healthcare system and are expected to be present in adequate quantity, dosage, quality at affordable prices at all times within a healthcare system. WHO updates this list every two years and uses the generic name of the drugs in the list. The countries favouring this step of WHO is expected to come up with a personalized National list that is based on the

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[14] Public Health, Innovation and Intellectual Property Rights, Report of the Commission on Intellectual Property Rights, Innovation and Public Health, World Health Organization, 2006.

[15] WHO, Essential Medicines and Health Products, <https://www.who.int/medicines/services/essmedicines_def/en/>.

[16] WHO, Essential Medicines and Health Products, <https://www.who.int/medicines/areas/access/supply/en/>.

[17] *Ibid.*

National burden of disease. However, it must be noted that a large share of the WHO EML includes off-patent drugs.

The Indian jurisdiction has been more than a decade old on price control measures to regulate the overpricing of essential life-saving drugs through the National Pharmaceutical Pricing Authority (NPPA) under Drug (Prices Control) Order (DPCO). The National List of Essential Medicines (NLEM) is prepared by Ministry of Health and Family Welfare is an exhaustive list of medicines that is on the priority list of the Government and form part of the scheduled drugs. Drugs form part of the NLEM based on the aspects like prevalence of disease in the population, safety and efficacy of the medicine, and affordability of the drug. DPCOs are issued under Section 3 of the Essential Commodities Act[18] to ensure the affordability of essential medicines, which are listed in NLEM, to the general public.

The method that is adopted by India in monitoring, controlling, and checking up on the high prices of drugs is to set up a maximum limit which a bulk drug[19] or its formulation[20] cannot exceed. The level of price ceiling on these drugs differs on the basis of classification in which they fall.[21] Currently, India uses a blend of different pricing techniques to control drug prices. These are:

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[18] The Essential Commodities Act, 1955 is a legislative text to ensure the uninterrupted supply of the goods that are considered essential under the Act. It prescribes for punishment in cases of hoarding and black-marketing of essential commodities or selling commodities at a price higher than what is prescribes by the Government. The list includes drugs, fertilisers, pulses and edible oils, and petroleum and petroleum products. The Government, thus, regulates the production, supply and distribution of essential commodities and make them available to the common masses at a reasonable cost.

[19] A bulk drug is any pharmaceutical, chemical or biological product including its salts, esters, stereoisomers and derivatives, conforming to pharmacopoeia or other standards and which is used as such or as an ingredient in a formulation. (Source: The Drugs Prices Control Order, 1995).

[20] A formulation is a medicine processed out of bulk drugs for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease in human beings or animals, but shall not include any medicine included in the Ayurvedic, Homeopathic or Unani system of medicines. Hence, the DPCO is applicable only to allopathic drugs. (Source: The Drugs Prices Control Order, 1995).

[21] The drugs have been divided into scheduled formulations and non-scheduled formulations. For scheduled formulations, the prices are regulated while for non-scheduled formulations a monitoring mechanism is prescribed to check the average increase in the prices of drugs per year which is set at 10% within a year.

- **Market-Based Pricing Method**:[22] DPCO, 2013 uses market-based pricing method[23] to determine the ceiling prices of scheduled drugs under the following class:

  i. Calculation of ceiling price of a scheduled formulation of specified strengths and dosages as specified under the first schedule[24],

  ii. Calculation of ceiling price of scheduled formulation in cases of no reduction in price due to absence of competition[25],

  iii. Calculation of ceiling price in cases of other strengths or dosage forms of the scheduled formulation is not available in the schedule but there are other scheduled formulations in same sub therapeutic category as that of the scheduled formulation[26],

  iv. Calculation of ceiling price in cases where the other strengths or dosage forms of the scheduled formulation are not available in the schedule and there is no sub therapeutic category of the scheduled under consideration.[27]

- **Pharmacoeconomics Evaluation**[28]: Pricing Regime in India applies the method of pharmacoecomic evaluation for the calculation of ceiling

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[22] In India, just before the coming of National Pharmaceutical Pricing Policy, 2012 cost based pricing method was used for determining the ceiling price for essential life-saving drugs. The reason behind shift from cost based pricing method to market based pricing method can be found in the standing committee report on pricing of drugs with special reference to Drugs (Prices Control) Order, 2013. The Government submitted that it is very difficult to arrive at a cost-based pricing due to non-divulgence of actual cost by every company. The Government decided to go for market based pricing to bring in more transparency, less intrusive Inspector Raj and to encourage innovation and research in the field. *See* Fifty-fourth report of standing committee on "Pricing of drugs with special reference to Drugs (Prices Control) Order, 2013", Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals), (2018-19).

[23] Market-based pricing is defined as a "process of setting prices of goods/services based on the current market conditions, and prices are set according to mutual decision between sellers and buyers". *See* Renganathan R., Vijayabanu C., Srinivasakumar V., Vijay Anand V., "Pharmaceutical Pricing Policy and Control: Indian Perspective," 9 (6) Asian J. Pharm Clin Res, 305, 305-08 (2016).

[24] Or. 4 of DPCO, 2013.

[25] Or. 6(1) of DPCO, 2013.

[26] Or. 6(2) of DPCO, 2013.

[27] Or. 6(3) of DPCO, 2013.

[28] *See* Folino-Gallo et al., PHIS Glossary: Glossary for pharmaceutical policies/systems developed in the Pharmaceutical Health Information System (PHIS) Project, 2011, Vienna, WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies. The glossary of Pharmaceutical Health Information System (PHIS), defines the term Pharmacoeconomic Evaluations (PEs) as "the practise that often involve a cost-effectiveness analysis (CEA) to examine the value of medicines, usually defined in terms of its consequences (e.g., Quality-Adjusted Life Years (QALYs) gained) relative to its cost. The comparative analysis of alternative courses of action in terms of both their costs and consequences". Thus, a pharmacoeconomic evaluation means evaluating the therapeutic use of the medicine to determine the pricing of a certain drug. So by applying this method, the price of a particular drug is determined in proportion to the therapeutic use that it provide in comparison with the similar medicines that are available in the market.

price of new drug where the price to retailer of a new drug is not available in domestic market[29]. This fixing of price is done on the recommendation of a Standing Committee of Experts.[30] The retail price of such new drug is fixed by adding sixteen percentage margins to retailers on the price to retailer.[31]

- **Tendering and Negotiations:** The public healthcare system in India also applies tendering and negotiations in cases of Government schemes like Pradhan Mantri Bhartiya Jan Aushadhi Pariyojna (PMBJP)[32], Ayushman Bharat Yojana, etc. at Central level along with each State's[33] medical tendering processes.

Although a major part of scheduled drugs are off-patents, DPCO has also incorporated drugs that are patented[34]. The recent Amendment of 2019 to the DPCO, 2013 has exempted patented medicines from the purview of price control for a period of five years from the date of commencement of its commercial marketing by the manufacturer in the country.[35] The DPCO, 2013 has resulted into percentage reduction in prices, as claimed by the Government, of more than 40% with respect to maximum price is seen in cases of 59 drugs while 792 drugs witnessed a price reduction of up to 40% with respect to maximum price.[36]

Though Government intervention pre-calculates the risks and possible positive outcomes that it wants to achieve, sometimes though well planned, often ends up undermining the ability of the markets and leads to outcomes that were not premeditated for. Similar is the case with DPCO, 2013. The DPCO, 2013 contains the list of all drugs that are included in NLEM and this list is updated every now and then to include all the necessary life-saving drugs into its domain. With every revision of NLEM, the items on the list is increasing and thus showing the dedication with which Government is acting to bring

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[29] Or. 5 of DPCO, 2013.

[30] Or. 5 (2)(i) of DPCO, 2013.

[31] Or. 5(2)(ii) of DPCO, 2013.

[32] Supply of Drugs to Bureau of Pharma PSUs of India (BPPI) is done through e-tendering. To strike out the possibility of any stock-out situation, BPPI is supplementing supply by direct purchase of medicines from private sector companies through open tendering process in addition to procurement from Central Public Sector Undertakings so as ensure availability of adequate medicines and to avoid any stock-out situation. The details of BPPI e-tendering can be accessed from <http://janaushadhi.gov.in/tender.aspx>.

[33] Public Health is included under concurrent list. Therefore, each State is free to frame its own tendering process.

[34] Entecavir, Raltegravir, Sofosbuvir, Trastuzumab, etc.

[35] Para 32 of DPCO, 2013. Inserted by 2019 Amendment. Prior to this Amendment, manufacturer of new drug, if developed through indigenous Research and Development, for a period of five years from the date of commencement of its commercial production in the country was exempted from price ceiling regulations.

[36] Fifty-fourth report of standing committee on "Pricing of drugs with special reference to Drugs (Prices Control) Order, 2013", Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals), (2018-19).

down the prices of essential drugs within the limit that is easily affordable to larger section of citizens. But expanding the list of drugs and capping the prices of the same cannot itself enhance the affordability and accessibility to what is so called essential life-saving drugs. The outcome of Economic Survey of 2019-2020 clearly establishes the given facts. The story of DPCO, 2013 is not so a successful one. Important highlights of Economic Survey of 2019-2020 is discussed as below[37]:

- It was witnessed that application of provisions of DPCO, 2013 induced increased price of regulated drug as compared to unregulated drug of similar therapeutic category. The increase in prices was more prominent for already costly formulations (the increase in the price was about 2.4 times than prevailing before being regulated by DPCO, 2013) than for already cheaper ones (the price was reported to increase by about 21 percent).
- The price at which drugs are sold in hospitals is higher than retail shops, as against the predicted norm of having cheaper drugs at hospital because they buy the drugs in bulk and form part of dispensing pack than that available at retail shops. The formulations prices of the regulated drugs witnessed a surge of Rs 99 per mg while those of unregulated formulations reported increase by only Rs 25 per mg.
- Estimates show that the prices of regulated active ingredient increased on average by Rs 71 per mg. The unregulated active ingredient reported an increase in price by Rs 13 per mg.
- Those drugs that are regulated through DPCO and are primarily sold through retail outlets witnessed a small increase of Rs 0.23 per mg, while those of unregulated by it saw a price increase by about Rs 1.72 per mg.
- The DPCO, 2013 has negative impact on drugs that are majorly sold through hospitals. A meagre reduction of drug prices is witnessed in case of drugs sold through the retail chemists. Thus, overall impact of DPCO, 2013 on controlling of drug prices has remained a negative one.

The price ceiling regulations are more than a decade old way to regulate drug prices in India. The government spent nearly a decade from 2002 until 2012 to decide on the design of the regulation and ended up relying on the market-based pricing strategies in the latest version of Pricing regulation i.e., DPCO, 2013.The efforts were made to enhance accessibility of drugs by expanding the list of essential medicines on which price capping can be done. Though the government claimed that the price ceiling under DPCO, 2013 has resulted in decreased drug prices[38] and thus enhanced affordability, Economic

[37] Economic Survey, 2019-20, Ministry of Finance, <https://www.indiabudget.gov.in/economicsurvey/>.

[38] *Supra* note 36.

Survey depicts the failure of NPPA in bringing down the prices of essential drugs.

III. ACCESSIBILITY AND AFFORDABILITY UNDER INDIAN PATENT REGIME

The patent regime has a crucial role to play when it comes to the overpricing of patented drugs. To balance between incentivizing the owner of the new invention (private interest) and making available the knowledge of the invention to the society (public or social interest) through the patent system is an intricate process and the most debated one. Patent law thus provides for the subject-matter of the inventions on which monopoly rights are provided for a fixed time span, exceptions, and limitations to the patented inventions. Patent legislation has a significant impact on the pharmaceutical sector. This is so because a patented drug price generally depends on:

- The will of the pharmaceutical company that has patented the drug, i.e., what amount they want to charge.
- The flexibility of the patent regime existing in the jurisdiction where a pharmaceutical company has applied for the grant of patents.
- Scope and limitations of the existing patent legislation.
- The nature of drug pricing and the extent of the price ceiling in cases of patented drugs; if any
- Substitution of the drug available in the market with the generic competition.

It is the extent of flexibility in patent legislation that determines whether Multinational Companies (MNCs) will patent a product in that jurisdiction and reap the profit that it has estimated or not. The ratification of the TRIPS Agreement by India and the introduction of its provision in the Indian Patent Act, 1970, through timely amendments, have a great impact on the trend of the pharmaceutical patent. The following graph shows the trend of pharmaceutical patent filing in India from 1998-99 to 2017-18.

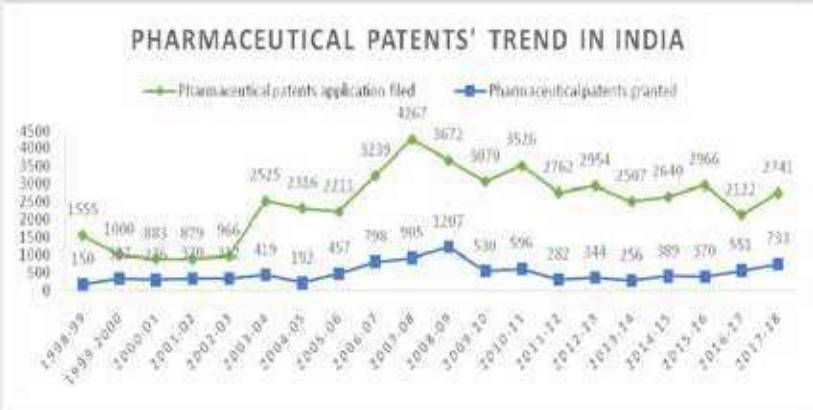

Fig 4.1: Number of pharmaceutical patents application filed vs. Pharmaceutical patents granted by the Indian Patent Office. (Source: Annual Report of Indian Patent Office)

The significant changes that took place concerning that of pharmaceutical patents were through the Amendment Act of 1999, 2002, and 2005. It may be inferred from the above data that:

- An increase in the filing of pharmaceutical patents can be seen from the time frame of 2002-03 to 2007-08. A steep increase in the rate of filing can be seen from the period of 2005-06, i.e., just after the introduction of the Amendment Act of 2005. Also, from 2004-05 to 2008-09. Thus, it may be concluded that being TRIPS compliant has boosted the rate of both filing and grant of the pharmaceutical patents in India.
- The graph shows that the number of pharmaceutical patents granted in the initial period from 1998-99 to 2004-05 is stunted. However, bringing in compliance with the TRIPS has helped the pharmaceutical industry. The peak of patent filing and rate of the grant has been on a peak from the period 2004-05 to 2008-09. The reasons for the sudden increase in the rate of filings are primarily due to the patent applications relating to enhanced processes, novel formulations, and the presence of different dosages than on the invention of a new drug based on a new molecule. This was so because, new molecule requires considerable R&D, sufficient finance, and the substantial capacity to produce the same.[39]

[39] P. Gokhale and S. Kannan (2017), "Patenting Trends in Indian Pharmaceutical Industry", Annals of Library and Information Studies, Vol. 64, No. 4, December, pp. 260-267. *See* Bibek Ray Chaudhuri et al., "Pharmaceutical Exports and Patents in India – An Empirical Investigation", W.P. No: EC-19-39 April 2019 (Apr. 5, 2020, 9.58 p.m.) <http://cc.iift.ac.in/research/Docs/WP/39.pdf>.

- The year 2012 and 2013 brought turmoil in the area of pharmaceutical patents where the first compulsory license was granted and on the application of the most controversial provision of Section 3(d), Natco's patent application was rejected, respectively.[40] The rate of the grant of pharmaceutical patents is not that significant if gone by the time frame of 2011-12 to 2017-18. The rate of filing is also decreased during this time frame, which may be due to the abovementioned events that run in the background. In this regard, various studies suggest that the inclusion of Section 3(d) in the patent legislation, though, has been criticized but did not impact the filing of pharmaceutical patent applications.[41]

IV. PATENT LAW AND THE PHARMACEUTICAL INDUSTRY

The Pharmaceutical Industry of India is the lifeline for the world's generic supplies.[42] India is considered to have the most cost-competitive healthcare facilities in comparison to other Western or Asian Countries.[43] This character of the Indian healthcare system is attributable to its policies and the maximum use of TRIPS flexibilities, at least in relation to the Pharmaceutical sector.[44] The Patent Act, 1970 of India, has major provisions that act as a check on the overpricing of the pharmaceutical inventions in order to enhance the affordability of life-saving drugs.

The very criteria of patentable subject matter vis-à-vis provision of Section 3(d) is criticized by the big Pharma Companies of the developed nations.[45]

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[40] *See infra* Part III-A (discussing the patent provisions of India and cases where these provisions were invoked in order to reject patent or dilute the monopoly rights).

[41] P. Gokhale, *Id.* at 264.

[42] India is the largest provider of generic drugs across the globe and thus, India is often termed as "pharmacy of the world". Indian pharmaceutical sector industry supplies over 50 per cent of global demand for various vaccines, 40 per cent of generic demand in the US and 25 per cent of all medicine in UK. Presently over 80 per cent of the antiretroviral drugs used globally to combat AIDS (Acquired Immune Deficiency Syndrome) are supplied by Indian pharmaceutical firms. With 71 per cent market share, generic drugs form the largest segment of the Indian pharmaceutical sector. Indian Pharmaceutical Industry Analysis, <https://www.ibef.org/industry/indian-pharmaceuticals-industry-analysis-presentation#sthash.qPWNb7FZ.dpuf>.

[43] IBEF, Indian Healthcare Industry Report (Feb. 8, 2020, 5.28 p.m.) <https://www.ibef.org/industry/healthcare-india.aspx>.

[44] Emmanuel Oke, "Exploring the flexibilities in TRIPS: Lessons from India's Pharmaceutical Patent Law", Common Law Bulletin, 41(1), <https://www.researchgate.net/publication/275719756_Exploring_the_flexibilities_in_TRIPS_Lessons_from_India's_pharmaceutical_patent_law>.

[45] US has kept India under priority watchlist for its IP provisions since 1989. It is pressurizing India to amend its patent laws in order to delete its anti-evergreening provision of § 3, to extended term of patent protection for the time lost in grant of patent etc.

In the pharmaceutical and agricultural chemical sectors, India continues to lack an effective system for protecting against the unfair commercial use, as well as the unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for such products. In the pharmaceutical sector, Section 3(d) of the Indian Patents Act restricts

Section 3(d) is the rule against evergreening[46] and also forms the ground of filing pre-grant and post-grant opposition under Section 25 of the Act. Sec 3(d) clearly states that

> *"the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant, is not patentable*."

The explanation to this section clarifies as to what are the substances that are to be considered as the same under this section. It further states that:

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

WHO list of essential medicines have a significant number of drugs that are nothing but the outcome of incremental innovations.[47] This point towards the

patent-eligible subject-matter in a way that fails to properly incentivize innovation that would lead to the development of improvements with benefits for Indian patients. India still lacks an effective system for notifying interested parties of marketing approvals for follow-on pharmaceuticals in a manner that would allow for the early resolution of potential patent disputes. Despite India's justifications of limiting IP protections as a way to promote access to technologies, India maintains extremely high customs duties directed to IP-intensive products, such as medical devices, pharmaceuticals, information communications technology (ICT) products, solar energy equipment, and capital goods.

United States Trade Representative, 2019 Special 301 Report, (May 19, 2020, 7.09 p.m.), <https://ustr.gov/sites/default/files/2019_Special_301_Report.pdf>. *See* also Soma Das, "Big Pharma Groupings Urges US to ask India to Change its IPR Policies", T*he* E*conomic* T*imes*, Feb. 12, 2015; Ramesh Shankar, "PhRMA Concerned over Sect 3(d) of India's Patents Act as it Fears other Emerging Markets may Emulate it as a Model", Pharmabiz.com, Feb. 12, 2016.

[46] The term "evergreening" has neither been defined nor used under S. 3(d) of the Patents Act, 1970. This is the name given to the strategy, commonly used by pharmaceutical companies, whereby a minute or trivial and non-significant modifications are introduced to the existing patents in order to file fresh patent application for the same. In this way, the period of protection is extended beyond 20 years and market monopoly is enjoyed for all those extended terms. *See* ICTSD, WHO, UNCTAD, Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective — A Working Paper (2006).

[47] As per a study conducted in 2007, it was found that 60% of the total drugs on the WHO list of essential medicines are mere incremental improvement on the previously existing medicines. *See* White & Case LLP and Dua Consulting, The Value of Incremental Pharmaceutical Innovation: Benefits for Indian Patients and Indian Businesses, Coalition for Innovation, Employment and Development June 2009, p. 4; J. Cohen et al., The role of follow-on drugs and indications on the WHO Essential 12 Drug List, 31 Journal of Clinical Pharmacy and

need to encourage pharmaceutical companies to increase their share in innovation related activities and to encouragemore and more investments in this sector of pharmaceutical in order to reap the benefits of efficient patent protection that provides for the protection of incremental innovation. However, the Indian position is diametrically opposite to this norm. Indian judiciary through *Novartis AG* v. *Union of India*[48] decision made it clear that the main idea behind expressly providing Section 3 in the Patent Act was to limit the patentability as the matters contained in this section are deemed to be not inventions under the Act. Section 3(*d*) is an absolute ground for rejection. The *Novartis case*[49] thus makes it clear that to overcome this barrier, the patented invention in question must show significant "enhanced therapeutic efficiency" over the original, known, and existing substance. Thus efficacy is the only way by which defect under Section 3(d) be overcome.

India took the step against the rule of evergreening in order to protect society from any adverse scenario that may take place due to the extended term of protection. India, being a developed nation and one of the most populated countries of the nation, cannot afford the higher prices of life-saving drugs charged from its citizens on the name of inventions (that is a mere trivial change to the existing patent) for an extended period of time than that is actually prescribed under TRIPS. This provision is criticized because it affects the market of Pharma companies in India. A recorded "45% of all rejected pharmaceutical patent applications, Section 3 (d) was cited as the reason for rejection."[50] This is because of this provision, many inventions that hold a patent in the US has been not under patents in India.

In a report published by WHO in 2003, it was found that for more than half of the total population in Asia and Africa, accessibility of essential life-saving drugs is still a dream.[51] The prime reasons that have resulted in limited accessibility in these areas could be because of the insufficient production facilityalong with the inadequacy of the specific local conditions. Thus providing the right incentive to the Pharmaceutical companies in the form of patent protection for the incremental innovation can help the low-and middle-income countries in advancing the accessibility issue of life-saving medicines.[52] The concern over the high priced medicines can be dealt by looking for different

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Therapeutics 6, (2006). Nearly one-quarter of the therapeutic indications described by the WHO Essential Drug List are treated by medicines originally indicated to treat some other disease or condition. This means that a big portion on pharmaceutical innovation is dependent on incremental innovation, GSK Public Policy Positions, May 2019, <https://www.gsk.com/media/2943/incremental-innovation-policy.pdf>.

48 (2013) 6 SCC 1.

49 *Ibid.*

50 Feroz Ali and Sudarshan Rajagopal, "How India Rejects Bad Patents", *The Hindu*, Dec. 27, 2017.

51 WHO (2004) (Feb. 20, 2020, 8.00 p.m.) The World Medicines Situation Report, <http://apps.who.int/medicinedocs/en/d/Js6160e/9.html#Js6160e>.

52 *Ibid.*

possible solutions like that of Compulsory license (in cases where drugs are not available at reasonably affordable prices), price regulation (where a price cap is set on the essential drugs in order to enhance the affordability of drugs), etc.[53]

The provision that severely affects Drug industries is contained in Chapter XVI, which is related to the grant of the compulsory license and is stretched under Sections 82 to 94.[54] Even the Patent Rules, 2006 covering rules 96-102 of Chapter XIII, expands the provision in relation to the same. Section 84 provides for the grant of the compulsory license. It states that any person interested may make an application to the Controller for grant of a compulsory license on the patents on any of the following grounds:

a) Reasonable requirement not been satisfied; or

b) Not available at reasonably affordable prices; or

c) Not workedwithin the territory of India.

The application can only be filed after the lapse of three years from the sealing date of the patent. Any person, including a license holder, may make an application for the grant of the compulsory license. Rule of estoppel does not apply in the cases of the person claiming the abovementioned grounds for the compulsory license based on the reason for any admission made by him not matter whether he is in such a license or by reason of his having accepted such a license.

The Natco Pharma was the first company in India to apply for a compulsory license under Sec. 92A to manufacture and the generic version of drugs that were manufactured by Roche Ltd. and Pfizer for treating lung cancer and renal cancer respectively to Nepal. However, due to certain technical incongruities, the same was withdrawn.[55] Later in the year 2012, India witnessed its first and the only successful application and invocation of Compulsory license under Section 84. The compulsory license was granted to Natco Pharma Ltd. against the manufacture and sale of Bayer's Nexavar[56]. The Intellectual Property Appellate Board (IPAB) upheld the decision of Controller General of Patents and held that Natco has successfully proved the criteria for grant of compulsory license as laid down under Section 84 of the Act in the following ways:

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[53] The possible solution may be found in Patent law itself in the provisions of Parallel import of low-cost drugs under S. 107-A (b), forming patent pool by the Government under S. 102.

[54] The Patents Act, 1970 (39 of 1970) [as amended by Patents (Amendment) Act, 2005 (15 of 2005)].

[55] Shamnad Basheer, "Natco Withdraws 'Doha' Compulsory Licence Application", (Apr. 14, 2020, 7.17 p.m.) <https://spicyip.com/2008/09/breaking-news-natco-withdraws-doha.html>. *See* Shamnad Basheer, "Roche vs NATCO: India's First 'Doha Style' Compulsory License?" (Apr. 14, 2020, 7.17 p.m.) <https://spicyip.com/2008/01/roche-vs-natco-indias-first-doha-style.html>.

[56] Nexavar is the commercial name of the Bayers' patented drug Sorafenib that is useful in treating liver and kidney cancer in India. The average price of this drug was Rs 2.8 lakh a month.

- Reasonable requirements of the public were not fulfilled as Nexavar was accessible to only 2% of the Indian patients.
- Nexavar's cost was as high Rs 2.8 lakhs per month as against Natco's proposal to sell it at Rs. 8800 per month, which is 97% cheaper than that of the then-existing Nexavar's price. Thus, Bayer's drug fulfilled the criteria of the non-availability of drugs at a reasonable price.
- Bayer's drug was not worked in India as no efforts were made by the Bayer to grant a voluntary license, as is the requirement laid down under Sec. 84 (1)(c).[57]

Parallel import and 'exhaustion rights' are interrelated concepts. Exhaustion of Rights means when patent holder first sells his goods in the market, his right over the product get exhausted and he further cannot impose restriction on subsequent sell or use. Thus, this doctrine was laid down in order to restrict the patentee's exclusive right over the good once it is sold. According to this doctrine, "a patented item's initial authorized sale terminates all patent rights to that item. In general, it means giving up all the rights with respect to the sale of the goods to a third party to whom sell is made. Parallel import, on the other hand, refers to the "import of goods outside the distribution channels contractually negotiated by the manufacturer/IP owner."[58] In simple terms, Parallel import means importing an original good that is protected by patent rights from the exporting country where the product is legally purchased by the third party, which in turn exports the patented product to the importing country. In this process, distribution channel is independent of IP owner whose product is imported.

India follows international exhaustion in cases of patented products and thus parallel import is legalised in India Sec. 107A(b) of Patent Act, 1970. Before introduction of 2005 Amendment, Parallel import in India was valid only when prior consent is obtained by the patent holder of the patent.[59] With the inclusion of 2005 Amendment to the Act of 1970, Section 107-A(b) was amended to provide that there would be "no infringement if there has been an importation of patented products by any person from a person who is duly authorized under the law to produce and sell or distribute the product."

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[57] IPAB Order Sheet, *Bayer Corpn.* v. *Union of India* (OA/35/2012/PT/MUM), para 13, (Apr. 2, 2020, 8.24 p.m.) <https://www.pharmamedtechbi.com/~/media/Supporting%20Documents/Pharmasia%20News/2012/September/IPAB%20Orde%20Bayer%20Natco%20Sept%20%202012.pdf>.

[58] See, Christopher Heath, Parallel Imports and International Trade, <http https://www.wipo.int/edocs/mdocs/sme/en/atrip_gva_99/atrip_gva_99_6.pdf >.

[59] Before Amendment of 2005 S. 107-A (b) of the Patent Act, 1970 provided that the importer should be "duly authorized by the patentee to sell and distribute the product".

V. PATENT POOL – A SOLUTION TOWARDS AFFORDABILITY OF PATENTED DRUGS

The concept of "Patent Pooling" is new to the Indian jurisdiction and in recent years is seen as a possible solution to the accessibility issues in relation to healthcare facilities. A Patent Pool is defined as an agreement between two or more patent owners to licence their patents to one another or to third parties. A patent pool comes into play where the patent holders hold complementary patent and not a substitute patent. A patent pool provides easier solutions to the inventor whose technology is so complex that it requires a complementary patent in order to achieve efficiency however, such complementary patent belongs to another patent holder. One of the objectives of patent pool is to compile numbers of patents held by various countries so as to boost development and easy access to medicines for poor people residing in developing countries.[60]

Indian Patents Act, 1970 neither talks about the formation of patent pools nor expressly bars it. Though many beliefs that Section 102 of the Indian Patents Act, 1970 may act as a helping provision for establishing patent pool which is managed and controlled by the Government in the public interest.[61] But its intersection with anti-competitive practices has proved to be a barrier in its formation. Patent pool may anytime result into anti-competitive if the members of the pool do not provide license on Fair, Reasonable and Non-discriminatory (FRAND) terms.

The Medicines Patent Pool (MPP) was proposed by Mėdecins sans frontiėres[62] (MSF) in order to help the developing countries primarily by providing cheaper Anti-Retroviral drugs that are used in the treatment of HIV-AIDS and other drugs used in treating Hepatitis C, Tuberculosis etc. through patent pool. It brought together complementary patent holders relating to the manufacture, sale and distribution of the essential drugs and then sublicense it to generic companies of the low and middle-income countries.[63] Currently, generic manufacturers like Aurobindo, Cipla, Dr Reddy's, Sun Pharma, Zydus Cadila etc. forms the part of MPP in providing low-cost generic drugs to the developing

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[60] Manas Bulchandani, Akshay Khanna, "Patent Pooling in the Indian Scenario", 4 IJL 15-21 (2018).

[61] Section 102(1) of Indian Patent Act, 1970: Acquisition of inventions and patents by the Central Government. The Central Government may, if satisfied that it is necessary that an invention which is the subject of an application for a patent or a patent should be acquired from the applicant or the patentee for a public purpose, publish a notification to that effect in the Official Gazette, and thereupon the invention or patent and all rights in respect of the invention or patent shall, by force of this section, stand transferred to and be vested in the Central Government.

[62] MSF are also referred as "Doctors Without Borders" in English. It is an International Non-Governmental Organization that provides healthcare facilities especially in conflict ridden zones or the Nations that suffers from endemic diseases.

[63] Strategy, Medicines Patent Pool, <https://medicinespatentpool.org/who-we-are/strategy/>.

nations suffering from high priced HIV, TB and Hepatitis C drugs.[64] Big Pharma Companies like Pfizer, Gilead Sciences, Roche etc. that hold patent over various drugs that are found useful for treating the abovesaid diseases have joined hands to make this patent pool a successful solution to the high priced drugs in low and middle income countries.[65] Thus, Patent Pool may be seen as a probable solution to the high cost patented drugs and its affordability concern.

VI. CONCLUSION

The criteria determined for issuing a compulsory licence, the rule against evergreening, and the provisions of Parallel import under the Act provide for the key to tackle the monopoly issue that can result in overpricing of patented medicine. Thus the easy accessibility and enhanced affordability of drugs in India can, in a way, be attributed to the Patent Regime's flexibilities as prescribed under the Indian Legislation. The fact that patent applications are still on the rise even after the ruling of the Natco-Bayer case shows that companies, though not happy, still cannot afford to lose a big market share of the world. Though the US market is pushing India to play by its rules, India does not want to yield ground to US negotiators.[66] The fact that the Controller has rejected many compulsory licence applications after the criticism and threat that India faced after the invocation of compulsory licensing provision, one may conclude that India is playing safe in order to avoid any disagreements at the world level.

The latest amendments to provision of DPCO, 2013 has tried to strike out a balance between the private right of the inventor and that of social rights by exempting patented drug from pricing regime for a period of five years from the date of commencement of its commercial marketing by the manufacturer in the country.[67] Apparently, DPCO and Patents may not seem to have any direct link, but a common thread can still be seen woven the two concepts. Both Patents and pricing regime focuses on the betterment of human lives. While patent achieves this goal by introducing better and useful inventions to the society, the Pricing regime achieves it by enhancing the affordability of essential drugs so that Quality-Adjusted life years can be enhanced if not

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[64] Products Licensed, Medicines Patent Pool, <https://medicinespatentpool.org/what-we-do/global-licence-overview/licences-in-the-mpp/?text=&patent_holder=&partner=&disease=&country=&isSearch=1>.

[65] *Ibid.*

[66] Tushita Dogra, "India: Pharmaceutical Patents a Threat to India's Drug Industry?" (Last Updated on March 14, 2018), <https://www.mondaq.com/india/food-and-drugs-law/682550/pharmaceutical-patents-a-threat-to-india39s-drug-industry>.

[67] Para 32 of DPCO, 2013. Inserted by 2019 Amendment. Prior to this Amendment, manufacturer of new drug, if developed through indigenous Research and Development, for a period of five years from the date of commencement of its commercial production in the country was exempted from price ceiling regulations.

saved. Also, few patented drugs also make part of the scheduled formulation of DPCO, 2013. Thus, DPCO helps in dealing with the monopoly issue that patent has assigned to the inventor without being jeopardized to the societal needs.

The current drug pricing maybe employed to enhance the accessibility, affordability, and availability of essential life-saving drugs if the Purchasing power of the population is taken into consideration while determining the price ceiling. For example, a drug X is an essential drug and is required by 40% of the Indian population on whom the disease is prevalent. If by market-based price ceiling, the drug price is calculated to be Rs 1 lakh per tablet, this price itself will go beyond the purchasing power of the patient, while Government may claim that it has reduced the price to a greater extent. While pondering into the question that was flagged by Economic survey report regarding the negative impact of DPCO, 2013, an expert committee maybe set up to study the impact of shifting from cost-based pricing to market-based pricing. In order to provide clarity, the term "efficacy" should be explicitly defined. Further, the accessibility issue may be dealt with Government intervention in promoting'patent pooling' in cases of pharmaceutical innovations and an effective supervisory mechanism be established to check the instances of reverse payments. This will require clear provisions for the setup of Patent Pool under the Patent Act, 1970 and will help in defying any future issues that may arise in the relation of the same. "Awareness" towards generic drugs is the key to the success of drug pricing regulation. So, awareness programs should be organized to bring in faith and awareness about the quality of the generic drugs.