PATENTS OVER HUMANS - A GLOBAL DILEMMA

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INTRODUCTION

Change in Policy- Patents for Pharmaceutical Products, 2005

India, a member of the TRIPS agreement since 1995 went on to have a complete change in policy with regards to providing patent protection to pharmaceutical drugs and products to implement the provisions given under the same.[1] In 2005, in order to comply with the requirements of TRIPS, the Indian government introduced product patents on pharmaceuticals.

This was a major setback to India's already flourishing generic drug industry that had spanned almost over the last three decades. The pharmaceutical industry with this changed policy gave way to grant of pharmaceutical product patents and an eventual monopoly over drug-pricing.

In the main Doha Ministerial Declaration of 14 November 2001, WTO member governments stressed that it is important to implement and interpret the TRIPS Agreement in a way that supports public health — by promoting both access to existing medicines and the creation of new medicines. WTO members were under obligation to implement TRIPS provision by 2000, 2005, or 2016, depending on their level of development.[2]

Some developing countries delayed patent protection for pharmaceutical products (and agricultural chemicals) until 1 January 2005. This was allowed under provisions that say

[1] *TRIPS and India*, available at http://www.rajdeepandjoyeeta.com/trips-a-india.html
[2] *TRIPS and pharmaceutical patients*, WTO OMC Fact Sheet, available at https://www.wto.org/ENGLISH/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf

a developing country that did not provide product patent protection in a particular area of technology when the TRIPS Agreement came into force (on 1 January 1995), has up to 10 years to introduce the protection. However, for pharmaceuticals and agricultural chemicals, countries eligible to use this provision (i.e. countries that did not provide protection on 1 January 1995) had two obligations. They had to allow inventors to file patent applications from 1 January 1995, even though the decision on whether or not to grant any patent itself need not be taken until the end of this period — Article 70.8. This is sometimes called the "mailbox" provision (a metaphorical "mailbox" is created to receive and store the applications). The date of filing is significant, which is why the mailbox provisions were set up. It is used for assessing whether the application meets the criteria for patenting, including novelty ("newness"). And if the government allowed the relevant pharmaceutical or agricultural chemical product to be marketed during the transition period, it had to — subject to certain conditions — provide the patent applicant an exclusive marketing right for the product for five years, or until a decision on a product patent was taken, whichever was shorter. Article 70.9[3]

Position of India

India was given an extended period of time to make its patent regime complaint to TRIPS. Consequently India passed the Patents Amendment Act, 2005 which came into force on 1st January, 2005. Earlier India had allowed for the manufacture of generic versions of many drugs. Through this amendment it has now implemented a product patent regime and product patents in the pharmaceutical sector.

[3] *TRIPS and pharmaceutical patients*, WTO OMC Fact Sheet, available at https://www.wto.org/ENGLISH/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf

Pursuant to TRIPS obligation, India amended its Patent Act in 1999 and inserted section 11A to provide that applications claiming pharmaceutical inventions would be accepted and put away in mailbox which would be examined in 2005. There is a provision of issue of automatic compulsory licence in case of grant of patent of those mail box application, provided the generic companies have made a significant investment and were producing and marketing the drug covered by the mailbox application prior to 2005.

SIGNIFICANCE:

The most essential factor to be determined will be the ultimate aim of medicinal invention - to serve human life. Therefore, what will be established here is that medicinal affordability must weigh over individual company profits and providing patents that limit its sale only at higher prices fails the entire purpose of medicinal development. Hence, this will be an attempt to understand the true meaning and requirement of medicinal drugs

This paper achieves utmost significance as the dispute between pharmaceutical patent protection and the need for low cost drugs forms one of the most central question of debate for the government of any nation. Is the particular government in question promoting pharmaceutical company profits or is taking a socialistic approach and promoting human life and longevity? Hence, the prospect of preserving human rights becomes imminent. An attempt shall be made to answer this debatable question which is

of prime importance to the Government of a country. The research paper via the other components will also focus heavily on human rights, especially, Right to Life as enshrined under Article 21 of the Indian Constitution. The essence of this Article will be complemented with other legislative sources such as The Patents Act, India, 1970.

Another facet to this paper will be to understand the concept of competition that ensues between the original drug inventor companies and generic drug manufacturing companies. The nature of the competition as desired by the former is essentially a monopoly over drug sale in the market. However, in reality as the latter companies set in, profit margins for the former drop due to their act of manufacturing similar drugs at lower prices. As part of this research, an attempt shall be undertaken to provide possible solutions that shall benefit both the disputing parties. Hence, recommendations of such a kind will be provided that shall be preserve profit interests of original drug producing companies and shall also make public access to medicines at low cost a viable option.

RESEARCH PROBLEM / HYPOTHEIS:

Objective 1: Should patent protection or monopoly rights of manufacturing be given to medicinal drugs that are of a life-saving nature and are rare in making which as a consequence may put forth exorbitant prices for sale?

The TRIPS Agreement

Article 70[4]

Protection of Existing Subject Matter

8. Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:

(a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;

(b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and

(c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).

The new amendment gave rise to a clear distinction in the manner of production of pharmaceutical products:

Originator (Innovator) drugs- The medicinal drugs developed are novel and have been synthesized chemically for the first time by the manufacturing company post extensive research. The same is marketed after thorough development, modifications and trials conducted both on humans and animals. The maker of such a novel drug applies for patent in order to achieve a monopoly status over sale of the product. This grant of patent

[4] Article 70, The TRIPS Agreement

serves a dual purpose. Firstly, it provides the company with the recognition as the creator of a novel drug and adds to its significance and credibility in the market. Secondly, such a patent turns out to be an absolute bar on other manufacturing companies from making a similar or exact replica of the drug. Therefore, the right to make and sell the drug vests solely with the originator company. These drugs are named as branded drugs.

Generic drugs- Drugs that are a replica or are of a similar make and composition as an innovator or original drug are termed as generic drugs. The chemical synthesis of such drugs contain the same active ingredient as to be found in the original drug. They are also identical in strength, in dosage form and in route of administration.

Implications of this distinction lays in the variance in pricing of the drug that has been explained below:-

Higher Prices of Original Drugs:

In case of an original drug, the sale price of the same is significantly high, sometimes even exorbitantly higher than a generic remake of the same. This is due to the increased production cost in case of the former.

Cost of production involves heavy expenditure incurred in developing the medicinal product from scratch and in conducting clinical trials. The expenditure for manufacturing a drug with the appropriate composition and formula is very high. At the same time, the same has to be tried clinically thoroughly prior to marketing and usage and any adverse side-effects have to be removed or minimized to make it user-friendly. The next step is to advertise and market the drug to ensure future sales which again guarantees heavy expenses. To make up for such heavy expenditure, it is suitable to opt for patent protection. Patent protection ensures monopoly over sales of the pharmaceutical product for an entire period of twenty years that is till the patent recognition is reserved with the company for its product. The company during this period puts up higher selling prices

in order to compensate for its heavy expenditure and production costs that have gone in manufacturing the drug. Higher rates of selling provide manifold profits as desired by the companies.

The generic drug makers on the other hand, incur no expenses in discovering a new make or composition for a drug. They do not have to experiment in order to find the correct formula and dosage for a drug. They just replicate the ingredients used in the original drug hence, minimizing experimentation costs. The generic drug making companies also do not indulge in clinical trials as the same are completed and declared safe by the originator companies already. These also come up with bioequivalent versions of the originator drugs by implementing certain changes or modifications in the ingredients required in formulating the drug. In all, the cost of production in such generic drugs can be seen to be lower as compared to their original counterparts. The entry of the generic version of the pharmaceutical product makes the same medicinal drug now available at lower prices increasing the popularity of the product among end consumers.

The costs associated with discovering a compound, turning this discovery into a suitable drug candidate, and getting it to market, have risen dramatically. Patent protection and the market exclusivity that comes with it help to ensure a return on investment. A patent holder has the right to exclude others from making, using, and selling the patented invention for a defined period. Therefore, patented drugs are temporarily safe from the competition of generics, often resulting in substantial revenues.[5]

Competition in the Pharmaceutical industry and its effects:-

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[5] H. Gupta, S. Kumar, R.S. Gaud and S.K. Roy, *Patent protection strategies*, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3146086/

The major beneficiaries of the generic drug industry are the final consumers of the pharmaceutical products as it brings them substantial savings. The pharmaceutical buyers have to spend comparatively less on purchasing the generic version of the original drug and yet obtain the same results. This factor only highlights how detrimental the development of generic drugs is to the profit earning aspect of the originator drug companies. Therefore, the latter secures its interests by obtaining a patent and eventually a monopoly over the medicinal drug that prevents the generic drug making industry to begin making replicas of the said product till the patent period lasts.

Such grant of patents may serve the interests of the drug manufacturing companies, however, it deals a blow to the general public and the patient's purchasing power of such high priced medicinal drugs. The credibility of the innovator drug companies lies in the fact that they manufacture life-saving drugs whose dire need is felt by patients worldwide. Newer drug inventions are giving rise to more advanced and sophisticated drugs that are catering to specific fatal diseases, increasing the demand for such drugs.

It shall not be correct in coming up with a proposition that states that patent protection to pharmaceutical products should be discarded altogether, rather a balance, a common ground has to be searched for that protects the profit margin of innovator drug companies as well as makes the sale of pharmaceutical drugs available at feasible prices.

The complexity in banning patents for pharmaceutical products lies in the fact that such a step would adversely affect the incentive for the companies that are involved in making original medicinal drugs. The innovator companies engage in experimental processes, followed by numerous clinical trials. This endeavor needs to be complimented with apt advertising and marketing of the product. In return of such heavy expenditure, sales monopoly by way of patent protection is their way sole way of earning profit that can compensate for their prior expenditure. This opportunity is seized to set discretionary prices that are too high than the affordable standards of the general public. If grant of

patents is banned, then the companies would not be encouraged in taking up such huge expenditure in return of which they would not even have an opportunity to earn profit, there shall be no mechanism of reimbursement for the cost of production undertaken by the said company. Consequently, the pharmaceutical industry would slack in innovation of newer drugs, this would show its effect in a dropping rate of discovery of new medicinal drugs. If such a situation is faced, then there shall be no new breakthroughs in the discovery and development of life-saving drugs which would form to be a major impediment in the health sector of the country. It is for the above reason that patent protection to medicinal and pharmaceutical products cannot be disallowed.

<u>Objective 2:</u> Can the concept of providing patent protection to pharmaceutical medicinal and drug invention prove to be violative of human rights?

The second objective of the paper needs to be addressed in a two-fold fashion, firstly, it becomes important to determine the kind of fundamental right, whose violation is being alleged here is in reality a recognized fundamental right under the Constitution of India.

Secondly, the prime focus will be to adjudge whether the deprivation of people from affording such highly priced medicinal drugs amounting to breach of a fundamental right.

"It is health that is real wealth and not pieces of gold and silver." – Mohandas Karamchand Gandhi (Father of the Nation)

The development of a nation does not rest solely on the grounds of industrialization, infrastructure, globalization of economy, etc.; rather the most major decisive factor stands out to be human resource and capital. A nation shall only then embark on a path towards

unfound prosperity and success if manpower is at its best display and effectiveness in the country. Human resource is hence, the prime necessity of any nation.

Nations may be endowed with incomparable reserves of natural minerals and resources which are certainly the essential factors of production, but all such factors will be rendered useless if the same are not yielded by human capital. Human capital manages to make an efficient utilization of such natural resources and minerals.

India as global leaders describe is the storehouse of human resource, India within itself holds the potential to unleash human capital that is to be found in scarcity among other nations. This significant a disparity can be the prime weapon of spearheading India's development regime. India is presently vied for its young population that is mostly to be found in the age group of 18 to 30 years.

[6]Taking into account the youth population, i.e. the people between age group of 18 to 30, India leads the world, so we can definitely become the Human Resource capital of the world.

Recently Indian Prime Minister Narendra Modi launched number of schemes to provide training to about 40 crore people in various sectors by 2022. Mr. Modi announced these schemes to fight poverty and to make India Human Resource Capital of the World. Various initiatives related to skill development, boosting education, supporting new entrepreneurs, improving exports and handicrafts are a great way of ensuring that the human resources in the country are used effectively for its development.

A reading of the above will provide a greater insight into the endeavors undertaken by the Government of India in empowering and educating the Indian youth. This is to make them ready and stead-fast in contributing to the nation's development.

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[6] *Can India become the human resource capital of the world?,* available at http://www.careerride.com/view.aspx?id=24226

If India's population today is a tool for development, could this have been possible if the country still lagged at healthcare facilities and had a poor mortality rate, the answer is clearly no. India has evolved significantly and has seen the highs of healthcare industry with life-changing discoveries in the medicinal and drug industry.

[7]Infant mortality rate (deaths/1,000 live births)

India

Country	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
India	64.9	63.19	61.47	59.59	57.92	56.29	54.63	34.61	32.31	30.15	49.13	47.57	46.07	44.6	43.19

Definition of Infant mortality rate: This entry gives the number of deaths of infants under one year old in a given year per 1,000 live births in the same year; included is the total death rate, and deaths by sex, male and female. This rate is often used as an indicator of the level of health in a country.

[8]MORTALITY RATES – 2016

- Life Expectancy 68.45 Years
  - Male 67.26 Years

[7] *Infant mortality rate (deaths/1,000 live births),* available at http://www.indexmundi.com/g/g.aspx?c=in&v=29,

[8] Available at http://www.geoba.se/country.php?cc=IN

- Deaths Per 1000 — 7.30 Per 1,000
- Infant Mortality Rate — 40.45 Per 1,000 Births
  - Female — 41.79 Per 1,000 Births
  - Male — 39.24 Per 1,000 Births
- Mortality Rate - Age 1-4 — 14.61 Per 1,000 Births
  - Female — 18.19 Per 1,000 Births
  - Male — 11.38 Per 1,000 Births
- Mortality Rate - Under Age 5 — 54.46 Per 1,000 Births
  - Female — 59.22 Per 1,000 Births
  - Male — 50.17 Per 1,000 Births

The above figures indicate that India now as a country provides excellent, world-class medicinal facilities with medical tourism developing as an aspect as well. India's healthcare services are now attracting foreign patients for cheaper and efficient treatment.

Given this backdrop, it will be apt to determine whether right to health is recognizably, a fundamental right under the Constitutional protection in India. An analysis of the Judicial Response presented below will prove that Right to Health is now an embedded offshoot or extended understanding of Right to Life and Personal Liberty under Article 21 of the Indian Constitution.

[9]The Supreme Court of India has emphasized in Vincent vs. Union of India that a healthy body is the very foundation of all human activities. Article 47, a Directive Principle, lays stress on improvement of public health and prohibition of drugs injurious to health as one of the primary duties of the State. The Court has observed -

"…maintenance and improvement of public health have to rank high as these are indispensable to the very physical existence of the community and on the betterment of these depends the building of the society of which the constitution makers envisaged. Attending to public health, in our opinion, therefore, is of high priority- perhaps the one at the top."

[10]Article 21 of the Constitution guarantees protection of life and personal liberty to every citizen.

[11] The Supreme Court has recognized the rights of the workers and their right to basic health facilities under the Constitution, as well as under the international conventions to which India is a party. In its path breaking judgment in Bandhua Mukti Morcha v Union of India, the court delineated the scope of art 21 of the Constitution, and held that it is the fundamental right of every one in this country, assured under the interpretation given to art 21 by this court in Francis Mullin's Case to live with human dignity, free from exploitation. This right to live with human dignity enshrined in art 21 derives its life breath from the directive principles of state policy and particularly clause (e) and (f) of art 39 and arts 41 and 42. It must include protection of the health and strength of workers, men and

[9] MP JAIN, Indian Constitutional Law, pg 1181
[10] Issues in Medical Ethics Vol XI No 4 October–December 2003, HEALTH AND LAW The fundamental right to health care K MATHIHARAN Advisor, Institute of Legal Medicine
[11] Bandhua Mukti Morcha v. Union of India (AIR 1984 SC 802).

women; and children of tender age against abuse; opportunities and facilities for children to develop in a healthy manner and in conditions of freedom and dignity; educational facilities; just and humane conditions of work and maternity relief. These are the minimum requirements, which must exist in order to enable a person to live with human dignity. No state, neither the central government nor any state government, has the right to take any action which will deprive a person of the enjoyment of these basic essentials. The Supreme Court has held that the right to live with human dignity, enshrined in Article 21, derives from the directive principles of state policy and therefore includes protection of health.

[12]Further, it has also been held that the right to health is integral to the right to life and the government has a constitutional obligation to provide health facilities.

[13] The Supreme Court, in Paschim Banga Khet mazdoor Samity & ors v. State of West Bengal & ors, while widening the scope of art 21 and the government's responsibility to provide medical aid to every person in the country, held that in a welfare state, the primary duty of the government is to secure the welfare of the people. Providing adequate medical facilities for the people is an obligation undertaken by the government in a welfare state. The government discharges this obligation by providing medical care to the persons seeking to avail of those facilities. Article 21 imposes an obligation on the state to safeguard the right to life of every person. Preservation of human life is thus of paramount importance. The government hospitals run by the state are duty bound to extend medical assistance for preserving human life. Failure on the part of a government hospital to provide timely medical treatment to a person in need of such treatment, results in violation

[12] State of Punjab v. Mohinder Singh Chawla (1997) 2 SCC 83
[13] Paschim Banga Khet Mazdoor Samity v. State of West Bengal (AIR 1996 SC 2426 at 2429 para 9).

of his right to life guaranteed under Article21. Failure of a government hospital to provide a patient timely medical treatment results in violation of the patient's right to life.

[14] The Supreme Court, while examining the issue of the constitutional right to health care under arts 21, 41 and 47 of the Constitution of India in State of Punjab v Ram Lubhaya Bagga observed that the right of one person correlates to a duty upon another, individual, employer, government or authority. Hence, the right of a citizen to live under Article 21 casts an obligation on the state. This obligation is further reinforced under art 47; it is for the state to secure health to its citizens as its primary duty. Similarly, the Court has upheld the state's obligation to maintain health services.

In [15]Consumer Education and Research Center vs. Union of India, the Court explicitly held that the right to health was an integral factor of a meaningful right to life. The court held that the right to health and medical care is a fundamental right under Article 21.

In [16]CESC Ltd. vs. Subash Chandra Bose, the Supreme Court relied on international instruments and concluded that right to health is a fundamental right. It went further and observed that health is not merely absence of sickness: "The term health implies more than an absence of sickness. Medical care and health facilities not only protect against sickness but also ensure stable manpower for economic development. Facilities of health and medical care generate devotion and dedication to give the workers' best, physically as well as mentally, in

[14] State of Punjab v. Ram Lubhaya Bagga (1998) 4 SCC 117.
[15] AIR 1995 SC 636
[16] AIR 1992 SC 573,585

productivity. It enables the worker to enjoy the fruit of his labour, to keep him physically fit and mentally alert for leading a successful economic, social and cultural life. The medical facilities are, therefore, part of social security and like gilt edged security, it would yield immediate return in the increased production or at any rate reduce absenteeism on grounds of sickness, etc.

[17]With the recognition that both the Indian Constitution and the fundamental right of life emphasize human dignity, began to address the importance of health to Indian citizen. In the DPSP, Article 47 declares that the State shall regard the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties.

In Virender Gaur vs. State of Haryana,, the Supreme Court held that environmental, ecological, air and water pollution, etc., should be regarded as amounting to violation of right to health guaranteed by Article 21 of the Constitution. It is right to state that hygienic environment is an integral facet of the right to healthy life and it would not be possible to live with human dignity without a humane and healthy environment.

In [18]Consumer Education and Research Centre vs. Union of India, [19]Kirloskar Brothers Ltd. vs. Employees' State Insurance Corporation, the Supreme Court held that right to health and medical care is a fundamental fight under Article 21.

Concerning such a crisis, the innovator and generic drug industry must fraternize than aggravate competition to come to the aid of public welfare. The ultimate aim

[17] Bandhua Mukti Morcha AIR 1984 SC 812
[18] (1995) 3 SCC 42.
[19] (1996) 2 SCC 682, AIR 1996 SC 3261

of medicinal drug discovery needs to be understood as a life-saving mechanism that caters to human lives.

In the opinion of the researcher, such unaffordability renders a single implication-plain denial of access to healthcare services. If the patients are kept deprived from accessing such medicines, it will amount to a denial of the right to have a healthy life, an extended understanding of Article 21 of the Indian Constitution that lays down the Right to life and personal liberty. This will only add to disputes between the pharmaceutical companies and generic drug makers. To prevent this, the court of law must instill faith in the Government and allow it to regulate drug-pricing for pharmaceutical products in the markets. Therefore, the problem is not with regards to the grant of patent to such pharmaceutical companies for their manufactured products, the dispute arises when the sale prices of the drugs are beyond the purchasing capacity of people. This is when governmental intervention is needed to keep a thorough check on such companies in order to regulate their prices. Patent protection must not be seen as a tool for obtaining monopoly status and profit margins, rather it must be seen as a tool that provides recognition and fame for the novel creation of an intellectual property.

<u>Objective 3:</u> What role can the Government play in order to establish a balance and regulate patent rights of companies in order to secure access to such medicines at low costs for the public- with special focus on compulsory licensing and nationalization of products under the Government?

DIRECTIVE PRINCIPLES OF STATE POLICY

47. Duty of the State to raise the level of nutrition and the standard of living and to improve public health.-

The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties and, in particular, the State shall endeavour to bring about prohibition of the consumption except for medicinal purposes of intoxicating drinks and of drugs which are injurious to health.

Minerva Mills vs. Union of India has upheld the significant relation that a Fundamental Right conferred by Part III of the Constitution has with the Directive Principles of State Policy under Part IV of the Constitution-

"… The Directive Principles of State Policy have to conform and run as subsidiary to the Chapter of Fundamental Rights. Never the less, in determining the scope of the Fundamental Rights, the court may not entirely ignore the Directive Principles but should adopt the Doctrine of Harmonious Construction and should attempt to give effect to both as much as possible.

Hence, for the government, ideally, Directive Principles hold the same level of primacy that Fundamental Rights hold. In the researcher's opinion, the Directive Principles are the ideal goals that a country must strive to achieve, on the other hand, Fundamental Rights are the means one can achieve the same. This means that if improving public health and proving medicinal facilities to all is India's directive policy, its goal, then by understanding Right to Health as part of the Fundamental Right enshrined under Article 21, Right to Life and Personal Liberty, the country is providing a tool in the hands of the public to secure implementation of the said directive principle.

Further, in [20]M.C. Mehta vs. Union of India, [21]Rural Litigation and Entitlement Kendra v. State of U.P., Subhash Kumar vs. State of Bihar , the Supreme Court imposed a positive obligation upon the State to take steps for ensuring to the individual a better enjoyment of life and dignity and for elimination of water and air pollution. [22]Unnikrishnan, JP vs. State of A.P., the maintenance and improvement of public health is the duty of the State to fulfill its constitutional obligations cast on it under Article 21 of the Constitution.

Given the circumstance, it is the duty of the government to see that citizens of the country are not being deprived of medical facilities and are obtaining access to newly discovered pharmaceutical drugs. The patented drugs should not be arbitrarily or whimsically priced to procure benefits for individual companies, they should on the contrary be sold at affordable prices.

[20] (1987) 4 SCC 463, AIR 1988 SC 1037.
[21] AIR 1987 SC 359
[22] AIR 1993 SC 2178 , (1993) 1 SCC 645.

Recommendation

To ensure that pharmaceutical patented drugs are available at reasonable prices, the Government must encourage:-

1. **Compulsory Licensing[23]:-**

Keeping the generic drug industry at bay for a period of twenty years from manufacturing duplicates of the original drug results in market exclusivity for the branded drugs, there is complete discretion/monopoly over the drug pricing. This adversely affects the buyers of pharmaceutical products who are compelled to purchase the same at exorbitantly high prices. To cater to this problem, the concept of compulsory licensing was developed and was made a part of the Patents Act, 1970 which allows the generic drug industry from obtaining a permit or allowance to make replicas of the original drugs at lower prices.

A compulsory license is a type of permit or specifically stating, a license provided by law that allows a third company from using the intellectual property of another by paying the latter a remuneration or set fee. Illustrating further, a generic company A can obtain the rights to manufacture the pharmaceutical product of an innovator drug making company, B by paying a certain sum of money that must be pre- determined and agreeable to both the companies. On payment of such money, the generic company obtains the access or permit to manufacture duplicate drugs or bioequivalent versions of the original drug. The sale of the same is at lower prices comparatively and is a boon for patients intending to purchase the drug.

The effect of compulsory licensing serves a dual purpose, it addresses two major concerns that had evolved ever since pharmaceutical products became patentable since 2005 in

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[23] *TRIPS and pharmaceutical patients*, WTO OMC Fact Sheet, available at https://www.wto.org/ENGLISH/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf

India. This concept highlights the drug-pricing issue and makes pharmaceutical products available at lower prices. Also, it increases the ambit of public access to medicinal drugs.

[24]**Section 84 of the Patents Act, 1970**, governs compulsory licensing in India,

84. Compulsory licences

(1) At any time after the expiration of three years from the date of the grant of a patent, any

person interested may make an application to the Controller for grant of compulsory licence on

patent on any of the following grounds, namely:—

(b) that the patented invention is not available to the public at a reasonably affordable price, or

Clause (b) acts as a safeguard against the pharmaceutical drugs being sold at soaring prices, generic replicas of these drugs ensure that they are made accessible at reasonable rates to the general public.

[24] Section 84, The Patents Act, 1970