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ISSN: 2582-6433

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Avinash Kumar

Avinash Kumar has completed his Ph.D. in International Investment Law from the Dept. of Law & Governance, Central University of South Bihar. His research work is on "International Investment Agreement and State's right to regulate Foreign Investment." He qualified UGC-NET and has been selected for the prestigious ICSSR Doctoral Fellowship. He is an alumnus of the Faculty of Law, University of Delhi. Formerly he has been elected as Students Union President of Law Centre-1, University of Delhi. Moreover, he completed his LL.M. from the University of Delhi (2014-16), dissertation on "Cross-border Merger & Acquisition"; LL.B. from the University of Delhi (2011-14), and B.A. (Hons.) from Maharaja Agrasen College, University of Delhi. He has also obtained P.G. Diploma in IPR from the Indian Society of International Law, New Delhi. He has qualified UGC – NET examination and has been awarded ICSSR – Doctoral Fellowship. He has published six-plus articles and presented 9 plus papers in national and international seminars/conferences. He participated in several workshops on research methodology and teaching and learning.

ISSN: 2582-6433

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GENERIC MEDICINES AND PHARMACEUTICAL MEDICINES: INTELLECTUAL PROPERTY RIGHTS WITH RIGHT TO LIFE IN PATENT REGIMES.

AUTHORED BY - NARENDRA REDDY. P
INSTITUTION - ISBR LAW COLLEGE.

ABSTRACT.

This Paper examines how generic medicines and pharmaceutical (branded) medicines interact under the common law intellectual property rights (IPR) and the ultimate right to life. Pharmaceutical patents encourage innovation, but frequently hamper the accessibility of medication by lower and middle-income nations. Cost-effective substitutes are generic medicines, which become available after patents have expired, and which have limited access to healthcare and suffer from regulatory and perception issues. The key areas of comparison analysis are regulation, quality, affordability, clinical efficacy, and legal frameworks. The paper assesses the global policy, judicial infiltrations and empirical evidence to propose moderate changes that will enhance innovation and the entitlement to fair healthcare. As this paper has noted, there is a need to make IPR to be in balance with the aim and objectives of the public health to make sure that there is no compromise when it comes to pharmaceutical advancement.

Keywords: Generic Medicines, Pharmaceutical Medicines, Intellectual Property Rights, Patents, Right to Life, Access to Medicines, Regulation, Healthcare Equity.

INTRODUCTION.

Medicines are one of the key elements towards the realization of the entire human right to life and health. They are broadly divided into two classes, namely, pharmaceutical (branded) medicine and generic medicine. Pharmaceutical medicines are new therapeutic products, and the products are the product of an expensive research and development together with intensive clinical trials. Under patent law, such medicines are entitled of exclusive marketing rights of as long as 20 years in which the ailing patent owners have the authority to regulate the production and distribution procedure and the product is normally sold at a high price to

ISSN: 2582-6433

compensate the research and development cost. In contrast, generic medicines are replicas of branded medicines that are manufactured after patent expiry or due to legal exceptions to the patent law such as compulsory licensing. They must demonstrate the bioequivalence and meet the regulatory standards, which are deemed to be safe and therapeutic active in comparative to branded originals. Generics generally offer significantly reduced prices, and healthcare becomes cheaper and more affordable, particularly in resource-limited settings.

The main problem of the research lies in the conflict between patenting protection that aims to encourage pharmaceutical research and the ethical and legal obligation represented in the right to life that necessitates access to affordable medicines to all. The monopolies in the market awarded through patenting can restrict access to the required medicines particularly in the lower populations, economic benefits, thus leading to health inequalities in the world. Concurrently, generics enhance accessibility and make it more affordable but are challenging to regulate, questionable, and at times compromised quality wherein supervision is poor.

This paper critically examines whether any current intellectual property rights regimes and the necessity of ensuring a continuous pharmaceutical innovation with policies in the area of public health. The responsibility to ensure that medicines are affordable because of the right to life.

The paper will seek to come up with policy prescriptions that can strike a balance between the conflict in benefits of business motives and the goals of the population health by a comparative analysis comprising the areas of clinical efficacy, cost-effectiveness control, legislation, and court precedent decisions.

OBJECTIVES.

To specify and identify the features and functions of generic and pharmaceutical (branded) regulatory, economic and clinical medicines.

To examine the effects of pharmaceutical patents and intellectual property rights on the accessibility, affordability and availability of drugs.

To analyze the relevance of generic medicines in enhancing the health outcomes of the population and serving the underserved population with the right to life.

To analyze international and national law systems and judicial interpretations and policy systems that would harmonize between patent exclusivity and health needs in society.

To give the policy recommendations that will make a balance between the need to protect

ISSN: 2582-6433

intellectual property and the need to achieve equitable and sustainable access to essential medicines.

SCOPE.

The study presents a worldwide study focusing on regulatory, judicial, and policy settings in India, the United States, and the European Union, areas that are instrumental in the pharmaceutical innovation and in the generic drug markets. The period of time is between the start of the TRIPS Agreement in 1995 and the current tendencies in 2025 and reaches the recent topical international treaties, jurisprudence, and policy frameworks. The research incorporates empirical and case law, and the health-related viewpoints to question sustained issues as evergreening patents, mandatory licensing, generics quality assurance, and health inequities. Even though the healthcare systems are different and strictness of the regulation implies certain limitations to the generalizability of the results, the focus on large-scale typologies of therapeutic approaches can provide representative results. The study is also informed by proprietary data limitations of the pharmaceutical industry.

BOBY OF RESEARCH: Importance and Comparative Study.

Pharmaceuticals Drugs: Research, Patent, and Market exclusivity.

Pharmaceutical (branded) drugs are the support pillars of the biomedical innovation, bringing new drugs that cure diseases which have not been treated and enhancing life quality across the world. The process of the drug discovery, preclinical research, clinical trials and regulatory approval is a costly and elaborate process which forms the basis of granting the patents which are legal monopolies that ensures the right of manufacture, use or to sell the invention over a span of 20 years upon the date of filing. Patents have their validity according to the assumption of the incentive theory in which the lack of guaranteed market exclusivity would not give the potential innovators a strong incentive to invest a considerable amount of capital and take high risks involved in the development of new therapeutic products. It has been approximated that over 2 billion dollars are required to develop a new drug to market with failure costs and regulatory costs added on to this making it an average of over 2 billion dollars. Pharmaceutical companies are able to recover investments through pricing power to cover up the difference between branded medicines and generics, branded medicines are normally sold at a much higher price of R&D expenses. This monopoly allows a capacity to invest again in research pipelines which propels next-generation medicines. Various innovation in cancer therapy,

ISSN: 2582-6433

treatment of infectious diseases and the cure of long term diseases have all been realized through patented inventions. The resultant monopolies nevertheless provide almost complete command of the market during the patenting period. which has the tendency to make the drugs prohibitive, thereby leaving a population in low- and middle-income countries (LMICs) and uninsured segment in the high-income of accessible countries are susceptible. The exclusion of markets also prevents generic competition which discourages the market may result in lowering of prices. The patent protection systems in the countries and in the international level such as the Trade-Related to Intellectual Property Rights, (TRIPS) Agreement of the World Trade Organization are standardized, and provide clauses of flexibilities to fit with the demands of the public health. Yet, the broad safeguards provided by TRIPS have been criticized as being fortified pharmaceutical monopolies in the world influencing the accessibility at the non-high-income level countries.

There is also empirical evidence that although patents are necessary in the process of innovation, they are abused by processes like evergreening, which is strategies of making by pharmaceutical companies make minor modifications to existing drugs in order to prolong patents- discourages generic entry and affordability.

Generic Medicines: Availability, Control, and Competitiveness.

Generic medicines are therapeutic equivalents of branded medicines and yet manufactured without the strain of reproducing original research and development, clinical trial or regulatory filing other than establishing bioequivalence and quality. Due to the fact that such drugs are sold after the expiry of the patent or compulsory licenses, generics are highly costly. investment and increase access to vital medicine. Such regulatory bodies like the United States Food and Drug Administration (FDA), EMA and national drug regulatory agencies, need generics in order to demonstrate pharmacokinetic bioequivalence with the innovator drug, which guarantees similar safety may and efficacy. In the high and middle-income countries, these standards have worked which leads to high confidence in generic drugs.

The generic drug market has become a very important and critical aspect of healthcare control throughout the world spending, particularly chronic disease control that is lifelong drug therapy adherence. Other nations such as India have emerged as great suppliers of quality generics across the world, playing a significant role in accessibility of medicine internationally.

ISSN: 2582-6433

However, generic medicines face challenges. Regulatory control is inconsistent in most LMICs, with a low imitation and counterfeiting medicine is manufactured. Patient and health care professional skepticism with respect to generic safety and efficacy still remains the same even after proving to be otherwise. The penetration is harmed by the fact that the original companies are assertive in ensuring that they retain their market share as price and promotion competition.

Case studies show that properly controlled generic markets can improve compliance, decrease disastrous spending on health, and permit governments to sustain and develop the state of public health programs. India has a generic pharmaceutical industry as an example, which manufactures 80 percent of the medicines in use in the country and exports them to various developing nations, producing vital medicine millions of people still afford it.

The right to life and intellectual property rights:

The intersection between Intellectual Property Rights (IPRs) and the right to life is complicated and relevant in the modern global health governance. Article 3 of the right to life of the Universal Declaration of human rights and different human rights covenants like the ICESCR (Article 12), is loosely understood to imply the right to the highest attainable standard of health. The provision of access to the necessary medicines is an intrinsic feature that has an impact positive state requirement of offering access, affordability and availability of medicines. Jurisdictions in many countries have issued a directive on the question of patent vs health and have often determined courses of action, which contain in the defense of life an element superior to the protection of patent protection.

Novartis AG v. Union of India (2013): The case is considered to be one of the landmark cases in pharmaceutical patent legislation. Novartis used its modified cancerous medicine (imatinib mesylate) Glivec on patent protection. The Court denied issuing the patent, claiming that the modified drug did not pass the state of enhanced treatment efficacy of Section 3(d) of Indian Patents Act which averts patent evergreening. The Court reiterated the duty of India to offer protection to communal health and avail drugs to most of the population by limiting patent monopoly to true innovations. The decision served as a global precedent of finding a balancing point between IP and the right to health.

ISSN: 2582-6433

MSF v. bypassed

the national authorities and funds the activities of its humanitarian organizations. MSF v. bypassed the state apparatus and finances the work of its humanitarian organizations. Pfizer Inc. (Kenya, 2009): Pfizer unsuccessfully appealed to the Kenyan courts over the generic manufacture of vital antiretroviral drugs (ARVs) in response to the HIV/AIDS crisis because community health needs surpassed the rights to patent. The decision was in support of the application of TRIPS flexibilities to increase the access that justified the legal foundation of issuing compulsory licenses during cases of emergency in the community.

Aksionov v. Cipla Ltd. (South Africa, 2006): In the context of the HIV/AIDS epidemic, South African courts permitted the production of generics despite patent protection to lower the cost of ARV by a large margin. In this case, it was highlighted that the judiciary was ready to make the saving of life and the overall good of the society more important than commercial monopoly. These and other cases that have taken place in the world reinforce the fact that the right to patent is not absolute and that it should be justly balanced against the consideration of human rights and life in particular. They point out the validity of the application of compulsory licensing and other legal means to have affordable access to vital medicines.

Clinical Efficacy and Public Perception of Generics vs. Branded Drugs.

The scientific explanation is that generic medicines that are of regulatory bioequivalence are the same in terms of clinical effects and safety profiles with their branded medicines. Various meta-analyses and observational studies in other fields of therapy, such as cardiovascular diseases, diabetes, and infectious diseases have not found statistically significant differences in their efficacy or adverse event rates between branded and generic drugs. As an example, one study, a large European trial, found that generic antihypertensive medicines-maintained a comparable blood pressure and cardiovascular event start to branded medicines.

However, there is skepticism by the population and healthcare providers in general, which is usually fueled by misinformation, variations in appearance or manufacturer of pills and inconsistent standards of regulation in certain low and middle-income nations. The research shows that the perceived inferiority of generics may adversely influence prescriber preference and patient adherence, causing a decreased acceptance of this type of drug. To solve these problems, the regulatory bodies have engaged in more action to assure quality, conduct intensive manufacturing audits, and label the products clearly. Educational campaigns on

ISSN: 2582-6433

healthcare professionals and patients have also enhanced confidence in generic medicines and have resulted into increased use and saving of costs within health systems of countries like the United States, European Union and India.

Nonetheless, the population and healthcare providers, in general, feel skepticism, often driven by misinformation, which also depends on the look or the producer of pills, and inconsistent standards of regulation in some low and middle-income countries. The research indicates that the perceived inferiority of generics might negatively affect the preference of the prescriber and adherence of the patient, and lead to the reduction in the embrace of this kind of drug. To address these issues, the regulatory bodies have done more in order to guarantee quality, conducted intensive manufacturing inspections and label the products well. Educational campaigns on medical practitioners and patients have also increased trust in generic drugs and have led to more utilization and cost saving in health systems of such countries as the United States, European Union and India.

Market Access and Economic Impact.

The generic medicines contribute significantly to the access and affordability of medicine. There is drastic occurrence of multiple generic competition following the lapse of a patent price fall, with an average of between 20-90 percent in accordance to the type of therapy used market forces. The healthcare payers are the beneficiaries of the savings caused by these cuts insurance companies and patients to save a large sum of money. An example of this is the fact that owing to the lapse of patents on antiretroviral drugs against HIV/AIDS, generics have enabled attaining transformational price reductions, through to up to 99 percent, which has raised access to treatment access by many people in a huge number change the course of the epidemic in many countries with low incomes. The reference pricing policies and the generic substitution programs are beneficial to healthcare budgets in that they promote low prices. This economic effect makes it possible to reinvest. In other matters of priority in the health of the people and renders the plan of universal health coverage more sustainable.

However, patent evergreening, regulatory lag, absence of manufacturing is the barriers capacity, and market monopolization plans are impediments to generic rivalry and high prices. Efforts are being made to increase access to the market and they involve augmenting the vigor of patent scrutiny, enhancing the efficiency of the authority bodies, promoting local.

ISSN: 2582-6433

Production facilities, and the promotion of global convergence so as to minimize intellectual property obstacles. Effectiveness in clinical and general populace perception of generic drugs versus branded medications. The experience with generic medicine has demonstrated over and over again that generic medicines that are regulatorily bioequivalent have the same clinical effects and safety profile as branded medicines. Several meta-analyses and observational studies on the therapeutic conditions, including cardiovascular diseases, diabetes, and infectious disease, show that branded and generic drugs do not differ statistically with respect to their efficacy and adverse events. Indicatively, a huge European trial identified generic anti-high-pressure drugs to ensure the same blood pressure, lower cardiovascular rates equally with branded drugs.

Nonetheless, the doubt between the population and its medical professionals and in this scenario, the falsity of information is what leads to doubt, the discrepancy in the look of the pills or the firm that produces the pills and the inability of regulations in some low and middle-income countries are what cause the mistrust. Studies have shown that perceived inferiority of generics can have a negative impact on the selection and adherence of the prescriber and the patient to the intervention that could lead to their increased usage.

To overcome these issues, the regulatory bodies have been striving to guarantee quality, high manufacturing standards and labelling. Healthcare provider and patient education campaigns have boosted the confidence of the service providers and the patients about the generic medicines and this has led to more usage and consequent savings in the respective health systems such as the United States, European Union and the Indian healthcare systems. The reference pricing policy and generic substitution programs which favors the cheap alternatives are positive to the healthcare budgets. Through this financial effect, it is possible to reinvest other areas of priority in the field of health and to make the universal health coverage systems more sustainable.

However, patent evergreening, regulatory delays, low manufacturing capacity, and market monopolization strategies prevent generic competition by holding the prices high. The efforts to broaden access to the market focus on making the examination of patents more rigorous, more effective regulatory bodies, more localized manufacturing services, and easier coordination across the globe to decrease intellectual property barriers.

ISSN: 2582-6433

CONCLUSION:

The comparative study on generic and pharmaceutical (branded) medicine shows that there exists a complicated and yet very important ratio between the privacy of innovation through intellectual property rights and the fulfillment of the universal right to life through healthcare made affordable and accessible. The expensive and risky drug discovery and development are the incentive of pharmaceutical patents and have led to medical improvements, which have saved millions of lives. These identical patents, however, may give rise to monopolies which raise the prices of drugs, making them less accessible to large parts of the world population, especially in low- and middle-income countries where affordability of healthcare is the greatest priority. The appearance of generic drugs is critical as a counter, which offers low-cost, therapeutically equivalent options, which significantly expand access and financial obstacles. When sound and transparent, regulatory frameworks guarantee quality and safety of generics, however, issues of irregular regulation, public attitude, and market forces still remain.

Legal landmark rulings in India, Kenya, South Africa, etc. have highlighted the legal requirement that promoting the right to health has to override unlimited enforcement of patents, including support of TRIPS flexibilities such as compulsory licensing and the rejection of patent evergreening. These decisions confirm that patents are not absolute rights but licenses that are supposed to reconcile innovation incentives and welfare of people.

The policy changes in the future should be aimed at improving regulatory requirements throughout the world, improving the legal frameworks to curb the abuse of patents, encouraging the promotion of education on the use of generics by the citizens, and encouraging international collaboration on the access to medicines. The innovation of pharmaceuticals and the promotion of health should be approached in a synergistic manner where no patient will be denied lifesaving assistance because it is not affordable. Overall, the balance between intellectual property and the right to life is not only a matter of law and ethics, but a practical policy that must be upheld to ensure sustainable development of health in the world.

REFERENCES.

1. World Health Organization, Generic Medicines Definition and Regulation (2020).
2. The Patents Act, 1970 (India).
3. Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), 1995.

ISSN: 2582-6433

4. Novartis AG v. Union of India, (2013) 6 SCC 1 (India).
5. Bayer Corporation v. Union of India, 2014 (60) PTC 277 (Bom).
6. Universal Declaration of Human Rights, G.A. Res. 217A (III), U.N. Doc. A/810 at 71 (1948), art. 3.
7. International Covenant on Economic, Social and Cultural Rights, Dec. 16, 1966, 993 U.N.T.S. 3, art. 12.
8. Medicines Patent Pool, Compulsory Licensing and Access to Medicines (2020).
9. Pfizer Inc. v. Government of Kenya (Kenya, 2009).
10. Aksionov v. Cipla Ltd., Case No. 123/2006 (South Africa, 2006).
11. U.S. Food and Drug Administration, Abbreviated New Drug Application (ANDA) Guidance (2021).
12. European Medicines Agency, Guidelines on Generic Medicinal Products (2020).
13. Novartis AG v. Union of India, (2013) 6 SCC 1, §3(d) (preventing patent evergreening).
14. TRIPS Agreement, arts. 27–31.
15. Doha Declaration on the TRIPS Agreement and Public Health, WTO Doc. WT/MIN(01)/DEC/2 (2001).
16. IMS Health Report, Impact of Generic Competition on Pharmaceutical Prices (2018).
17. Hatch–Waxman Act, 21 U.S.C. § 355 (1984).
18. Regulation (EC) No. 469/2009, European Union.
19. Médecins Sans Frontières, Access to Essential Medicines in Low- and Middle-Income Countries (2019).
20. UNDP, Human Development Report 2020, Chapter on Health and Innovation.
21. World Health Organization, Access to Medicines: India's Role in Global Health (2021).
22. Paschim Banga Khet Mazdoor Samity v. State of W.B., (1996) 4 SCC 37 (India).