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BREAKING THE PILL MONOPOLY: CONSUMER JUSTICE IN THE AGE OF PHARMACEUTICAL POWER

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ABSTRACT

The real problem in healthcare is not a deficiency in treatments, but control over prices. When survival is priced based on patents, patients are bound by profit interests. This paradox is at the core of international debate over drug monopolies and consumer rights.[2] *Innovation often sets up barriers that restrict affordable access to essential medicines. The gap between intellectual property rights and the right to health has fueled inequalities, leaving millions without means to access lifesaving drugs. Access to medicines is viewed in this essay as a dual entitlement, seen as a right of consumers as well as a fundamental right of humans.*[3] *The essay is a comparative legal analysis that considers the operation of compulsory license, legal opposition to patent evergreening, and TRIPS agreement limitations on equitable fair play in healthcare. Further it looks at how monopolistic acts, patent evergreening, and unintelligible pricing models undermine consumer rights and public health examining in particular the tension between fostering innovation and a compelling need for equitable fair play in healthcare. The research advocates a rights approach that reframes boundaries in protecting*

[1] Intern- Lex Lumen Research Journal.
[2] World Health Organization (WHO) (2022) **Global Report: Access to Medicines and Universal Health Coverage**, Geneva: WHO Press.
[3] United Nations (1966) **International Covenant on Economic, Social and Cultural Rights**, Article 12, New York: United Nations.

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consumers in the pharmacy industry. The core objective delves upon breaking up the monopoly is not a principle of market fairness alone; it is ensuring the right to health transcends profit and becomes a universal principle. The medicine monopoly has no place in a society committed to fairness, justice, and preserving life itself.

KEYWORDS: Pharmaceutical Monopolies, Compulsory Licensing**,** Patent Evergreening**,** Fair Pricing.

1.INTRODUCTION

The pharma sector is among the most oligopolistic industries across the globe, yet plays a vital role in safeguarding public health. Unlike other products, drugs are essential to stay alive and do not carry the status of optional consumer items. As medical prescriptions and pressing health needs determining choices, individuals with this dependency have little negotiating power. Due to this asymmetry of structure customers are especially vulnerable to exploitation by multinational pharmaceutical firms.

Medicine is universally accepted as the foundation of human advancement with access to medication constituting the very basis of this concept. Under this domain the drug industry holds disproportionate influence by deciding who receives lifesaving drugs and for how much. Though innovation in science has provided revolutionary treatments underlying economic frameworks tend to rank profit above accessibility. This conflict comes into its sharpest focus in developing nations where health systems are strained and millions have a dearth of access to inexpensive medicines. In these places, regulation of the drug companies is not merely about business but about constitutional justice involving the basic right to health. The unprecedented hegemony of pharmaceutical companies is primarily due to the intellectual property system and more so patent protection. Patents with the intention of rewarding research and innovators often become tools for profit maximization by corporations.

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The contentious practice of "evergreening," or keeping monopolies going by making small product modifications on existing products, serves as an example of this abuse. Hindering the entry of generic medications into the marketplace, evergreening increases prices and restricts access exacerbating health disparities. The resulting monopolies push global debate regarding how to balance promoting innovation and ensuring equitable access, and produce deep legal, ethical, and societal challenges. For the population in low- and middle-income countries where out-of-pocket spending prevails in healthcare financing such exorbitant pricing directly constrains access to life-saving medicines.

1.2 OBJECTIVE AND SCOPE OF THE STUDY

The essay critiques the issues of pharmaceutical monopolies from the perspective of consumer justice. It attempts to examine the character of monopolistic undertakings in the pharmaceutical industry and thus evaluates the adequacy of current legal norms in balancing innovation with consumer well-being and research the role of judicial interventions in defining access to drugs in India. In addition, it delves into developing matters like the consequences of digital medicine and changing patient rights. Lastly it promotes policy recommendations that will create a balanced course of action that maintains the incentive for innovation while making the good things that come out of medical progress available and affordable to everyone.

CHAPTER 2: PHARMACEUTICAL MONOPOLY AND CONSUMER RIGHTS

Pharmaceutical monopolies are largely the consequence of patent regimes which confer inventor's exclusive control over their inventions for a specified period. The

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justification for such exclusivity is to encourage research and reward innovation.[4] This system though tends to get problematic when transnational corporations take advantage of loopholes in the law and regulation to ensure perpetuation of dominance. Techniques like "patent clustering," "evergreening," and 'bullying litigation' against generic producers of drugs effectively stall competition hence ensuring artificially high prices of drugs. The resultant legal repercussions of such monopolistic behaviour are dire for consumers. Public goods like essential drugs stop being sold and instead become commodified preying on both access and affordability. In India this is especially problematic with the prevalence of out-of-pocket spending on health, leaving consumers particularly exposed to drug price management by pharmaceutical companies.[5]"Evergreening" is one of the most contentious practices of pharmaceutical patenting. By introducing minor changes to established medicines.e.g., modifying dosage forms, delivery modes, or even packaging companies seek to revive or prolong patent duration. India has led the way against such practices by Section 3(d) of the Patents Act, 1970 which specifically excludes patentability of new forms of known substance unless they lead to improved therapeutic efficiency. This provision has been upheld by judicial decisions as well most prominently in Novartis AG v. Union of India (2013), when the Supreme Court denied a patent application for an altered cancer medicine laying stress on public health considerations above corporate interests.[6] Evergreening through patents has far reaching implications that go far beyond corporate boardrooms and directly influence the daily lives of consumers. Most directly it affects the drug prices which

[4] Correa, C.M. (2000) **Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options**. London: Zed Books.
[5] World Health Organization (WHO). (2018) **Access to Medicines and Health Products: Report of the Director-General**. Geneva: WHO.
[6] Supreme Court of India. (2013) **Novartis AG v. Union of India**, Civil Appeal Nos. 2706–2716 of 2013, Judgment dated 1 April 2013.

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makes the needy ones unaffordable to purchase. When drug manufacturers are able to extend monopoly rights through small modifications of drugs generic entry is delayed. Generics on average cut the price of medicine by 60–80% without them consumers particularly in developing nations such as India are compelled to pay astronomical prices for necessary treatment. That cost increase often leaves life-saving medicines in the hands of the affluent alone while millions are priced out of range. Another implication is the loss of consumer choice. In an open pharmaceutical market consumers ought to reap the reward of a variety of affordable choices. Evergreening tactics limit such diversity pushing patients to settle for high-cost branded products even when therapeutically similar generics would have done.

Such monopolistic conditions undermine the principle of fairness in consumer rights, where access to choice is paramount. Evergreening also raises ethical and social issues, most notably in societies with extreme income disparities. Patients often have to make the painful decision between bankruptcy and not being treated at all. This further aggravates healthcare inequities most heavily burdening vulnerable populations such as the poor, rural communities, and those lacking health insurance. Legally evergreening challenges the intellectual property protection and constitutional rights balance. In India where Article 21 of the Constitution is the source of the right to health, extended monopolies challenge the State's responsibility to provide healthcare access.[7] In the Novartis case (2013), courts have understood that consumer interest and public health cannot be sold to Commercial interests.[8] Thus the consequences reach public trust in healthcare systems when consumers feel that profits are ahead of patient concerns confidence in pharmaceutical corporations and regulatory bodies

[7] Supreme Court of India. (1989) **Consumer Education & Research Centre v. Union of India**, AIR 1995 SC 922 (affirming right to health under Article 21).

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deteriorates the trust in intellectual property law itself conceived as a balance between innovation and public good in its inception is undermined by the erosion of such trust. In short evergreening places economic, legal, and ethical costs on consumers exaggerating inequalities in access to healthcare. It highlights the importance of enacting comprehensive legislation on the critical importance of protecting basic human rights to private of open judicial control absolute Intellectual Property Rights. Internationally, consumer protection in health has been directly connected to balancing the Intellectual Property Rights with public health. The Doha Declaration on TRIPS and Public Health, It has been clarified in the 2001 that the TRIPS Agreement shall not stifle the freedom of member states to control the access to medicines, thereby justifying the adoption of compulsory licensing and parallel imports.[9] Such an international position signifies an acknowledgement that medicines are not like other commodities but rather fundamental goods that are associated with the right to health.[10] In India, consumer protection is based on constitutional and legal provisions. Article 21 rights to health with a reinforcement through Article 47 places an obligation upon the State to enhance public health.[11] The Patents Act, 1970, specifically Section 3(d) and compulsory licensing provisions, prevents access from being weakened by monopoly practices.[12] Reinforcing this Consumer Protection Act, 2019 safeguards patients as consumers of healthcare services giving them the power against deceptive

[9] WTO. (2001) **Doha Declaration on the TRIPS Agreement and Public Health**. WT/MIN (01)/DEC/2, 14 November 2001. Geneva: World Trade Organization.
[10] United Nations. (2000) **General Comment No. 14: The Right to the Highest Attainable Standard of Health (Article 12, ICESCR)**. New York: UN Committee on Economic, Social and Cultural Rights.

[11] Government of India. (1950) **Constitution of India**, Articles 21 and 47. New Delhi: Ministry of Law and Justice.
[12] The Patents Act, 1970 (as amended by the Patents (Amendment) Act, 2005), Government of India.

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trade practices and exploitative pricing, therefore harmonizing legal protection with social justice.[13]

Chapter 3: LEGAL AND REGULATORY FRAMEWORKS

The Trade-Related Aspects of Intellectual Property Rights (TRIPS), 1995 of the WTO imposed minimum standards on intellectual property protection, including patents for pharmaceuticals.[14] Article 27 required product patents for drugs, heavily limiting countries like India that had so far not granted such patents to encourage generic manufacturing. TRIPS, while intended to promote innovation, raised questions regarding access to medicines for developing countries. The Doha Declaration on TRIPS and Public Health (2001) brought welcome clarity by confirming that TRIPS "should not prevent members from taking measures to protect public health." It openly provided for compulsory licensing and parallel imports through Articles 31 and 6 of TRIPS, giving countries the authority to manage epidemics and affordability issues. This statement was a landmark, restating that intellectual property should be read in line with the public health objectives, reviving the patient's rights in healthcare worldwide.[15] India's Patents Act, 1970 previously excluded product patents on medicines and agrochemicals, permitting process patents alone. This enabled Indian companies to reverse engineer drugs and establish a robust generics market, keeping drug prices extremely low. TRIPS compliance revived product patents through the Patents (Amendment) Act, 2005.To avoid monopolistic exploitation, India enshrined

[13] Consumer Protection Act, 2019, No. 35 of 2019, Government of India.
[14] WTO. (1995) **Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)**, Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, 15 April 1994. Geneva: World Trade Organization.
[15] United Nations. (2000) **General Comment No. 14: The Right to the Highest Attainable Standard of Health (Article 12, ICESCR)**. New York: UN Committee on Economic, Social and Cultural Rights.

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public interest provisions. Chief among them is Section 3(d), which prohibit patents for new forms of established substances unless they show greater therapeutic efficacy. This section is a pillar of India's opposition to patent evergreening.[16] Sections 84 and 92 also allow compulsory licensing when patented drugs are not available at affordable prices or in a national emergency. Indian patent law, then, achieves a balance honorific to innovation but privileging access to affordable drugs as a public interest Bayer Corporation v. Natco Pharma (2014) – India's first compulsory license for Bayer's anticancer drug Sorafenib Tosylate. The Controller General of Patents invoked Section 84 on grounds of excessive cost and insufficient availability. Treatment costs were halved by Natco's generic version, reaffirming that patent rights cannot take precedence over accessibility.[17] ***Novartis AG v. Union of India*** (2013) – The Supreme Court affirmed the denial of a patent to Glivec under Section 3(d), holding that trivial changes in the absence of therapeutic progress did not qualify for patent protection. The judgment reaffirmed India's intention to avoid evergreening and maintain public access to drugs.[18]

Roche v. Cipla (2009) – In a case involving a cancer medication the Delhi High Court ruled in favour of Cipla by weighing the public interest factor making an early judgment that access to drugs constitutes a valid counterbalance to enforcing patents.[19] The cases demonstrate a consistent judicial trend that prioritizes affordability and access over exclusivity by monopolies, which upholds constitutional assurances under Article 21.[20]Outside of patent law, India uses competition regulation

[16] The Patents Act, 1970 (as amended by the Patents (Amendment) Act, 2005), Section 3(d), Government of India.
[17] **Bayer Corporation v. Natco Pharma Ltd.**, (2014) 60 PTC 277 (IPAB).
[18] **Novartis AG v. Union of India**, (2013) 6 SCC 1.
[19] **F. Hoffmann-La Roche Ltd v Cipla Ltd** [2009] (Delhi High Court).
[20] Constitution of India, art. 21.

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to protect consumer welfare. The Competition Act, 2002, Sections 3 and 4, specifically outlaws anti-competitive agreements and abuse of dominant market position. Pharmaceutical companies tend to practice cartelization, predatory pricing, refusal to license, or excessive pricing, which have the immediate effect of undermining consumer welfare.[21] The Competition Commission of India (CCI) has proved to be a watchful regulator. For instance, in the case of ***Varca Druggist v. Chemists and Druggists Association of Goa (2012)***, the CCI fined trade associations for supply constraints and price hikes, ruling that such behaviour violated Section 3.[22] Likewise, the CCI has probed multinational pharma majors on "pay-for-delay deals" and licensing curbs that hinder generic entry.[23]

Chapter 4: CHALLENGES AND EMERGING ISSUES

4.1 Life-Saving Drugs Pricing and Affordability Issues

Pricing of medicine remains the most challenging issue within global health. Life-saving drugs especially for cancer, HIV/AIDS, and orphan diseases, come at prices unaffordable to the ordinary consumer particularly in low and middle-income nations.[24] In India where over 60% of healthcare expenses are borne out-of-pocket, inflated pricing frequently forces families into catastrophic expenditures or denial of treatment.[25] This raises critical concerns of distributive justice whether life-saving

[21] Competition Act, 2002 (India), ss 3–4.
[22] **Varca Druggist & Chemists v Chemists and Druggists Association of Goa** (2012) CCI Case No. C-127/2009.
[23] Competition Commission of India, **Suo Motu Proceedings in the Pharmaceutical Sector** (CCI, 2018).
[24] World Health Organization, **Medicines in Health Systems: Advancing Access, Affordability and Appropriate Use** (WHO, 2014).
[25] National Sample Survey Office (NSSO), **Key Indicators of Social Consumption in India: Health** (Ministry of Statistics and Programme Implementation, 2019).

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drugs should be treated as commodities subject to market forces or as public goods essential to human survival. To meet this challenge, the Drugs (Prices Control) Order, 2013 gives the government the mandate to control prices of essential medicines in the National List of Essential Medicines (NLEM).[26] Even though gaps exist in enforcement and multinational corporations still resist price controls reflecting the continuing conflict between profitability and public health.

4.2 The Conflict between Intellectual Property and Public Health

Pharmaceutical monopolies reveal a profound paradox and patents encourage expensive research and innovation, yet at the same time restrict access through the preservation of prohibitively high prices. While richer countries hoarded vaccines, poor countries experienced acute shortages and there were calls for a TRIPS waiver of COVID-19-related technologies. In India this conflict has been avoided by provisions for compulsory licensing and a robust judicial philosophy of consumer welfare. However, the international opposition to waiving patents in crises is an indication of how intellectual property continues to prevail over public health interests. The challenge in the future is to rethink patent regimes to better balance rewarding innovation with the constitutional and human rights responsibility of making everyone healthy.

4.3 Generic Medicines and Access to Essential Drugs

Generic drugs are a lifeline for millions of patients as they present an affordable option to costly patented medicines. India referred to as the "pharmacy of the developing world," is critically involved in the provision of generics domestically and globally.

[26] Government of India, **Drugs (Prices Control) Order, 2013**, GSR 122(E), 15 March 2013.

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Their supply is however most often hindered by lengthy lawsuits by multinational firms aiming to hold up generic entry. Misinformation campaigns also erode consumer's confidence in generics and myths regarding their safety and efficacy are usually spread by interested parties. Moreover, poor consumer awareness concerning the therapeutic equivalence of generics also inhibits their penetration. Legal protection including Section 3(d) of the Patents Act and compulsory licensing has given legal recourse to Indian courts to protect the position of generics. However more vigilant regulatory actions combined with public education campaigns are called for to counter corporate opposition and keep generics available and dependable for consumers.

4.4 Digital Healthcare, AI-Driven Pharma, and Exploitation of Consumer Data

The accelerated adoption of digital technologies in health care presents challenges and opportunities. Pharmaceutical manufacturers increasingly use AI-driven drug development, tailor-made medicine, and telemedicine platforms, which hold out the promise of efficiency and novelty.[27] But these developments also pose urgent questions about consumer protection of data and exploitation. Patient data tend to be reaped for commercial or targeted marketing purposes without proper consents and doubts arise under privacy legislation.[28] In India the Digital Personal Data Protection Act, 2023 is created to provide a framework for the protection of personal health data but loopholes exist when it comes to enforcement especially against large multinational companies.[29] Further AI-based algorithms could bring bias into play

[27] World Health Organization, **Ethics and Governance of Artificial Intelligence for Health** (WHO, 2021).
[28] United Nations Conference on Trade and Development (UNCTAD), **Data Protection and Privacy Legislation Worldwide** (UNCTAD, 2023).
[29] Government of India, **Digital Personal Data Protection Act, 2023** (Act No. 22 of 2023).

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which could result in discriminatory healthcare treatment. As digitalization gathers momentum, more robust regulatory structures, ethical principles, and open data governance will be essential so that technology supports instead of eroding consumer rights in healthcare.

Chapter 5: POLICY SUGGESTIONS AND FUTURE DIRECTIONS

5.1 Improving Compulsory Licensing Mechanisms

Forced licensing continues to be the best means of guaranteeing affordable availability of life-saving drugs. India should look into how to broaden the scope and effectiveness of such mechanisms especially for life-saving medicines that continue to be exorbitantly priced. Clear guidelines, expedited approvals, and stringent enforcement would encourage domestic producers to make cheap substitutes while upholding patent rights.

5.2 Encouraging a Generic Medicine Culture

Generics are vital to improve affordability and accessibility. Government schemes run by Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) in the form of running Jan Aushadhi Kendras must be taken to every corner of the country. Consumer trust for safety and efficacy of generics must be achieved through awareness programs. Public and patient education and health professional training can dispel myths around, check use of costly branded drugs, and popularize generics.

5.3 Providing Transparency in Drug Pricing and Clinical Trials

To ensure accountability in the pharmaceutical industry, transparency is critical. Requiring the disclosure of clinical trial results, pricing strategies, and even the costs associated with R&D would enable regulators, juries, and even the public to contest the fairness of the drug price-fixing. Disclosure suppresses the asymmetry of

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information, prevents nonsensical inflation of costs, and increases public trust. The reasonable pricing regulations in place for essential and patented drugs ensure that innovation does not overshadow the public health needs. Other countries have implemented measures such as open access registries for trial transparency and conducting cost-effectiveness analyses to demonstrate how transparency promotes equity. In the end, transparency promotes the alignment of innovation and accessibility which fosters equilibrium between pharmaceutical progress and the right to health.

5.4 Sustainable Models: Balancing Innovation with Equity

A rational regulatory approach should weigh the benefits of pharmaceutical research against the diagnostics of consumer equity Hybrid approaches constitutional patent system protective of the public interest, compulsory licensing, and price controls. Innovation and equity access are complementary. International collaboration, in the context of ethical convergence of cooperating corporations, should master the global frontier. Ultimately, public welfare must supersede all in the context of stable pharmaceutical regulation. Innovation should not be a disincentive. Medicines must be affordable, accessible and dependable.

Chapter 6: CONCLUSION

The pharmaceutical industry creates barriers to access lifesaving medicine based solely on a person's ability to pay rather than based on their medical needs. This has continued uninterrupted until the present day and paradoxically exists because of India's existing legislative protections and constitutional provisions under Section 3 (d) of the Patents Act; compulsory licensing; consumer protection legislation; and the activism of the judiciary regarding the Rights of Consumers in the health sector.

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Despite India's existing legal protections, exorbitant prices and a lack of availability continue as does the systemic inequity in accessing basic health care.

Under Article 21 of the Constitution, each citizen has a constitutionally protected right to health; however, ironically it is often a citizen's ability to afford health care that determines their survival. Therefore, medicine must be regarded as a vital component of society that should not be profited from but rather treated as such through effective enforcement, equitable and transparent pricing structures, and compassion towards patients and families. Consumer Justice in the Health Sector is based upon and protected under Article 21 of the Constitution of India, which has been interpreted broadly by the courts as encompassing protection of the right of every Indian citizen to have access to basic medicines. The legal protections under Article 21 allow for citizens to make petitions against monopolistic schemes which inhibit or inflate the costs of lifesaving medicines. Additionally, in light of the Consumer Protection Act, 2019 medical care is now considered a service and allows patients to sue for breaches of service, unfair trade practices, or deceitful acts.