INTELLECTUAL PROPERTY RIGHTS IN THE FIELD OF MEDICINE

Ms. Mitali Singh, Amity University, Noida

ABSTRACT

The intersection of intellectual property rights (IPR) and healthcare, particularly in the field of medicine, presents a complex landscape with profound implications for innovation, access to essential medicines, and public health. This paper delves into the multifaceted dynamics of IPR within the healthcare sector, focusing on the pharmaceutical industry and the challenges it poses to equitable healthcare access. Drawing upon an extensive review of literature, the study evaluates the impact of IPR protection on healthcare innovation, pricing, distribution, and the advancement of new drugs and medical technologies. It examines the intricate relationship between IPR laws, human rights, and the right to health, emphasizing the importance of balancing innovation incentives with public health imperatives. Additionally, the research explores the role of international agreements such as the TRIPS Agreement in shaping IPR frameworks and their implications for access to medicines, particularly in low- and middle-income countries. Moreover, the paper discusses various strategies and initiatives aimed at addressing the barriers posed by IPR to access to essential medicines, including voluntary licensing agreements, technology transfer mechanisms, and the role of entrepreneurial innovation. Finally, the study underscores the urgent need for a holistic approach that prioritizes public health concerns, fosters innovation, and ensures equitable access to healthcare for all.

Keywords: Intellectual Property Rights (IPR), Healthcare, Innovation, Medicines, Pharmaceutical.

INTRODUCTION

India's strong, egalitarian, and dynamic IPR system, in compliance with the TRIPS Agreement, is crucial in expanding and developing its knowledge economy. To maximize the benefits of intellectual property to India's economy and culture while safeguarding the public interest, a comprehensive IPR Policy is needed.[1] IPRs are crucial for innovation and protecting health rights globally, regionally, and nationally. Human rights institutions promote IPR models, fostering a conducive environment for innovation. IPR impacts the pharmaceutical sector by influencing treatment pricing, distribution, and pharmacological discoveries.[2] Over 100 nations have urged the WTO to waive COVID-related patents to boost vaccine manufacturing temporarily, but developed nations have opposed this, leading to the Doha Declaration. This study examines the economics of IPR and vaccines during pandemics.[3]

REVIEW OF LITERATURE

- Basant R, Srinivasan S.,[4] The study explores the impact of intellectual property protection on India's healthcare innovation growth, highlighting the interconnected processes of improved healthcare access innovation, particularly in the pharmaceuticals sector.
- Brigitte Tenni,[5] The study explores the impact of intellectual property laws on patients' access to prescribed medications, suggesting that this data could guide the development of trade and intellectual property legislation.
- Motari, M., Nikiema, JB., Kasilo, O.M.J. et al., [6] The authors discuss the WHO's efforts to bridge the gap between intellectual property, innovation, and medicine access by assisting countries in implementing TRIPS flexibilities.

[1] "Significance of Indian Pharmaceutical Patent Laws" (Lexology) https://www.lexology.com/library/detail.aspx?g=1b13bcbb-27b9-4e51-a152-6abc53eb6f18 accessed February 16, 2024

[2] "Improving Access to Health: Activating in the Intellectual Property and Health Nexus | New Tactics in Human Rights" (January 26, 2011) https://www.newtactics.org/conversation/improving-access-health-activating-intellectual-property-and-health-nexus accessed February 16, 2024

[3] *Ibid*

[4] Basant R, Srinivasan S., "Intellectual property protection in India and implications for health innovation: emerging perspectives," Innovation and Entrepreneurship in Health, 3:57-68, (2016).

[5] Tenni, B., "What is the impact of intellectual property rules on access to medicines? A systematic review." Global Health 18, 40 (2022).

[6] Motari, M., Nikiema, JB., Kasilo, O.M.J. et al., "The role of intellectual property rights on access to medicines in the WHO African region: 25 years after the TRIPS agreement," BMC Public Health 21, 490 (2021).

- Mohamad AyubDar and Tran Vang-Phu discuss the potential benefits of enhanced IPR legislation, including the Doha declaration, TRIPS, and initiatives by WIPO, WTO, and WHO, in addressing the global health crisis.
- T G Agitha,[7] The author, discusses the impact of patents and data exclusivity on healthcare costs, emphasizing the need for governments to ensure robust intellectual property protection.

ISSUES

- Examining how IP influences pricing, distribution, and innovation in the pharmaceutical sector.
- Investigating how IP protection influences the advancement and distribution of new drugs and medical technologies.

OBJECTIVES OF THE RESEARCH

- To study the protection of IP influence on the advancement and distribution of new drugs and medical technologies.
- Evaluate the challenges and obstacles to accessing essential medicines and medical technologies in countries with weak IP protection systems.

METHODOLOGY

The research methodology is Doctrinal, using the inductive method to identify trends and establish general conclusions. References include JSTOR, Westlaw PubMed, SCOPUS, Lexis Nexis, e-Newspapers, statutes, and judgments. Primary data includes Acts, Rules, Regulations, Judgments, Commentaries, Published Reports from Governmental Bodies/Institutions, WIPO, WHO, WTO, and UN agencies, and secondary data like books and professional journals.

THE RIGHT TO HEALTH

Article 25 of the UDHR, adopted on December 10, 1948, includes a provision for the right to health care for all people. That Article provides that *"Everyone has the right to a standard of living adequate for the health and well-being of himself and his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in*

[7] T.G, Agitha, "Impact of IP on public health: The developed country scenario," Journal of Intellectual Property Rights. 18. 382-389. (2013).

circumstances beyond his control."[8] Like other rights, the State cannot guarantee the right to health, as various factors beyond human control influence health. However, it must provide nutritious food, medical care, clean living conditions, and access to diagnostic and therapeutic medications and high-tech equipment for illness detection, prevention, and treatment to help people live healthier lives.

PATENT

The patent system is crucial for promoting innovation and healthcare access, but it struggles to tackle major public health issues like HIV/AIDS, malaria, TB, and avian flu. It provides exclusive rights and voluntary licensing channels for pharmaceutical creation, but some argue it lacks financial incentives for researchers to address underserved markets. Patent rights may limit patient access or increase medication costs. The broad scope of patents in early research raises concerns about patent thickets and royalty stacking, which could stifle future innovation.[9]

COPYRIGHTS

The healthcare industry heavily relies on informatics, making copyrights crucial for intellectual property protection. Protecting databases and software can prevent major violations, emphasizing the importance of safeguarding these fields through copyright laws. The healthcare industry recognises databases' growing significance as the "informatics" impacts corporate technology. These databases, including patient data, chemical structure and gene sequencing, and medical treatment efficacy studies, require significant annual capital outlays. They often qualify for copyright protection under copyright laws.[10]

TRADEMARKS

The healthcare industry uses trademarks for intellectual property protection, including names of pharmaceutical medications, medical equipment, and branding campaigns. However, consumers' confusion about product sources could harm healthcare and related businesses, as consumers lack clarity about product sources.[11] Business owners should create distinctive

[8] Drishty MA, "The Effects of Intellectual Property Rights on Access to Medicines" (Legal Desire Media and Insights, February 24, 2020) https://legaldesire.com/the-effects-of-intellectual-property-rights-on-access-to-medicines/ accessed February 20, 2024.

[9] "Patent Law and Global Public Health – IPX" https://ipxcourses.org/patent-law-and-global-public-health/ accessed February 20, 2024

[10] "Report of the United Nations secretary-general's high-level panel on access to medicines," (2016).

[11] John, "Global Surgery 2030: Evidence and Solutions for Achieving Health, Welfare, And Economic Development." The Lancet, 574. (2015).

brands to set their products apart from competitors. Conducting a trademark search before launching a new healthcare product or service can help determine potential infringement and mark availability. Trademark law protects labels, logos, and other indicators but does not protect underlying commodities or ideas.[12]

ACCESS TO ESSENTIAL MEDICINES AND HEALTH

Since the epidemic has spread over the globe and affected everyone. "The United Nations Covenant on Economic, Social and Cultural Rights (UNESCO) describes the relationship between IPR and human rights in straightforward terms. The right to health (Article 12) and the right to profit from scientific development are only two examples of how the document makes plain the goal of penetrating needed pharmaceuticals and advancing technologies (Article 15)."[13] According to Article 12, everyone's medical necessities, as well as other healthcare products and services, should be easily accessible to everyone who need them. Sustainable Development Goal (SDG) emphasises the need for universal health care and the dissemination of information about the need for vital medications and "access to safe, effective, quality and affordable essential medicines and vaccines for all". In order to "promote research, development, innovation and increase access to medicines, vaccines, diagnostics and related health technologies to improve the health and wellbeing of all".[14]

The WHO explained the concept of essential medicines as "the priority health care needs of the population", and "access to medicines depends on four factors: rational selection, affordable prices, sustainable financing and reliable health systems." Equipment, drugs, and improved therapy must be easily accessible, readily available, and acceptable to the general public. Adherence to medical ethics and a sincere interest in medical standards concerning individuality are prerequisites for acceptability. The availability of medication is more important than its cost in cases of a medical emergency.

TRIPS AGREEMENT AND ACCESS TO MEDICINE

The TRIPS mandates basic safeguards for the production, development, and preservation of works of art. In most cases, this shield covers products that need substantial initial investment in R&D, such as pharmaceuticals. Investors are given monopoly rights, and the new and better

[12] "Improving Access to Health: Activating in the Intellectual Property and Health Nexus | New Tactics in Human Rights" https://www.newtactics.org/ accessed February 21, 2024.
[13] Townsend, "What is the impact of intellectual property rules on access to medicines? A systematic review." *Global Health* **18**, 40 (2022).
[14] *Ibid*

drugs are patented thanks to intellectual property rules. Investors set exceptionally high prices for these drugs as part of the establishment of a monopoly market protected by intellectual property laws. As a result of the price increase, fewer people will be able to use the service.

Insulin's the ludicrously high price is a prime illustration of the pharmaceutical industry's practice of price gouging. Insulin is distinctive among medicines used to treat diabetes, which is not contagious from person to person. Although it was first created in 1921, getting your hands on it has proven to be a challenge ever since. In 1923, when the insulin patent was initially being developed, its creators chose not to have their names included. They both agreed that the public had a right to insulin. Thousands of individuals still can't get their hands on insulin almost a century after it was first developed. The monopoly of only three global corporations is to blame for this obstacle. As a result of this issue, many individuals make the tragic decision to consume dangerously low-quality or counterfeit pharmaceuticals because they are desperate to save money.

When pharmaceutical conglomerates patent life-saving treatments, it undermines patients' ability to access such treatments. Unless a worldwide campaign is launched in opposition, these abuses will assume monster proportions in the post-Covid world. Developing nations should be free to take use of TRIPS' national-level flexibilities to the fullest extent possible. The IPR framework established by TRIPS allows little room for state discretion. Pharmaceutical companies should immediately cease artificially inflating drug prices. Problem-solving, rather than problem-creation, should be the focus of R&D efforts.

IPR AIMED AT IMPROVING ACCESS TO HEALTHCARE

Under response to criticisms from poor nations and calls for greater leeway under the TRIPS agreement to improve access to vital medicines, the WTO proposed the WTO Doha Declaration on "TRIPS and Public Health" in 2001.

In response to criticisms that the Special 301 Report is biased, Consumers International has released an IP Watchlist that examines which nations have the most consumer-friendly intellectual property laws and enforcement practices.

Several notable institutions have acknowledged the potential significance of technology transfer to firms in underdeveloped countries.

The Medicines Patent Pool looks to be a promising initiative with significant potential for growth. For this reason, the Pool seeks to negotiate "with patent holders to share their

intellectual property with the Pool, and then licencing it to other producers to facilitate the production of affordable generic medicines well-adapted for use in resource-poor settings." The potential cost savings from patent pooling

The "Special 301 Report of the USA Trade Representative (USTR)," evaluates the state of intellectual property protection and enforcement abroad.

The WTO proposed the TRIPS Agreement, which establishes baseline protections for IP among WTO member nations.[15]

IPR AS A BARRIER TO ACCESS TO ESSENTIAL MEDICINES

Access to vital drugs is hampered by intellectual property (IP)-related considerations such as patent, data exclusivity, and trade secret protection. To protect competition from generic copies of their treatments, pharmaceutical corporations patent their products. The first challenge posed by patent law is defining "patentable subject matter."

The existence of patent laws poses a hindrance to the development of life-saving drugs. The two primary classifications within the pharmaceutical industry are small-molecule drugs and biosimilars. The synthesis and commercialization of small-molecular-weight drugs is a straightforward process. Biosimilars, similar to vaccines, incur higher costs compared to small molecule generics due to their inability to be synthesised. Prior to commercialization, generic companies are required to conduct clinical trials for biosimilars. Data exclusivity is a regulatory provision that safeguards the proprietary marketing approval data of the Food and Drug Administration (FDA). In contrast to patents, data exclusivity is characterised by its irrevocable nature. Researchers studying generic biologics may be granted a period of 12 years during which they have exclusive access to data, even in the absence of a patent.[16]

The EU pharmaceutical industry wants the EU-India Free Trade Agreement to enforce data exclusivity and ban generic medication manufacturers from developing therapies without first conducting costly and time-consuming clinical studies. India must retain generic pharmaceutical manufacture as the developing world's pharmacy. A trade secret owner's main prerogative is managing how their secret is utilised and disseminated. Trade secret rules

[15] Gold Richard E, "In the eye of the policy storm' published in final edited form as: Genetics in Medicine," 12 (4 Suppl) (2010).
[16] *Bilsky v Kappos 561 US – (2010)*

protecting biologics production have two solutions: Technology Transfer Centres and Patent Materials Disclosure A repository of all relevant process information.

DEVELOPMENTS IN MAKING MEDICINES AFFORDABLE

This chapter provides how intellectual property rules may affect patients' ability to get HIV treatment and other medications. It's a primer for those in the community who are working to address health challenges like HIV. The availability of necessary medications has become a critical concern in public health. There are still major obstacles to ensuring that those in need have access to low-cost medications and other health innovations. In 2015, the WHO issued updated treatment guidelines for HIV, bringing the total number of people who may begin treatment to 37 million, up from 28 million. This is independent of CD4 count. Second- and third-line antiretroviral medicine are too expensive for many patients in developing countries since their prices are two- and fifteen-times higher than those of first-line treatment, respectively (1).[17]

Access to medications is complicated by the existing intellectual property system in many ways:

The TRIPS Agreement of the World Trade Organisation limits market competition by requiring a maximum patent period of 20 years for all products, including pharmaceuticals.[18]

TRIPS-plus provisions: Intellectual property clauses that go above and beyond TRIPS basic criteria are common in regional and bilateral free trade agreements. Patent term extensions are a common feature of these TRIPS-plus clauses. (“evergreening”); minimum market exclusivity introduced; minimum data exclusivity conditions required for clinical data submitted to regulatory bodies (monopoly) periods; patent linkage measures, i.e. linking the patent and marketing approval procedures; stricter border and enforcement measures; reducing the scope of patent challenges, reducing the grounds for compulsory licencing, and reducing the manufacturing and import of generics by signatories. The Trans-Pacific Partnership (TPP) agreement, negotiated by nations in the Pacific in October 2015, contains various TRIPS-plus elements that may affect patients' ability to pay for pharmaceuticals.

[17] “Differences in costs of and access to pharmaceutical products in the EU, Study, Directorate General for Internal Policies,” Policy Department A: Economic And Scientific Policy, (2011).
[18] “Pharmaceutical Sector Inquiry,” Final Report, European Commission (2009)

The Indian Patent Act, which lets Indian companies sell generic products at lower prices to other poor countries, is in danger of being undermined by free trade agreements.

VOLUNTARY LICENCES

To ensure that medical innovations are accessible to everyone, patent holders may voluntarily enter into licencing agreements with third parties that provide them permission to use their inventions in return for compensation. In 2010, with the help of UNITAID, the Medicines Patent Pool (MPP) was established, and since then, several pharmaceutical firms have signed voluntary licencing agreements for HIV therapies. Companies that create goods have the option of licencing them to MPP, which then sub-licenses them to generics manufacturers that meet certain criteria in exchange for royalties on sales made in developing nations. Royalty-free licences have been granted for several paediatric preparations. Promoting formulations that suit the requirements of the poor globe, including as fixed-dose, paediatric, and heat-stable formulations, is another goal of MPP in addition to reducing costs and increasing access to generic copies of newer drugs. As of late, MPP has expanded its purview to include pharmaceuticals for treating hepatitis C and multidrug-resistant tuberculosis, and it has made the full text of all licences accessible to the general public. [19]

The lack of many middle-income nations that contribute to the global disease burden makes voluntary licencing via bilateral agreements or the Medicines Patent Pool (MPP) difficult. TB killed 1.5 million people worldwide in 2013, up from 1.3 million in 2012. By 2020, most HIV patients will live in middle-income nations. Hepatitis C is prevalent in middle-income countries.[20]

RISKS OF FREE TRADE AGREEMENTS

More and more bilateral and multilateral trade agreements include stringent TRIPS-plus measures that go above and beyond the minimum protections granted under TRIPS. These factors often contribute to the difficulty of acquiring reasonably priced medical equipment. The most common criticism levelled about TRIPS-plus provisions is that they offer patent holders too much discretion to raise prices by, for example, extending the duration of their patents or

[19] Damodaran AD. "Indian patent law in the post TRIPS decade: S&T policy appraisal. J Intellect Prop Rights." (2008)

[20] "Controller General of Patents, Designs and trademarks. History of Indian Patent System" < http://www.ipindia.nic.in/history-of-indian-patent-system.htm> accessed April 13, 2024.

delaying the entrance of rivals into the market "or at least making it more difficult to achieve price reductions as products come off patent."[21]

ENTREPRENEURIAL INNOVATION

The widespread use of smartphones and the Internet in India has led to the development of many cutting-edge healthcare products. Many of these innovations have been presented by new companies because they provide lucrative commercial prospects and also improve healthcare access, two important societal goals. Many of these inventions fall beyond the purview of TRIPS but may have a significant impact on a range of public health issues if they could be scaled up.

Several IP-based biomedical companies have been formed in recent years, demonstrating that the healthcare business is ripe for entrepreneurship. Unfortunately, there is no central database of such up-and-coming businesses. Dr Gayatri Saberwal found two highly intriguing characteristics (by personal conversation) after surveying fifty similar businesses:

These IP-based biomedical firms cover a wide range of specialisations and approaches. Many businesses focus on diagnostics, biologics, medical devices, and the development of new drugs, either via traditional chemical methods or through the use of proprietary software.

Almost all (44 out of 50) hold intellectual property or want to get it in the near future. More than half of these businesses (27 out of 58) have either applied for or been awarded patents, and another 20% (10 out of 58) intend to do so in the near future. It's interesting to see how they utilise patenting beyond only preventing copycats from using their innovations to increase their funding, prestige, and leverage in business-to-business negotiations.

Many cutting-edge tools may give essential technological support to paramedics, frontline health workers, and primary health clinics, therefore enhancing the quality of treatment delivered by existing health care systems or paving the way for their expansion. Health care in India is prohibitively expensive and severely lacking in access, prompting the development of solutions like Swasthya Slate. The difficulty of obtaining institutional approval is a major barrier to the widespread use of diagnostic equipment.

[21] Prakash A and others, "Intellectual Property Rights and Indian Pharmaceutical Industry: Present Scenario" (PubMed Central (PMC)) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6044128/> accessed April 16, 2024.

IMPACT OF IPR ON PUBLIC HEALTH: GLOBAL PERSPECTIVE

TRIPS AGREEMENT

The TRIPS Agreement is a treaty governed by the WTO that establishes baseline protections for various forms of IP such as patents, trademarks, copyrights, and trade secrets. The TRIPS Agreement offers flexibilities for member nations to defend public health interests and includes clauses that acknowledge the significance of public health. Pharmaceutical items and procedures are protected under patent law according to the TRIPS Agreement. However, it also gives member nations the option of enacting public health protection and pharmaceutical accessibility policies. Compulsory licences are one method whereby governments might authorise the use of a patented innovation without the consent of the patent owners. It also empowers member nations to set their own standards for issuing patents and to decide for themselves whether or not to protect particular types of innovations, such as those used in medicine or surgery. There are provisions in the TRIPS Agreement that are meant to help developing nations, especially LDCs, deal with public health issues. To help LDCs have the legal structures in place for protecting intellectual property, it provides for transition periods for implementing some TRIPS commitments to be extended. The TRIPS Agreement also permits countries to grant compulsory licences for the manufacturing or import of low-cost generic drugs to tackle public health problems including HIV/AIDS, TB, and malaria. Using these methods, countries may ensure their people have access to quality, affordable healthcare while removing patent obstacles.

INDIA

The Patents Act of 1970 governs the patent system in India; section 3(i) of this law states that patents cannot be granted for innovations involving techniques for medical treatments if the goal is to increase the commercial worth of the goods. The method of making the pharmaceutical product, but not the material itself, is patentable if it is destined for use in food, medications, or medicine. However, in 2005, India implemented product patenting in accordance with the TRIPS Agreement under the "Patents (Amendment) Act, 2005." The Natco Pharma Ltd. decision is significant because it supported the new standard for patenting products. Before the legislation was changed, only the manufacturing or production method could be patented in India, but now finished products may be patented. The Natco Pharma Ltd. case puts additional weight on the provisions of Section 84 and Section 92 of the Patents Act that discusses compulsory licence, however, this provision only applies to new chemical units.

However, the government has increased market monopoly by corporate measures, such as mergers and acquisitions, collusion, and influence of powerful business competitors, by allowing product patenting (even to some degree, if not totally). However, the legislative goal was to strengthen domestic pharmaceutical firms, therefore no patent legislation protecting pharmaceutical chemicals seems to exist. Indian corporations have expanded into international markets to safeguard their interests outside of their native country due to a lack of legal recourse inside India.[22]

USA

The USA has the biggest and least limited prescription medication market and is the world leader in new drug development and testing, but it also has the least effective public-private shared insurance system, making it especially vulnerable to the negative effects of high drug prices. The USA reluctance to see health care as a means of achieving social justice helped pave the way for a market-based system. Healthcare in the United States is very expensive, as even Senator Bernie Sanders has admitted. "The simple fact is that the prices of patent medicines are a significant barrier to health for millions of uninsured and under-insured Americans, and people die because of it," he said at the opening of a hearing on "The High Cost of High Prices for HIV/AIDS Drugs and the Prize Fund Alternative" held by the "USA Senate Committee on Health Education, Labour, and Pensions (HELP) and Subcommittee on Primary Health and Agency." He claims that the USA has the world's least effective healthcare system despite being the most inventive nation in the world with the top colleges, drawing the brightest brains from across the globe. It spends more than any other nation on health care, both per capita and as a share of GDP, but with significantly worse results than countries that spend much less.[23] [

EUROPE

Despite having a bigger population and more comprehensive insurance coverage, Europe only accounted for 10% of worldwide pharmaceutical revenues. U.S. medicine costs are far higher, which accounts for most of the disparity. The wholesale cost in the USA was two to three times that of comparable pharmaceuticals in Germany and the United Kingdom. Consumers and insurers here pay two to four times as much as they would in other nations. Despite the FDA's

[22] Sampat BN, Shadlen KC. "Patent watch: Drug patenting in India: Looking back and looking forward." Nat Rev Drug Discov. (2015)
[23] Anna, R.R., & HusøyOnarheim, K. "Towards realising access to essential medicines for all: A Vision for 2035. The Lancet Youth Commission on Essential Medicines Policies." (2016).

worldwide reputation for rigorous assessment, pharmaceutical firms operating in Europe generally seek market permission in the USA first. When compared to the USA, the healthcare system in Europe is better managed and places a higher value on individual lives. However, healthcare spending as a whole among EU Member States has increased significantly over the last two decades, both in raw terms and as a percentage of GDP. Spending on pharmaceuticals is the European Union's third-biggest healthcare expenditure category, behind hospitals and outpatient care. After the patent expires, generic pricing is typically 25% lower than the original.[24]

UNITED KINGDOM (UK)

The NHS provides high-quality medical care to everyone in the UK. The cost of patent-protected pharmaceuticals is crucial when discussing IPR and public health. Even though the National Health Service (NHS) may negotiate prices with pharmaceutical companies, expensive patented drugs may hinder healthcare budget sustainability, affordability, and accessibility.

Due to copyrighted medication prices, the NHS may be unable to supply certain medical treatments or postpone their complete integration within the healthcare system. The above condition may prevent rare illness or specialty therapy patients from accessing cutting-edge, life-saving drugs. UK efforts preserve IPR and satisfy public health requirements. The Patents Act's compulsory licencing provisions allow the government to employ patented technologies without patent holders' consent. If the patent holder has misused their rights, there is a national emergency, or the public might profit from the invention in a non-commercial fashion, compulsory licencing may be utilised. These guidelines guarantee that life-saving pharmaceuticals are constantly available, particularly during public health emergencies or when patent holders oppose fair licencing conditions. Mandatory licencing may assist the UK handle life-saving medicine costs and availability. UK's NHS runs the Pharmaceutical Benefits Scheme (PBS) to make prescription medications affordable and accessible. Patients gain from PBS's government-pharmaceutical company medicine pricing negotiations. In these talks, the UK government seeks favourable pricing for patented pharmaceuticals to make them cheap and available to the NHS. PBS is vital to reducing IPR's consequences on public health. A comprehensive approach that balances patient demands and healthcare system finances

[24] "European Pharmaceutical Review," <https://www.europeanpharmaceuticalreview.com/> accessed February 16, 2024.

achieves this. Patented pharmaceutical prices dominate UK IPR-public health issues. The NHS has sought to minimise the cost of patented drugs by negotiating cheaper pricing and adopting forced licencing, but to little avail. These strategies and global agreements like the Agreement on TRIPS help the UK strike a balance between protecting IPR and providing affordable pharmaceuticals to its citizens.

AUSTRALIA

The Pharmaceutical Benefits Scheme (PBS) is a part of Australia's healthcare system that guarantees everyone has access to low-cost, high-quality prescription drugs. In order to provide affordable access to patented pharmaceuticals, the government negotiates with pharmaceutical corporations on behalf of the PBS. However, the enormous costs of patented drugs continue to be a significant element in the field of IPR and its effect on public health. However, the high price of patented pharmaceuticals may still pose challenges to the financial sustainability of the healthcare system and the capacity of patients to get certain therapies, despite the PBS's efforts to mitigate access and affordability difficulties. Australia abides by the terms of the TRIPS as a member of the WTO. Patents and other kinds of intellectual property protection are included in the international standards established by the Agreement on TRIPS. The Agreement on TRIPS creates a baseline for protecting intellectual property, but it also gives governments leeway to take precautions to protect the public's health. Compulsory licencing, parallel imports, and the flexibility to set their own patentability standards are all examples of this degree of freedom. The ability to handle public health challenges within national legal systems is made possible by these variations. Promoting generic pharmaceuticals is highly valued in Australia as a means of lowering drug prices and expanding access to healthcare. After a drug's patent has expired, generic versions of it are often considered a more cost-effective option for patients. Incentivizing the use of generic drugs helps reduce healthcare costs, broadens access to healthcare, and boosts competitiveness in the pharmaceutical market.

By encouraging the use of generic medications, Australia hopes to mitigate the impact of IPR on public health, particularly in regards to the cost and availability of life-saving therapies. The financial consequences of patented drugs and their availability within the healthcare system are at the heart of the debate over the impact of IPR on public health in Australia. In order to strike a balance between protecting IPR and ensuring that medications are affordable for all, various measures have been implemented, such as the Pharmaceutical Benefits Scheme (PBS), compulsory licencing provisions, and pharmaceutical benefit reviews. Australia's policy

includes promoting the use of generic medications and complying to international accords like the Agreement on TRIPS. The goal of this strategy is to efficiently address public health concerns while also handling the complications of IPR.

SINGAPORE

To encourage innovation and stimulate the economy, Singapore has established a stringent system to safeguard intellectual property. However, IPR need to be carefully considered to see how they affect public health care access in Singapore. Investment in medical research and development may be boosted by strong protection of IPR. Patents stimulate investment in new pharmaceuticals and healthcare technology by providing financial incentives and granting exclusive rights to do so. This has the potential to improve health care by leading to new and better medical therapies. Neglected tropical illnesses and uncommon diseases, for example, may get less funding due to the pharmaceutical industry's emphasis on lucrative markets and the greater expenses of research and development for novel medications. Singapore understands the need of striking a balance between IPR safeguards and public health concerns. The nation has taken steps to improve healthcare access and encourage innovation. The government of Singapore has set up a number of programmes to assist its citizens pay for expensive medical care, such as the Medication Assistance Fund and the Medisave system. The government of Singapore also has the authority to issue mandatory licences in the event of a national emergency, a public health crisis, or when prices become unreasonably high.

CONCLUSION

The healthcare access crisis threatens the world's poorest nations, and despite progress, barriers to quality healthcare must be eliminated. Public health concerns must be prioritized, and the IPR regime should be used to protect people's fundamental freedoms. The WHO should work with other organizations to improve healthcare for all people. Member states should devise a coherent framework with IPR; the enforcement mechanism in the least developed and developing nations is a significant problem. Human rights scholars should investigate the uncharted territory of IPR, and local policies should be based on societal analysis and issues consistent with the international IPR system. The WHO should guide member nations on IPR advancements and adjust medication regimes to lessen the adverse effects on human progress. The COVID-19 epidemic is a cautionary tale for the world, urging research-oriented inventions and universal health programs. A forward-thinking strategy is needed to educate and improve future standards in the IPR field.

This study has provided a comprehensive examination of the intricate relationship between intellectual property rights (IPR) and access to healthcare, particularly in the context of the pharmaceutical industry. Through an extensive review of literature and analysis of key issues, several important findings have emerged.

Firstly, it is evident that while IPR protection is crucial for fostering innovation and incentivizing research and development in healthcare, it also poses significant challenges to equitable access to essential medicines, diagnostics, and medical technologies. Patent monopolies, data exclusivity provisions, and trade agreements often result in high drug prices, limited competition, and barriers to generic drug manufacturing, particularly in low- and middle-income countries.

Moreover, the COVID-19 pandemic has underscored the urgency of addressing these challenges, as the global response to the crisis has been hampered by concerns over vaccine nationalism, patent barriers, and inequitable distribution of vaccines and treatments. Efforts to waive intellectual property rights for COVID-19 vaccines have highlighted the need for a more balanced approach to IPR that prioritizes public health and ensures universal access to life-saving technologies.

Furthermore, alternative models for drug development and technology transfer, such as voluntary licensing agreements, prize funds, and open-access initiatives, hold promise for addressing the shortcomings of the current IPR system and expanding access to affordable healthcare solutions.

In light of these findings, it is imperative that policymakers, international organizations, and stakeholders in the healthcare sector collaborate to reform intellectual property regimes in ways that promote innovation, protect public health, and advance the right to access essential medicines for all. This requires a holistic approach that considers the complex interplay between intellectual property rights, human rights, and public health imperatives, with a focus on achieving equitable and sustainable healthcare outcomes for individuals and communities worldwide.

Moving forward, it is essential to continue research and dialogue on these critical issues, seeking innovative solutions and advocating for policies that prioritize the well-being and dignity of all individuals, regardless of their socioeconomic status or geographical location. By harnessing the potential of intellectual property rights to serve the public interest, we can create

a more just and inclusive healthcare system that meets the needs of present and future generations.