INTEGRATING A HUMAN RIGHTS PERSPECTIVE INTO PATENT LAW TO PROMOTE PUBLIC HEALTH: LESSONS FROM THE ORPHAN DRUGS REGIME

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ABSTRACT

Patent is justified as a tool to stimulate innovation and promote societal progress. Though the emphasis is on public welfare and public interest, the theoretical aims and practical outcomes are disconnected. In reality, the patent system results in monopolistic practices, inflated prices, and restricted access which raise huge concerns especially in the healthcare sector. Attempts to harmonise patent law and human rights principles is not a new phenomenon and has been part of many international instruments. The TRIPS agreement and its flexibilities, is are significant steps aimed at balancing patent and human rights. The implementation of these however, is inadequate highlighting the gaps in the existing system.

This paper analyses the need to incorporate human rights principles into patent law by looking at public health impacts of patents. The challenges in the existing framework are studied through the case of orphan drugs. The patent system acts detrimentally to societal welfare by not promoting research and also restricting access. This is because the system is largely market driven giving priority to commercial interests rather than social values. This paper argues for a new approach where patent law is rethought in terms of public health and human rights. In the presence of a robust framework, innovation will be promoted giving due regard to factors such as incentivising socially valuable innovation and equitable access. Such a framework will align legal protections with public interest objectives.

KEYWORDS: Patent Law, Orphan drug, Rare Disease, Human Rights, Public Health, Innovation.

INTRODUCTION

Patents and human rights have always remained in tension. This has been a persistent challenge, the effects of which are enhanced in the healthcare sector. Patents are exclusive

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rights granted by an authority over an invention for a particular period. It aims at rewarding the creator and also promote innovation and technological progress in society. This exclusivity often results in monopolistic practices that undermine social welfare or may restrict access to technologies. Although international instruments defined the right over one's own creations, they are distinct from human rights which are fundamental and inalienable. Therefore, priority ought to be for human rights and any other rights must be enforced in harmony with them.

Patents protect a new product or process. However, making the invention available to the public is the discretion of the patent holder. They may decide whether to commercialize or market the invention or keep them at high prices. Broad patents may block further research. Moreover, profit driven priorities in the industry often result in lack of innovation in areas with limited commercial potential. This is especially harmful in health care, where it can limit access to life-saving treatments. A drug, for example, might resolve a health crisis but remain out of reach for patients due to affordability.

Orphan drugs are one of the most striking examples of the public health concerns raised by the patent system. They are used for the treatment of rare diseases. Drug development is difficult owing to multiple challenges such as lack of adequate natural history studies, varied symptoms, geographical disparity of patients, statistical hurdles in clinical trials, etc. The market size being small, the industry would be reluctant to divert resources and invest in orphan drug research and development since the recoupment of investment is unlikely. Out of the 6000 – 8000 rare diseases found around the world, only a few have approved treatment. In such commercially unviable areas, patents fail as a tool to encourage innovation. Furthermore, the limited number of available treatments are often priced so high that they remain inaccessible to many.

International instruments envisage the right to health as a human right, placing the responsibility on states to achieve the highest possible standard of health and well-being. The conflict between intellectual property rights and the human right to health has been debated for decades, with the TRIPS flexibilities and the Doha Declaration representing efforts to reconcile these two frameworks. These efforts aim to ensure there is innovation without undermining right to health. In reality, however, these are not adequately utilised thus increasing health disparities. The current scenario therefore, is inadequate in achieving public health goals, especially in neglected and underfunded areas such as orphan drugs. A different outlook in the regulatory framework is essential, which gives due importance to principles of human rights and public health in patents.

This paper describes the challenges of patent law in incorporating human rights concerns and addressing social welfare issues. The problems of patent system in not sufficiently promoting

innovation, and also in restricting access, are highlighted through the case of orphan drugs. This paper advocates for a rethinking of patents from the lens of human rights by incorporating structural reforms. Such a shift is essential in aligning patent law with public health objectives.

PATENT LAW AND HUMAN RIGHTS: LAYING THE THEORETICAL FOUNDATION

Though both patent law and human rights originates from different rationales, they share a broader common goal of improving the society. In fact, the protection of interests resulting from one's own creation have been enshrined in human rights instruments.[414] Patents are designed to encourage innovation, stimulate investment in research and enhance dissemination of knowledge.[415] Human rights are universal and inalienable. They are inherent rights possessed by virtue of being human and not granted or dependent on any legal recognition.[416] Health is a core element of human well-being, forming the basis for personal dignity and the overall welfare of society. A healthy population is essential for economic growth, national progress, and social harmony. The Universal Declaration of Human Rights affirms every person's right to adequate standard of living, including medical care.[417] The International Covenant on Economic, Social and Cultural Rights stipulates the right to the highest attainable standard of health and requires states to take deliberate steps to achieve this right. These measures include lowering mortality rates, improving child development and hygiene, preventing and treating diseases, and ensuring universal access to medical services.[418] This is reinforced by General Comment No. 14 from the Committee on Economic, Social and Cultural Rights. Sustainable Development Goal 3 of the United Nations further underscores the global commitment to ensuring healthy lives and promoting well-being of all ages.[419] The right to health is reaffirmed in UN resolutions concerning the 2030 Agenda for Sustainable Development, which emphasize both physical and mental health.[420]

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[414] *International Covenant on Economic, Social and Cultural Right* (adopted on 16 December 1966 entered into force on 3 January 1976) 993 UNTS 3 (ICESCR) art 15(1)(c); Universal Declaration of Human Rights (adopted 10 December 1948) UNGA Res 217 A(III) (UDHR) art 27

[415] Elizabeth Verky, 'Pharmaceuticals and Patents', *Law of Patents* (2nd edn, Eastern Book Company 2012); Gerard Marshall Raj, Rekha Priyadarshini and Jayanthi Mathaiyan, 'Drug Patents and Intellectual Property Rights' (2015) 71 European Journal of Clinical Pharmacology 403; Joo-Young Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines* (Routledge 2016)

[416] Lee (n 2)

[417] Universal Declaration of Human Rights (adopted 10 December 1948) UNGA Res 217 A(III) (UDHR) art 25

[418] International Covenant on Economic, Social and Cultural Right (adopted on 16 December 1966 entered into force on 3 January 1976) 993 UNTS 3 (ICESCR) art 12

[419] Transforming Our World: The 2030 Agenda for Sustainable Development (adopted on 25 September 2015) UNGA Res 70/1

[420] The right of everyone to the enjoyment of the highest attainable standard of physical and mental health in the implementation of the 2030 Agenda for Sustainable Development (adopted on 23 June 2017) UNGA Res 35/23

Although the right to health is part of economic and social rights and may not be fully realized immediately, states are obligated to make continuous progress based on their available resources.[421] At a minimum, they must guarantee access to essential and primary healthcare services. The right to health also entails the availability and affordability of safe, quality medical services without discrimination. States must also consider the unique health needs of different population groups and support the development of drugs and vaccines, especially in areas lacking sufficient research or investment.[422]

The right to health is a core human right that takes higher precedence. Other international instruments also support the goal of reaching the optimal health standard.[423] The UN Committee on Economic, Social and Cultural Rights in General Comment 17, underscores the importance of prioritizing right to health over intellectual property rights emphasising that protection for creators must not obstruct fulfilment of health needs.

In theory, patent system is designed to align with public policy objectives and promote societal development. Several perspectives attempt to justify the system, however, none fully captures the whole picture. The classic view associates it with property, where everyone has a natural right to enjoy the fruits of their own labour, including their intellectual labour. An inventor mixes their individual labour with existing resources to create new knowledge and therefore deserves a monopoly over the invention as an extension of their ownership. However, unlike physical objects, information is non-rivalrous and it's often built on prior knowledge.[424] Patents do not create distinct boundaries on rights since the grant of patents depend on what did not exist before and the benefits enjoyed by the patent holder depends on what product emerges post the grant.[425] Possession of an intellectual object requires an act from an authority and therefore it is difficult to determine who gets what as a natural right.[426]

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[421] United Nations Human Rights Office of the High Commissioner, 'Fact Sheet No. 21: The Right to Health' (1 June 2008) <https://www.ohchr.org/sites/default/files/Documents/Publications/Factsheet31.pdf> accessed 5th September 2024

[422] *Ibid*

[423] International Convention on the Elimination of All Forms of Racial Discrimination (adopted 21 December 1965, entered into force 4 January 1969) UNGA Res 2106 (XX) ICERD art 5; Convention on the Elimination of All Forms of Discrimination against Women (adopted on 18 December 1979, entered into force 3 September 1981) 1249 UNTS 13 (CEDAW) art 11, 12, 14; Convention on the Rights of the Child (adopted 20 November 1980, entered into force 2 September 1990) 1577 UNTS 3 (UNCRC) art 24; Convention for the Protection of Human Rights and Fundamental Freedoms (European Convention on Human Rights, as amended) (ECHR) art 3 ; African Charter on Human and Peoples' Rights (adopted 27 June 1981, entered into force 21 October 1986) (1982) 21 ILM 58 (African Charter); Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights (Protocol of San Salvador) (entered into force 16 November 1999) OAS Treaty Series No 69 (1988) reprinted in Basic Documents Pertaining to Human Rights in the InterAmerican System OEA/Ser L V/II.82 Doc 6 Rev 1 at 67 (1992)

[424] Lee (n 2)

[425] Robin Feldman, *Rethinking Patent Law* (Harvard University Press 2012)

[426] Lee (n 2)

Under the economic rationale, the patent is a tool to enhance technological progress. It lies in correcting market failure since creating knowledge is costly, but copying is cheap, and innovators lack incentive without protection. Patents enable recoupment of their investment and encourage innovation and commercialisation. The focus is on long-term societal benefits of innovation and knowledge sharing, with a short-term restriction. This raises the dilemma where the system intends to increase the production of knowledge by impeding the diffusion of knowledge. An appropriate balance between economic benefits and social costs is essential to the effectiveness of the patent system.[427]

Although patents aim to promote innovation, their effectiveness is often questioned. The impact of patents varies across industries. In the health sector, where innovation is critical, many important areas lack sufficient research because social needs don't always translate into profitable market demand. This raises doubts about whether patents are truly effective in encouraging invention. Moreover, patents can limit availability and affordability, raising further doubts. These challenges underscore the need for a more balanced and socially responsive approach that prioritizes equity and public well-being.

PUBLIC HEALTH IMPLICATIONS OF PATENTS: THE ORPHAN DRUG EXAMPLE

The orphan drug regime serves as a powerful case study to demonstrate the inadequacies of the patent system. It shows the reality where the market potential is prioritised over social necessity. This case highlights a dual failure of the patent regime: its inability to spur innovation and the resulting limitations on access.

Orphan drugs are pharmaceuticals designed for rare diseases. A rare disease is characterized by its low prevalence among people. Diseases like Haemophilia, Sickle Cell Anaemia, Gaucher's Disease, and Spinal Muscular Atrophy are illustrative examples. The term rare disease however, does not have a uniform definition. Different countries have placed varying thresholds on what is a rare disease. Other than the prevalence, factors such as disease severity and availability of alternate treatments are considered for forming the definition. In the United States, a disease is classified as rare if it impacts fewer than 200,000 individuals. However,

[427] *Ibid*; Christopher Buccafusco and Jonathan S Masur, 'Drugs, Patents, and Well-Being' (2021) 98 Wash. UL Rev. 1403; Richard D. Nelson and Roberto Mazzoleni, 'Economic Theories about the Cost and Benefits of Patents', *Intellectual property rights and the dissemination of research tools in molecular biology: summary of a workshop held at the National Academy of Sciences, February 15-16, 1996* (National Academy Press 1997); Ravinder Jha, 'Pharmaceutical Patents: Cathartic or Inhibiting' (2024) 27 The Journal of World Intellectual Property 428; Yi Qian, 'Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment? A Cross-Country Analysis of Pharmaceutical Patent Protection, 1978–2002' (2007) 89 The Review of Economics and Statistics 436

conditions affecting a larger population may also fall under this definition if the anticipated revenue from treatment would not be sufficient to offset development costs, as outlined in the Orphan Drug Act of 1983. The European Union defines a rare disease as one that is life-threatening or chronically debilitating and affects no more than 5 out of every 10,000 people, according to Regulation (EU) 141/2000. Australia adopts a similar criterion. Japan identifies rare diseases as those with fewer than 50,000 affected individuals.[428]

Almost 6000 – 8000 diseases have been identified, and in aggregate, a substantial population is affected by rare diseases. Very few of these diseases have approved treatments, and when treatments do exist, they are often extremely costly. The landscape is dynamic and complex, with varying symptoms, delayed and inaccurate diagnosis, lack of specialisation among healthcare providers, and a lack of awareness among populations. Developing drugs for rare diseases is especially difficult because of several challenges. Not enough information about the disease is known, making it hard to find treatment targets or measure how well a drug works. Suitable animal models may not be available, which limits testing before human trials. Clinical trials are also tough to carry out because there are very few patients who maybe geographically dispersed, and ethical concerns arise—especially when children or other vulnerable groups are involved. The small number of patients also means there isn't enough data to fully understand a drug's safety. On top of that, developing these drugs is very expensive, and companies are unlikely to earn back their investment due to the small market. As a result, many potential treatments are dropped early in the process. The high development costs, limited funding, and lack of adequate protections or incentives result in minimal interest and investment in the field. Only very few of these diseases have any approved treatment and where treatment is available it is highly expensive.[429]

High costs and low chances of success make drug developers focus only on projects with strong financial prospects. Since orphan drugs target small markets, recovering investments through

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[428] David C Pryde and Michael J Palmer (eds), *Orphan Drugs and Rare Diseases* (Royal Society of Chemistry 2014); Marilyn J Field and Thomas F Boat (eds), *Rare Diseases and Orphan Products: Accelerating Research and Development* (National Academies Press 2010); Elizabeth Hernberg-Ståhl and Miroslav Reljanović, *Orphan Drugs: Understanding the Rare Disease Market and Its Dynamics* (Woodhead 2013); Pedro Franco, 'Orphan Drugs: The Regulatory Environment' (2013) 18 Drug Discovery Today 163; Proteesh Rana and Shalini Chawla, 'Orphan Drugs: Trends and Issues in Drug Development' (2018) 29 Journal of Basic and Clinical Physiology and Pharmacology 437; A Lavandeira, 'Orphan Drugs: Legal Aspects, Current Situation' (2002) 8 Haemophilia 194

[429] Field and Boat (n 15); Pryde and Palmer (n 15); Rana and Chawla (n 15); Hernberg-Ståhl and Reljanović (n 15); Rosângela Caetano and others, 'Dynamics of Patents, Orphan Drug Designation, Licensing, and Revenues from Drugs for Rare Diseases: The Market Expansion of Eculizumab' (2021) 16 PloS One e0247853; R Rodriguez-Monguio, T Spargo and E Seoane-Vazquez, 'Ethical Imperatives of Timely Access to Orphan Drugs: Is Possible to Reconcile Economic Incentives and Patients' Health Needs?' (2017) 12 Orphanet Journal of Rare Diseases 1

sales is unlikely, leading to limited research and early discontinuation. Patent-related concerns also reduce commercial interest, which together restricts the availability of treatments and limits patient access. Despite patent protections, orphan drug development and access remain insufficient.

Patent law has inherent limitations, especially evident in the context of orphan drugs. Heavy dependence on market dynamics tends to create monopolies where manufacturers invest primarily in drugs that promise high financial returns. This market-driven approach often leads to increased R&D without true innovation, resulting mainly in "me-too" drugs and minor modifications of existing compounds rather than entirely new therapies with significant therapeutic value. Additionally, pharmaceutical companies tend to concentrate on diseases prevalent in wealthy countries, neglecting those more common in low- and middle-income nations.[430]

Due to small patient populations, companies find it difficult to recoup investments, which discourages research and development. The geographical variation in disease prevalence means a condition may be considered rare in one country but common in another. Firms tend to focus on more common diseases, even if existing treatments are available, since these markets promise higher profits. Additionally, the limited understanding of rare diseases' pathophysiology complicates drug discovery. As a result, orphan drugs remain underfunded and underdeveloped, attracting little commercial interest.[431]

The goal of patents is to secure investments and promote the development of socially valuable inventions. But this does not happen in reality. Any invention that is new, non-obvious, and industrially applicable is awarded a patent for a fixed uniform term. Factors such as the cost of development or the societal impact of the invention do not form part of the evaluation or grant process. Therefore, inventions such as drugs with high developmental costs would be rendered unpatentable, while inventions with low development costs may easily obtain patents. Therefore, firms would also be interested in securing strong patent protection and many treatments that could solve a potential health crisis would be disregarded since they lack patent

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[430] Fernando Antoñanzas, Carmelo Juárez-Castelló and Roberto Rodríguez-Ibeas, 'Pharmaceutical Patents, R&D Incentives and Access to New Drugs: New Ways of Progress at the Crossroad' (2011) 12 The European Journal of Health Economics 393; Jha (n 14); Buccafusco and Masur (n 14); Alexander Tabarrok, 'Patent Theory versus Patent Law' (2002) 1 Contributions in Economic Analysis & Policy

[431] Michael Abramowicz, 'Orphan Business Models: Toward a New Form of Intellectual Property' (2011) 124 Harvard Law Review 1362; Conor MW Douglas and others, 'Social Pharmaceutical Innovation and Alternative Forms of Research, Development and Deployment for Drugs for Rare Diseases' (2022) 17 Orphanet Journal of Rare Diseases 344; Field and Boat (n 15); Theresa M Wizemann, Sally Robinson and Robert B Giffin, *Breakthrough Business Models: Drug Development for Rare and Neglected Diseases and Individualized Therapies: Workshop Summary* (National Academies Press 2009)

eligibility.[432] The scope of the patent system is restricted to the invention and not the upliftment of sectors that need targeted investments. Therefore, research on drugs that could result in lifesaving treatments would not be pursued. Difficulties and expense of basic research, coupled with challenges in designing clinical trials, raise risks for manufacturers with little prospect of financial return.

Access to medicines is another significant issue, as many patients cannot afford patented drugs. Successful uptake of new treatments depends not only on their existence but also on reimbursement mechanisms and patients' purchasing power. Patents can restrict availability and affordability, undermining their intended goal of maximizing social welfare. These issues pose serious public health challenges, leaving many rare disease patients with unmet medical needs and highlighting the necessity for government intervention.[433] From a human rights perspective, individuals with rare conditions deserve equal protection and care as those with more common illnesses, placing a duty on states to uphold these rights.

RETHINKING PATENT: TOWARDS A NORMATIVE FRAMEWORK INCORPORATING HUMAN RIGHTS

The limitations of patent law evaluated from the public health perspective have been elucidated above with the illustration of orphan drugs. It fails to adequately address commercially nonviable areas. Moreover, the patent system does not fully align with social and human welfare goals. Hence, the need for a rights-based public health-oriented approach.

The attempts to reconcile the tensions between patents and human rights, especially in the right to health context, are not new. The TRIPS agreement was designed to balance the interests of innovators and to advance public health. The agreement emphasises on promotion of technological innovation and the dissemination of knowledge without undermining initiatives to promote and protect health.[434] Considering the impact on public health, the flexibilities provided in the TRIPS agreement can be viewed as early attempts to align intellectual property rules with broader human rights principles. The Doha Declaration reiterated this goal by emphasizing on need to support public health and ensure policy coherence.

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[432] Abramowicz (n 18); Shamnad Basheer, 'The Invention of an Investment Incentive for Pharmaceutical Innovation' (2012) 15 The Journal of World Intellectual Property 305; Tabarrok (n 17); Benjamin N Roin, 'Unpatentable Drugs and the Standards of Patentability' (2009) 87 Tex. L. Rev. 503

[433] Ruth L Okediji, 'Does Intellectual Property Need Human Rights' (2018) 51 NYUJ Int'l L. & Pol. 1.

[434] General Agreement on Trade-Related Aspects of Intellectual Property (15 April 1994) 1869 U.N.T.S. 299 art 7 and art 8 <https://www.wto.org/english/docs_e/legal_e/27-trips.pdf > accessed 19 September 2024

Since countries differ in their economic and administrative capacity, the effect of TRIPS agreement and its implementation also varies. Therefore the agreement allowed extended transition periods for developing and least developed countries to fully incorporate its provisions into national systems. For example, least developed countries have until 2033 to comply with TRIPS requirements related to pharmaceutical patents. During this time, they can use the "mailbox" system to accept patent applications and grant exclusive marketing rights for five years if such products are marketed.[435]

With the goal of safeguarding public health, TRIPS envisage for flexibilities. These include compulsory licensing, which allows governments to authorize the use of a patented invention without the patent holder's consent in the public interest, and parallel importation, which enables the import of patented products sold elsewhere, supporting affordability and access. [436]Additionally, TRIPS permits member states to define the scope of patentable subject matter.[437] Countries may also introduce exceptions to patent rights where it does not unfairly harm the patent holder.[438] These exceptions support access to medicines and vaccines, especially during health emergencies. Other flexibilities include allowing research use of patented inventions, early working provisions for generics (to obtain regulatory approval before patent expiry), and national discretion in data protection standards.

TRIPS flexibilities are important tools for aligning patent rights with public health needs, yet they remain largely underused. Although mechanisms like compulsory licensing and parallel importation can improve drug access without violating patent holders' rights, many countries hesitate to use them due to legal complexity, political pressure, and lack of clarity in implementation. The Doha Declaration reaffirmed countries' rights to use these flexibilities, but their practical application remains limited.[439] This gap highlights the need for a stronger commitment to public health over market-driven constraints.

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[435] *Ibid* art 65, 66, 70.8; World Trade Organisation, 'Trips and Pharmaceutical Patents' (September 2006) <https://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf> accessed 19 September 2024; World Trade Organisation, 'Compulsory licensing of pharmaceuticals and TRIPS' <https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm > accessed 19 September 2024

[436] n (21) art 31

[437] *Ibid* art 27

[438] *Ibid* art 30

[439] German Velasquez, 'The Right to Health and Medicines: The Case of Recent Multilateral Negotiations on Public Health, Innovation and Intellectual Property' (2014) 14 Developing World Bioethics 67; Lisa Forman, 'The Intergovernmental Working Group on Public Health, Innovation and Intellectual Property', *Realizing the Right to Development* (2013); Ana S Rutschman, 'Intellectual Property as Determinant of Health' (2021) 54 Vanderbilt Law Review 513; Frederick M Abbott, 'Health and Intellectual Property Rights', *Research Handbook on Global Health Law* (Edward Elgar Publishing 2018)

In the case of areas such as orphan drugs, the core issue is the lack of development which is out of the scope of these flexibilities since the latter is designed to promote access. The rare disease domain being commercially unattractive, there are investments in research and development. The lack of an existing framework prompted the exploration of alternate mechanisms to promote innovation. Several countries have implemented legal frameworks that offer economic incentives to promote the development of orphan drugs. The US Orphan Drug Act, EU Regulation 141/200, Australia's Therapeutic Goods Act, Medicines (Orphan Drugs) (Exemption) Order of Singapore, Taiwan's Rare Disease and Orphan Drug Act, 2000 are prominent examples. The key incentive provided across these frameworks is market exclusivity, which prevents approval of similar drugs for a set period. This period is independent of the patent term. Other incentives include tax credits, fee waivers, fast-track reviews, protocol assistance etc.[440]

Rethinking patent law requires a change in outlook where human rights (right to health in this context) form the core consideration and not market logic. This requires embedding patent law with public health safeguards. Public health determinants such as access, affordability, and availability, therefore, ought to be given due regard. Moreover, adequate resources should be dedicated to address the needs of marginalised and vulnerable sections of society. International instruments aim to achieve this goal by encouraging positive obligations from the part of the state. Ultimately, the goal is to ensure that the impact of patents do not undermine the rights of people.

Orphan drugs is an illustration of how a market-based approach violates basic principles such as dignity and non-discrimination. These implications are beyond the traditional scope of patent law. Further, the industry is often ignorant of the public health impacts, considering the prohibitive costs of research and development. Although the industry does not have an inherent obligation to protect and preserve the right to health, the state cannot shake off its responsibility. It is accountable to the people and has to take proactive steps to promote the right through encouraging research and promoting access. The reluctance of the industry to pursue research is primarily due to the high cost of development. Hence, separating the cost of development and price could be a good strategy, which can be achieved through incentives

[440] Adrienne YL Chan and others, 'Access and Unmet Needs of Orphan Drugs in 194 Countries and 6 Areas: A Global Policy Review With Content Analysis' (2020) 23 Value in Health 1580; Franco (n 15); Todd Gammie, Christine Y Lu and Zaheer Ud-Din Babar, 'Access to Orphan Drugs: A Comprehensive Review of Legislations, Regulations and Policies in 35 Countries' (2015) 10 PLOS ONE e0140002; Bao-cheng Liu and others, 'A Cross-National Comparative Study of Orphan Drug Policies in the United States, the European Union, and Japan: Towards a Made-in-China Orphan Drug Policy' (2010) 31 Journal of Public Health Policy 407

such as grants, rewards, and push and pull incentives. External funding sources should also be explored, which include those from the private sector, especially pharmaceutical companies. Moreover, public investment schemes and crowdfunding should be encouraged. Such efforts can increase interest in R&D since the cost of development can be brought down significantly by reducing the initial financial burden. Measures such as fee waivers, protocol assistance, etc., can ease the bureaucratic hurdles.

Integration of human rights into patent law requires a holistic approach that starts with the strict implementation of TRIPS flexibilities. Their proper utilisation firmly affirms the health priorities without compromising innovation. These flexibilities enhance the availability and access to medicines by acknowledging the rights and interests of patent holders and inventors, as well as members of the general public who require access to new and effective treatments. Thus, they serve public interests and societal development.

In addition to these, incorporating health providers in patent policy can also ensure that the requirements of public health are included in the intellectual property domain at an early stage. This increases diversity in stakeholder representation. Further, many irrelevant and redundant claims can be filtered in patent valuation with the involvement of health experts. Generic medicines can therefore make a timely entry, providing affordable medicines. Moreover, Health Impact Assessments and Health Technology Assessments could be effective tools in patent grant process, which can clearly assess the health implications of inventions, such as those on pricing and availability. Public-private partnerships and patent pools can promote collaborative research and data sharing. Transparency in pricing and disclosure of expenditure can also serve societal needs by enabling proper assessment and planning of healthcare policy and budget. Such a robust framework in no way hinders innovation. They only ensure that the fruits of the innovation are ultimately received by those in need.

CONCLUSION

Intellectual property rights, especially patents, significantly contribute to global healthcare. A proper framework ensures the balance between these domains. Patents are relevant in maintaining market competition, advancing consumer welfare and attracting foreign investment, all of which contribute to national development. A harmonised relationship can therefore ensure optimal results in the long run. Treating both as completely unconnected only undermines societal welfare. Measures such as TRIPS flexibilities, are positive steps in realizing this interconnection, but an international framework or effective guidelines is yet to be developed.

Orphan drugs is an example that reveals the inadequacies of the patent system and its adverse effects on public health. Rare diseases remain an ignored domain due to industry reliance on profits. Priority for common conditions is favourable since they generate profits due to high demand. Complexities in research and development due to a lack of adequate scientific understanding, insufficient infrastructure, and lack of expertise further discourage investment in research. Development is risky and costly, and the possibility of recoupment of investment is unlikely. Moreover, the scope of patent is limited to new and non-obvious inventions and is not to support areas that need public investments and policy backing. Therefore, patents not only fail to incentivise innovation but also hinder access and availability. The fundamental disconnect between the goals of patents and the needs of public health raises concerns where commercial incentives alone are insufficient.

A new framework is therefore essential, which includes mechanisms for funding, price regulation, and technology transfer. This would ensure that inventions serve public interest by being available and affordable. Such an inclusive outlook places commercial objectives at a lesser priority. Ethical concerns are also addressed in such a scenario. The emphasis shifts towards fairness, transparency and accountability. A revised framework supports technological advancements as well as equitable access. States should ensure the implementation of such a system without any financial strain on public resources. This also requires coordination among various stakeholders, especially international bodies and other institutions, including national intellectual property authorities and human rights organisations. The current global health challenges and health disparities reveal the urgent need for reshaping the intellectual property system. Embedding public health values into intellectual property governance can help in achieving true health equity and universal healthcare.