



Human Rights approach to intellectual property and access to medicines

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Abstract

The paper highlights on human rights approach to intellectual property rights and access to medicines in healthcare sector in India. A human rights approach to intellectual property (IP) and access to medicines considers the right to health and the need for affordable medicines. In the pharmaceutical industry, patents, trademarks, copyrights, trade secrets and regulatory exclusivities play a vital role in protecting pharmaceutical companies and creating a competitive landscape for drug development. Intellectual Property Rights law infringes on the different areas of Human Rights law, especially when economic, social and cultural rights are concerned. Intellectual property regimes request to balance the ethical and economic rights of creators and inventors with the broader interests and desires of the society. In 2025, the United Nations High Commissioner is to present a comprehensive study on the human rights approach to intellectual property and access to medicines. This article will be based on a compendium of good practices and an analytical study on challenges. Access to medicines is a fundamental part of the right to health. The right to health includes the right to prevent, treat, and control diseases. The balance between access and profit is a key issue in debates about intellectual property protection. Addressing the issue of antimicrobial resistance, the rise of antimicrobial resistance poses a significant threat to global health. The Trade-Related Aspects of Intellectual Property System (TRIPS) agreement is the most comprehensive international agreement on intellectual property protection. The TRIPS agreement includes exemptions and amendments, called "flexibilities". The TRIPS agreement can be used to support public health policies that promote access to medicines. The TRIPS agreement can be used to facilitate access to medicines in other countries. The patent system can stifle innovation. The patent system can divert patents from their purpose of encouraging innovation. The patent system can negatively affect early access to cheaper alternative products.

Keywords: Access to medicines, intellectual property, compulsory licensing, public health, international agreements, health systems, competition, pricing, and licensing, etc

Introduction

The human rights approach to intellectual property (IP) and access to medicines in India involves balancing IP rights with the right to health. This can be done by creating a flexible legal framework that includes mechanisms like compulsory licensing and fair use doctrines. Patenting life-saving drugs has made human life a commodity and has created conflicts and disasters during times of global healthcare urgency. While Intellectual Property Rights ("IPR") serve as a driving force for innovation and research through the creation of life-saving drugs, it also gives rise to conflicts. The application of IPR within healthcare systems creates tension between the exclusive rights granted by patents and the universal right to health. Human rights guidelines framed concerning the right to health include attainable standards of health concerning high pricing, inappropriate drug promotion, clinical trials, etc. but have not been modified with respect to the growing importance of IPR in the legal field to encourage access to affordable medicines during times of pandemics or epidemics. Health is a multifaceted concept, encompassing physical, mental, and social well-being. Its realization is influenced by a myriad of factors, including socioeconomic conditions, environmental factors, and access to healthcare services. Central to this is the availability of essential medicines, which are crucial for preventing, treating, and managing diseases. International human rights law recognizes the right to health as a fundamental right, with the International Covenant on Economic, Social, and Cultural Rights (ICESCR) being the cornerstone. This treaty outlines the

obligations of states to provide essential medicines and healthcare services to their populations. However, the realization of this right has been hindered by various challenges, including the high cost of medicines.

The Role of Intellectual Property Rights (IPRs)

IPRs, including patents, are intended to incentivize innovation by granting exclusive rights to inventors for a limited period. While essential for promoting research and development, these rights can also create barriers to access to medicines, particularly in developing countries.

The TRIPS agreement, under the World Trade Organization (WTO), sets minimum standards for the protection of intellectual property rights, including patents. While it has contributed to increased innovation in the pharmaceutical sector, it has also raised concerns about its impact on access to medicines.

Access to Medicines in Developing Countries

Developing countries face significant challenges in ensuring access to medicines. High drug prices, coupled with weak healthcare systems, often result in patients being unable to afford essential treatments. This is particularly acute for chronic diseases like HIV/AIDS, tuberculosis, and malaria. To address this issue, several mechanisms have been introduced, including compulsory licensing and parallel imports. Compulsory licensing allows a government to authorize a third party to produce a patented product without the patent holder's consent under specific circumstances. Parallel imports involve importing a product from another country where it is legally marketed at a lower price.

India’s Stance on Access to Medicines

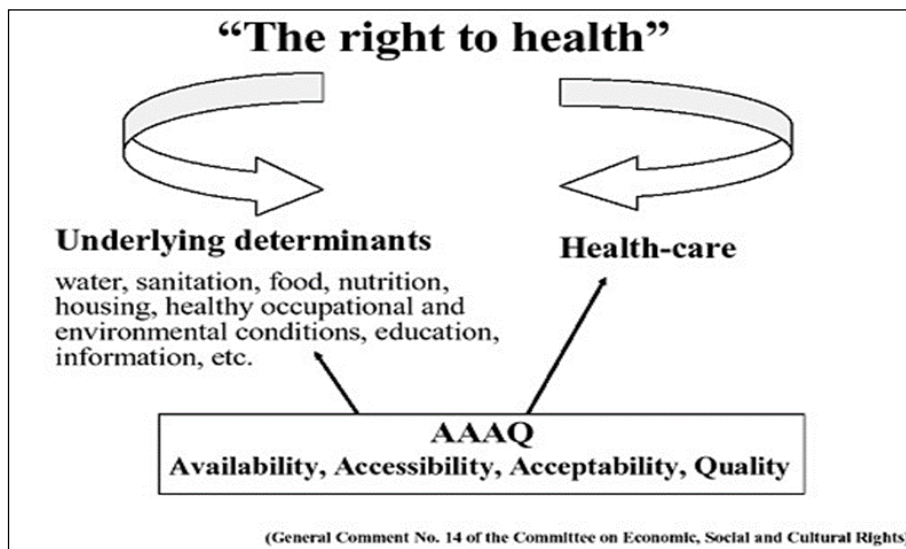
India has played a crucial role in promoting access to medicines. The country has a robust generic drug industry, which has significantly reduced drug prices globally. India has also been at the forefront of utilizing flexibilities provided under the TRIPS agreement, such as compulsory licensing, to address public health crises. However, challenges persist. The Indian pharmaceutical industry faces pressure from developed countries to strengthen intellectual property protection. Moreover, the rising cost of drug development and the increasing complexity of patent laws pose challenges to the generic drug industry.

“Human rights” are a set of formal law-based systems and obligations, as well as a group of normative claims about human flourishing and development. The 1948 Universal Declaration of Human Rights (UDHR) seeks to guarantee everyone a dignified livelihood with opportunities for personal development focusing more on the just distribution of material and non-material advantages. It is further reflected in the two 1966 covenants; the International Covenant on Economic, Social and Cultural rights (ICESCR) and the International Covenant on Civil and Political Rights (ICCPR) could be employed to support the three generations of human rights.

First Generation Rights: Classical Civil and Political Rights are traditional bastion of rights which guarantees the rights of the private individual such as the right to life, liberty and human dignity. European Courts have emphasized that the rights to human dignity and personal development constitute the basis for moral rights under *copyright law*, moreover, this right has been important to limit the extent of *patent protection* on biotechnological material.

Second Generation Rights: Social, Economic and Cultural human rights oblige public authorities to take active measures to provide for the community by granting individual rights to property, food, health care, labour and education. This set of human rights reflects the current discourse as to how intellectual property rights can affect access to knowledge and essential medicines.

Third generation Rights: Third generation human rights secure collective rights which include rights to membership in a cultural or indigenous community, access to a healthy environment, and rights to development or self-determination. These rights have much relevance today in the claims for protection of traditional knowledge, and for protection against excessive exploitation of indigenous knowledge by ethno-bio-prospecting.



Done to balance IP rights and the right to health

1. Compulsory licensing

Allows the government to grant permission to a third party to produce a patented product without the patent owner's consent. This can be used in public health emergencies.

2. Fair use doctrines

Create a legal environment that allows for the use of copyrighted material for certain purposes, such as research.

3. Ethical impact assessments

Ensure that innovators consider the societal implications of their creations early in the research and development process.

4. Responsible innovation practices

Identify and address potential human rights concerns throughout the lifecycle of an innovation. The issues with IP rights and access to medicines.

5. Restrictive IP laws

Can make essential medicines like vaccines inaccessible.

6. Overprotection of IP

Can occur when different IP laws protect the same topic simultaneously

7. Commodification of essential medicines: Can increase inequalities and national and international indebtedness.

The Rights of Inventors in Human Rights

The three most important intellectual property-related documents are the UDHR, the ICESCR and the ICCPR. These human rights instruments can be employed to bind states to design an Intellectual Property Rights system that strikes a balance between promoting public interests in areas of health, culture and education while protecting the

property rights of the inventors. Art. 27 of UDHR is the primary intellectual property provision which provides rights for *MORAL AND MATERIAL INTERESTS* resulting from any scientific, literary or artistic production. This is further complemented in Art.17 of UDHR which declares that everyone has the right to own property alone or in association with others and that no one should be arbitrarily deprived of his property. Art.12 further provides protection against interference with ‘privacy, family, home or correspondence’ and against attacks upon honour and reputation. These rights may be viewed as a further basis for certain types of specific rights which exist within the broader intellectual property rights such as an action for breach of confidence, trade secrets, moral rights and personality rights.

1. International Covenants

The two covenants were adopted 20 years later to make the UDHR freedoms binding as a matter of international treaty law. The ICCPR does not offer a positive basis for the protection of intellectual property rights but indirectly prevent attacks on honour and reputation.

Art.19 (2) of ICCPR guarantees everyone the right to freedom of expression which includes the right to receive and impart information and ideas on condition that by respecting rights and reputations of others. The ICESCR recognizes at a general level that a nation’s social and economic development is realized by improving methods of production, conservation and distribution of resources through technical and scientific knowledge and by developing efficient systems so as to achieve efficient development and utilization of resources. (Asrt.11.2). On a specific level it guarantees the protection of intellectual property as a human right for all creators.

2. Art.15 of ICESCR provides that ‘the State parties should recognize the right of every one:

- To take part in cultural life;
- To enjoy the benefits of scientific progress and its applications;
- To benefit from the protection of the moral and material interest resulting from any scientific, literary or artistic production of which he is the author

Thus, Art. 15 identify a need to balance the protection of both public and private interests in intellectual property. Art. 15 promote access to scientific and cultural rights as human rights whilst protecting the authors of scientific and cultural goods without specifying the modalities of such protection. Hence it recognized intellectual property rights as human rights. In a recent decision The European Court of Human Rights held that intellectual property undoubtedly attracted the protection of Art.1 of Protocol No. 1 of the European Convention on Human rights and this protection extends even to trade mark registration.

3. Intellectual Property Rights and Access to Medicines

Intellectual property (IP) has different forms; in the case of access to medicines, we are talking about patents. Patents are a public policy instrument aimed at stimulating innovation. By providing a monopoly through a patent—which gives inventors an economic advantage—governments seek to provide an incentive for R&D. At the

same time, the public benefits from technological advancement. This trade-off underpins patent systems everywhere. Governments need to maintain an appropriate balance between incentivizing innovation, on the one hand, and, on the other, ensuring that new products are widely available. High levels of IP protection in developing countries exacerbate, rather than help solve, the problem of access to affordable medicines. Extensive patent protection for new medicines delays the onset of generic competition. And because generic competition is the only proven method of reducing medicine prices in a sustainable way, such high levels of IP protection are extremely damaging to public health outcomes. The 1994 TRIPS Agreement represented the single greatest expansion of IP protection in history, but it also includes a range of public health safeguards and flexibilities, which were reinforced by the 2001 Doha Declaration on the TRIPS Agreement and Public Health. The relationship between human rights and intellectual property is a troubled one and is epitomized by the contentious issue of access to patented medicines.¹ Patent protection can interfere with access to medicine in two key ways: by granting monopolies in pharmaceutical production, raising the cost of medicines to often unaffordable prices; and by providing a profit mechanism that incentivizes research of diseases primarily affecting countries with lucrative markets over diseases prevalent in developing countries. 2. The result is a “global drug gap” wherein novel drugs are often inaccessible to most of the world’s population. Access to medicines as one of the most explicit examples of economics and trade rules conflicted with human rights, including the rights to life, health and development. She focused on how intellectual property rights had an impact on drugs, illustrated by the increase in drug prices in Malaysia of 28 per cent per year between 1996 and 2005 following the implementation of TRIPS. Over 2 billion people still lacked access to essential medicines, with drug pricing remaining a key obstacle to access. States should be held to account in the universal periodic review process for imposing TRIPS-plus provisions in free trade agreements as a violation of the right to health. United Nations Conference on Trade and Development (UNCTAD) mandate in that area was based on the 2012 Doha Mandate (TD/500/Add.1, para. 65 (j)), and its assurance of the supply of essential medicines. UNCTAD had observed an increased need to diversify and expand pharmaceutical production. In the future India might no longer be considered the “pharmacy of the world”. However, it was necessary to create awareness among policymakers and judges on the application of TRIPS flexibilities to enhance access to medicines.

World Trade Organization (WTO), highlighted the intersection of health, trade and intellectual property rights. The Doha Declaration on the TRIPS Agreement and Public Health was a major milestone in understanding those intersections, recognizing the importance of intellectual property in the development of new medicines while acknowledging possible effects on pricing—a basis for international policy discussions seeking to implement practically an appropriate balance between promoting access and innovation. Further recommended greater international cooperation to fulfil the right to health, required for sustainable development and outlined three broad areas for future work: (a) elucidation of rules, data and industry developments; (b) coordination of operations

and system-wide coherence; (c) implementation and action. Drawing on the study by WTO, the World Intellectual Property Organization and WHO, *Promoting Access to Medical Technologies and Innovation*, need to strengthen national health systems and to develop innovative procurement solutions within existing legal and policy frameworks.

During the interactive dialogue, comments were made by representatives of Colombia, India, Mexico, the Colombian Commission of Jurists, Knowledge Ecology International, the People's Health Movement-Safe Observer International, Third World Network, Universities Allied for Essential Medicines, as well as by Dr. Bermudez, Dr. Schiavon and Regina Kamoga, Executive Director, Community Health and Information Network, Uganda. They discussed the following: South-South cooperation; patent monopolies; TRIPs-plus provisions in free trade agreements; the fundamental unfairness of intellectual property regimes, particularly for middle income countries; definition of essential medicines; alternatives to TRIPs; the role of WTO; contribution of universities to innovation and development of medicines; barriers to research and development; antibiotic resistance and the challenge from intellectual property regimes that hampered the supply of effective antibiotics; the positive role of TRIPs in spurring innovation; the need for more compulsory licensing in developing countries.

The responsibilities of States in ensuring access to all medicines, not only essential medicines, and asserted that the current system of TRIPs exceptions and flexibilities was inequitable. The Optional Protocol to the Convention on Economic, Social and Cultural Rights, which had entered into force on 5 May 2013, established a legally binding petitions procedure, an important mechanism for interpretation and enforcement of the right to health. Mr. Taubman reiterated the importance of policy coherence across legal and policy regimes. He called for intellectual property experts to develop a stronger understanding of public health issues, and for health practitioners and policymakers to gain a practical understanding of TRIPs flexibilities. In general, as regards access to medicine, we see the human rights dialogue and remedies playing out differently for different issues, taking as examples the status of campaigns to deal with affordability and access to AIDS and cancer drugs, or the problems of underfunding of R&D for neglected diseases. There is much less attention to the right to obtain affordable drugs to treat cancer, than for AIDS.

Access to medicine is not the only issue for human rights. The affordability of medicines or the reasonableness of prices is also important. No one should be required to sell off all of their assets to pay for a cancer treatment, and price gouging in general can reduce one's quality of life in many other areas. If a government pays too much for one drug, it will have less money to pay for other drugs, other treatments, or other services and benefits. Innovation is also important, particularly for persons who have few or no effective treatment options.

Conclusion

Ensuring equitable access to medicines requires a multi-faceted approach. Strengthening healthcare systems, promoting generic drug production, and implementing flexible intellectual property regimes are essential steps.

However, several gaps need to be addressed to Strengthening global health governance in International cooperation is crucial for addressing global health challenges, including access to medicines. Addressing the issue of antimicrobial resistance, the rise of antimicrobial resistance poses a significant threat to global health. Investments in research and development of new antibiotics are essential. Promoting innovation for neglected diseases there is a need to incentivize research and development for diseases that primarily affect developing countries.

Ensuring transparency and accountability in the pharmaceutical industry in Greater transparency in pricing and research and development processes is essential to build trust between the industry and the public. The Doha Declaration came as a huge relief to developing and under developed countries as by virtue of it the countries can fully use the flexibilities granted in the TRIPs agreement without having to face opposition from the western countries. Therefore, even though there are rights that are for the individual benefit but when it comes to public health, individual rights are kept a notch lower.

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