International Journal of Law
www.lawjournals.org
ISSN: 2455-2194
Received: 09-08-2025, Accepted: 08-09-2025, Published: 23-09-2025
Volume 11, Issue 9, 2025, Page No. 63-71

# Life sustaining drugs and human rights: Ensuring access to essential healthcare

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**Abstract**
This paper examines the complex interplay between life sustaining drugs and the Right to Health, focusing on the impact of patent laws on access to essential medicines. The paper explores the philosophical and legal foundations of the Right to Health, as enshrined in various international treaties and national constitutions, with landmark judgements which declaring right to health as a fundamental right and discusses how IPR, particularly patent laws, affect public health. The conflict between high drug prices due to patent monopolies and the need for affordable medicines. Key international frameworks such as WHO, TRIPS Agreement and the Doha Declaration are reviewed for their role in addressing these conflicts. The paper highlights specific state responses, including legal cases that have navigated this tension. This paper examines the critical intersection of life-sustaining drugs and human rights, focusing on the right to health and equitable access to essential healthcare. As healthcare systems globally face disparities in the availability of vital medications, this study aims to uncover the barriers preventing equitable access to life-sustaining treatments.

**Keywords:** Life sustaining drugs - intellectual property rights (IPR) - right to health – world health organization (WHO) - TRIPS agreement- doha declaration - public health - access to medicines- drug pricing - pharmaceutical law – landmark judgements in health

## Introduction

Health plays a vital role in human life which is indispensable for the exercise of other human rights. As stated in Article 25 of the Universal Declaration of Human Rights (UDHR), 1948 health is part of the right to an adequate standard of living. The International Covenants, Treaties relating to human rights, and the various nation's constitutions recognize that a number of variables would be encompassed by the right to health. Despite of, millions of people in developing countries do not have access to the medicines that are required for treating diseases. One of the significant reasons for the lack of access to essential medicines required for treatment is the high prices fixed for those drugs. Monopolies are created by patents and they restrict competition in the pharmaceutical market and permit the patentee to set up high prices. It clearly indicates that the conflict between intellectual property rights and the right to health has been the focus of much debate [1]. The State cannot guarantee an individual's right to health in the same way as the other rights could be implemented, such as the right to freedom.

For instance, health is therefore a product of the combined action of a series of variables. The state does have to guarantee the right to health, however through the combination of situations which, like food, nutrition, medical assistance, hygiene, etc., contribute to the improvement of health. For instance, noticing the objectives of the TRIPS Agreement, Article 7 provides that the protection and enforcement of IPRs should be done in a manner conducive to social and economic welfare, and Article 8(1) of the TRIPS Agreement further permits states to adopt measures necessary to protect public health and nutrition as long as such measures are consistent with the provisions of the agreement. This paper elucidates right to health is primitive in concerns of human health through accessing essential life-saving medicines which are getting protection in the name of monopolies rights by patent law under Intellectual Property Rights and what are the events happened in many states to see through the right to health in intellectual property rights and also action taken by the United Nation in respect of human health.

## Concept of Life-Saving Drugs

Drugs or medicines play a crucial role in healthcare provision and thus help achieve a welfare state's goal. In the pharmaceuticals sector, drugs or medicines are classified into two categories depending upon their effects and the quantum of relief they provide – life-saving drugs and generic drugs.

Life-saving drugs generally mean a drug or such medicines which are used in an emergency and save someone's life [2]. They were defined by the Drugs Bank in 2017 as: "Life-Saving Drugs are those drugs which save lives in case of Emergency. Also, these drugs have the capability to hold life or prevent further damage and complications. These drugs are used in emergency situations, the intensive care unit. These drugs help patients close to life". These medications are used to treat specific emergency situations, such as "severe bleeding, hypertensive emergency, Myocardial Infraction (MI), respiratory failure, anaphylactic shock, status epilepticus, peripheral respiratory collapse, hypoglycemia, severe angina attack, pain relief in emergency rescue situations, acute asthmatic attack, anti-snake venom injection, rabies vaccine, and tetanus toxoid injection [3]."

The World Health Organisation (WHO) has defined life-saving medicines as "priority medicines that help in improving health, saving lives, and having the biggest impact on reducing morbidity and mortality". The Essential Medicines List (EML) and WHO treatment recommendations cover all life-saving medications, with the exception of a few pharmaceuticals that are prioritised for use in all healthcare systems [4].

Such drugs are special medicines that must be administered in an emergency to save the patient's life. Vardhman Health Specialities Ptv. Ltd., a WHO-certified distribution company, defines Life-saving drugs as "Emergency drugs which require immediate administration, within minutes, post or during any medical emergency or the medicines which have the potential to sustain life or prevent further complications" [5].

The Pre-Hospital Emergency Care Council (PHECC) [6], Ireland, also defines life-saving drugs and helps educate the general population regarding using such medicines in emergencies. Taking inspiration from global stakeholders, the Department of Health and Family Welfare under the Ministry of Health and Family Welfare issues the National List of Essential Medicines (NLEM) [7]. It updates it from time to time so that the concerned authorities should stock up as per the needs and requirements of such medicines. In September 2022, the department issued a list of 384 medicines under NLEM, which included cardiovascular medicines, anti-cancer agents, anti-allergic medicines, dialysis components, hormones and endocrine medicines and medicines for respiratory tract etc.

**International Aspects of Access to Medicine and Human Health**

The importance of healthy life has generally been acknowledged at the domestic and international levels. The right to health as a human right has been included in a number of international instruments bur, like other economic and social rights, it remains subject to frequent criticism for being vague in content and intersecting with too many other rights [8].

**Human Right Based Approach of Ensured Provision of Right to Health**

**"Idea of a better world is one in which medical discoveries would be free from patent and there will be no profiteering from life and death" [9]**

**-Mrs. Indira Gandhi**

Internationally, the right to health was first articulated in the 1946 Constitution of the World Health Organization (WHO), whose preamble "A condition of total physical, mental, and social well-being and not just the absence of disease or infirmity" as how health is defined. In addition, the preamble notes that "every human being has the fundamental right to enjoy the optimal health possible, regardless of ethnicity, religion, political affiliation, economic status, or social background" [10]**.** Since then, the right to health has been enshrined in international and regional human rights treaties as well as national Constitutions all over the world Examples of regional human rights treaties: Articles 11 and 13 of the European Social Charter, 1961; Article 16 of the African Charter on Human and People's Rights, 1981; Additional Protocol to the 1988 San Salvador Protocol is the American Convention on Human Rights in the Field of Economic, Social, and Cultural Rights. Following are the conventions that ensure the right to health in its provisions

- Article 25 of the Universal Declaration of Human Rights (UDHR), 1948 mentioned health as part of the right to an adequate standard of living. The 1966 International Covenant on Economic, Social, and Cultural Rights (ICESCR) reaffirmed the right to health as a fundamental human right, which adopted a broader definition of health that includes social determinants such as access to safe water and food, adequate nutrition, and housing, healthy environmental conditions, access to health-related education and information.

- Article 12 of the International Covenant on Economic, Social and Cultural Rights 1966 (ICESCR). It acknowledges that everyone has the right to the best possible level of bodily and mental well-being. The States Parties to this Covenant to achieve the full realization of this right shall include those necessary for treatment and control of epidemic, endemic, occupational, and other diseases and also the establishment of circumstances that would guarantee access to all medical care and services in the event of illness.

- Articles 11(1)(f), 11(2), 12 and 14(2)(b) in the Convention on the Elimination of all forms of Discrimination against Women 1979 (CEDAW);

- Articles 3(3), 23(3), 23(4) and 24 in Convention on the Rights of the Child 1989 (CRC);

- Article 5(e)(iv) in International Convention on the Elimination of all Forms of Racial Discrimination 1965 (ICERD).

Each and every state has accepted at least one international treaty on human rights that upholds the right to health. State commitments to upholding this right have also been made through international conventions, national laws and policies, and declarations made by the states.

**The Right to Access to Medicines**

Access to drugs is one of the components of the human right to health [11]. As expanded by the ESCR Committee, the core obligation of the right to health include the necessity to ensure the right of access to health facilities. especially for vulnerable or marginalized groups [12]. In the case of primary health care, this includes the promotion of a safe and adequate food supply and proper nutrition; an adequate supply of sage water and basic sanitation; immunisation against major infectious diseases; appropriate treatment of common diseases and injuries; and provision of essential drugs [13].

The World Health Assembly has, for instance, called on its member states to increase access to treatment and prophylaxis of HIV related illnesses through measures such as ensuring provision and affordability of drugs [14]. The UN Human Rights Commission has gone in the same direction with its resolution on HIV/AIDS stating that access to medication in this context is one fundamental element for achieving the full realisation of the right to the enjoyment of the highest attainable standard of physical and mental health [15]. In the Report to the 59th Session of the UN General Assembly [16], the Special Rapporteur noted the prominence of health in the MDGs and maintained that a specific entitlement to access treatment information is understood within the broader inclusive right to health. Paragraph 16 of the Report states: The right to health includes the right to health care, but it goes beyond health care to encompass safe-drinking water, adequate sanitation and access to health

related information. Further the right includes entitlements, such as the right to a system of health protection and access to essential drugs.

However, in 2001 the Commission on Human Rights adopted a resolution [17] recognising access to medication in the context of pandemics to be a fundamental aspect of the fulfilment of the right to health mentioned in paragraph 1 of the Resolution and in 2006, 61st Session of the UN General Assembly considered the report of the Special Rapporteur on the relationship between the right to health and access to medicines [18]. This Resolution 2001/33 calls upon the international community to cooperate with developing countries towards fulfilling this element and upon states to pursue policies to promote and improve access to medicines in the treatment of pandemics and to refrain from legislative or other actions that might impede that access.

Indeed, as identified in the Report, the right to medicines has been enforced in several jurisdictions. The results of successful individual and public interest litigation in health were analysed by the Director, Dr Hans Hogerzeil, and members of the WHO Department of Medicines Policy and Standards [19]. Examining successful litigation in developing countries, the authors investigate the use of the courts to fortify the circumstances necessary to fulfil the right to health. Noting that litigation should not be the mechanism by which to ensure that standards of health are met. But rather should preferably be used as a measure of last resort [20]

In 2007, the UN Special Rapporteur prepared draft Human Rights Guidelines for Pharmaceutical companies in relation to Access to Medicines [21]. Among various recommendations to contribute to research and development for neglected diseases. Regarding commercialisation and licensing, the guidelines deal explicitly with patents and licensing and request companies to respect the rights of all countries to access the flexibility available in TRIPS towards promoting access to medicines, including compulsory licensing and parallel imports. The Guidelines also recommend respect for the Doha Declaration on TRIPS and Public Health [22] as well as WTO Decision on Paragraph 6 [23],

The 2008 MDGs Report [24] also recognises the critical role of pharmaceutical companies in achieving the targets set out with respect to MDG 6. The Report notes the specific target for greater cooperation with pharmaceutical companies towards providing access to affordable essential drugs in developing countries. The Declaration of Alma-Ata was agreed at the International Conference on Primary Health Care, 12 Sep 1978. The Conference was concerned with the urgent need to address public health priorities through the establishment of primary health care in countries throughout the world. The Declaration of Alma-Ata is very significant as the first international declaration in primary health care and global health. The Primary Health care approach, where efforts are made to resolve health needs at the source of immediate access between practitioners and consumers, is identified as integral to WHO's approach to global public health.

The UN Political Declaration on HIV/AIDS (2011): This document reaffirms the commitment to providing universal access to HIV prevention, treatment, care, and support, including access to affordable antiretroviral drugs. UN High-Level Panel Report on Access to Medicines (2016): While not a binding document, this report provides recommendations on how to promote innovation and access to medicines in the context of international human rights.

United Nations Sustainable Development Goals (SDGs) [25], Goal 3 of the SDGs focuses on ensuring healthy lives and promoting well-being for all. Target 3.8 specifically addresses access to essential medicines and vaccines for all. United Nations Political Declaration on Universal Health Coverage (2019) This declaration emphasizes the importance of ensuring that all people have access to quality health services, including essential medicines, without facing financial hardship. World Health Organization (WHO) Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property (2008) UNITAID Statute (2006) UNITAID is an international organization that works to increase access to treatment for HIV/AIDS, malaria, and tuberculosis. Its statute focuses on innovative financing mechanisms to address market failures in the development and distribution of medicines

The WHO Model List of Essential Medicines (aka Essential Medicines List or EML, published by the World Health Organization (WHO), contains the medications considered to be most effective and safe to meet the most important needs in a health system. The first list was published in 1977 and included 208 medications. The WHO updates the list every two years. The Essential Medicines List (EML) was updated in July 2023 to its 23rd edition. This list contains 1200 recommendations for 591 drugs and 103 therapeutic equivalents.

**Constitutional Mandates and Judicial Interpretations**

The Constitution of India does not expressly recognize Right to Health as a fundamental right under Part III of the Constitution (Fundamental Rights). However, through judicial interpretation, this has been read into the fundamental right to life & personal liberty (Article 21) and is now considered an inseparable part of the Right to Life. Article 23 of the Constitution of India also indirectly contributes to protecting the Right to Health as it prohibits human trafficking and child labour.

The role of Indian Supreme Court in protecting the health of the public at large is noteworthy. The Supreme Court has repeatedly observed that the expression "life" in Article 21 means a life with human dignity and not mere survival or animal existence [26]. Right to life has a very broad scope which includes right to livelihood, better standard of life, hygienic conditions in the workplace & right to leisure. Right to Health is, therefore, an inherent and inescapable part of a dignified life. Olga Tellis v. Bombay Municipal Corporation [27], In this case, the Supreme Court of India recognized the right to livelihood as an essential part of the right to life under Article 21 of the Constitution. The judgment highlighted that access to healthcare services and a healthy environment are integral to the right to life.

In the case of Bandhua Mukti Morcha v. Union of India [28], the Supreme Court held that although the DPSP are not binding obligations but hold only persuasive value, yet they should be duly implemented by the State. Further, the Court held that dignity and health fall within the ambit of life and liberty under Article 21.

In the case of Paschim Banga Khet Mazoor Samity v. State of West Bengal [29], the scope of Article 21 was further widened, as the court held that it is the responsibility of the Government to provide adequate medical aid to every

person and to strive for the welfare of the public at large. Further, the Supreme Court in the case of Parmanand Katara v Union of India [30], held that every doctor at Government hospital or otherwise has the professional obligation to extend his services with due expertise for protecting life of a patient. In the subsequent case of Consumer Education and Research Centre V. Union of India [31], held that right to health and medical aid to protect the health and vigor of a worker, both while in service and post-retirement, is a fundamental right under Article 21.

Further, According to Article 19 (1) (g) of the Indian Constitution, the fundamental right of all citizens to practice any profession, or carry on any occupation, trade or business is subject to restrictions imposed in the interest of the general public under Article 19(6). The Hon'ble Supreme Court in the case of Burrabazar Fire Works Dealers Association and Others v. Commissioner of Police, Calcutta [32], held that Article 19 (1) (g) does not guarantee any freedom which is at the cost of the community's safety, health and peace.

The Supreme Court in C.E.R.C. V. Union of India [33], held that right to health, medical aid to protect the health and vigour of a worker while in service or post- retirement is a fundamental right under Article 21. One other issue relating to medical care and health arose in Mr. X. v. Hospital Z [34], in which the question before the court was can a doctor disclose to the would be wife (with whom the marriage is contracted) of a person that he is HIV positive or does it violate the right to privacy of the person concerned. The court answered both questions in negative. Further, the Court stated that the lady proposing to marry such a person is also entitled to all human rights which are available to any human being. Therefore, it includes the right to be told that a person, with whom she was proposed to be married, was the victim of a deadly disease which is communicable. The Supreme Court in this instance gave primacy to the Right to Health over right to privacy.

Right to Health is a part and parcel of Right to Life and therefore right to health is a fundamental right guaranteed to every citizen of India under Article 21 of the Constitution of India. We owe the recognition of this right to the fact that the Supreme Court of India, through a series of judicial precedents, logically extended its interpretation of the right to life to include right to health. People's Union for Civil Liberties v. Union of India [35], The court observed that the right to health is an integral part of the right to life and affirmed the State's responsibility to provide basic healthcare facilities and essential medicines.

The Supreme Court, while examining the issue of the constitutional right to health care under arts 21, 41 and 47 of the Constitution of India in State of Punjab vs. Ram Lubhaya Bagga [36], observed that the right of one person correlates to a duty upon another, individual, employer, government or authority. Therefore, it is the duty of the State to care for the health of the public at large and the Central Government and various State governments have, rightfully and proactively, taken various measures to contain the entry and spread of the COVID-19 pandemic.

The non-justiciable Directive Principles of State Policy incorporated in Part IV of the Constitution of India contained several articles such as Articles 38,39 (e) (f),42, 47, 48A. Article 38 of the Constitution of India provides that the State shall strive to establish a social order to promote the welfare of the people and undoubtedly there can be no welfare without protection of health and provides that the State shall adopt a policy whereby it can secure and protect the health and strength of workers as well as children [37]. The Constitution also casts a duty upon the States to provide opportunities so that the children of the nation can develop in a healthy manner [38]. The Constitution also casts responsibility on the States to provide good working conditions and maternity relief [39] as well as to raise the level of nutrition, improvement of public health and prohibitions of intoxicating liquor except for medicinal purposes [40]. Moreover, the State is also under a constitutional obligation for the protection of environments [41] and it is a well-accepted universal fact that environment protection has a direct impact on the health of the people.

**The Role of Intellectual Property Protection In Public Health Outcomes**

The current international framework protecting intellectual property rights, particularly patent rights, significantly restricts the enjoyment of the right to health. The right to health is directly impacted by patent rights, particularly in developing countries where the cost of pharmaceuticals keeps many patients from being able to afford them. "As intellectual property laws confer monopoly rights, they generally inflate prices," claims Sarah Joseph. This situation is problematic because products that are necessary for the exercise of human rights—like new medications—may be too expensive for the impoverished to purchase [42].

Therefore, in the health sector, intellectual property rights can provide an important stimulus for the development of new drugs and medicines in the field of pharmaceutical industry. However, the statement "The allocation of rights over intellectual property has significant economic, social and cultural consequences that can affect the enjoyment of human rights" by the United Nations Committee on Economic, Social and Cultural Rights in 2001 is also clearly indicative of the fact that intellectual property rights and the right to health were heading for a conflict. There were no references to human rights appearing in the major intellectual property treaties like the Paris and Berne Conventions, or even in the recently adopted TRIPS Agreement. However, there is a correlated provision on intellectual property and human rights, in an International Covenant on Economic, Social and Cultural Rights (ICESCR) mentioned in Article 15, Everybody has the right to benefit from advancements in science and their applications, as well as from the defense of their material and moral interests stemming from whatever creative work they are the authors of, be it literary or artistic and these rights are also outlined in the Article 27 of Universal Declaration of Human Rights(UDHR).

One key issue at the Special Session of the UN General Assembly (UNGASS) on Social Development was the right of people to essential medicines at affordable prices, and how this right is being undermined by patents and the intellectual property rights regime established by the WTO's TRIPS Agreement [43]. At the end of the 24th Session of the United Nations General Assembly Special Session (UNGASS) in Geneva, governments agreed, after tough negotiations, that they would be allowed to freely exercise options already available to them under international trade agreements to protect and advance access to life-saving and essential medicines.

**Doha Declaration and Public Health**

Certain governments expressed uncertainty regarding the interpretation of the TRIPS flexibilities and the extent to which their entitlement to utilize them would be upheld. A large part of this was settled at the Doha Ministerial Conference on 14th November 2001. The Doha Declaration is an excellent example of how a human rights issue can be raised in the trade context and can obtain the support of key developing countries [44]**.** The interpretation of TRIPS was called by the Doha Declaration that would permit the member States suffering crises of public health to balance patent protection with access to pharmaceutical products was addressed by the World Trade Organization (WTO) [45]. Professor Correa states that "the Doha Declaration has made the realization of public health a clearly stated purpose of the TRIPS Agreement." Therefore, it may be essential for members to limit or override certain provisions of the Agreement if local circumstances presented so extraordinary challenges as to warrant an exception for the public good. Members may, for example, decide whether patentability exclusions apply in situations involving unique public health emergencies as specified by the national government's notification, as opposed to routine, everyday health and nutrition initiatives.

**Clarifications Made in The Doha Declaration**

The Doha Declaration contains a number of important clarifications of certain TRIPS flexibilities while reiterating the commitment of members to the TRIPS Agreement. With respect to compulsory licenses and emergency situations, it clarifies that every member has the authority to give compulsory licenses and the discretion to choose the criteria for granting licenses. Such circumstances of extreme urgency and public health crises, including those relating to HIV/AIDS, tuberculosis, malaria, and other epidemics.

The TRIPS agreement, although providing hints at the problem of manufacturing the necessary drugs under compulsory licensing in developing countries that lacked sufficient resources, failed to consummate a proper solution. Many developing countries that lack the resources to synthesize drugs at a cheaper cost must depend on the original manufacturers who hold the patents. The TRIPS agreement further prevented developing countries from helping one another [46]. Under it, a country had the right to copy these drugs but did not have the right to export them, poorer member countries having no manufacturing capacity, an “expeditious solution” was sought by the Doha Declaration.

**Clarification Made in Concern of Parallel Importation**

In the pharmaceutical sector, the term "parallel trade" or "parallel importation" describes the legal practice of importing a medicine that has been produced lawfully without the patent holder's authorization**.** In another context, parallel importation refers to a practice where genuine patented products are acquired from the rights holder and subsequently sold through unauthorized trade channels or in a different market. These kinds of transactions known as parallel imports in the EU and much of the globe, or "grey market activities" in the US occur outside the original intellectual property (IP) rights owner's distribution system [47]. Let’s delve into the details

**1. Doctrine of Exhaustion**

- The concept of parallel importation closely tied to the Doctrine of Exhaustion. This doctrine states that once a patentee has sold their patented product, they cannot regulate its movement after the sale. The patent owner’s ability to regulate how an item is disposed of after it has been sold by them or with their permission is often restricted under the intellectual property law exhaustion theory.
- In other words, they cannot control its resale or redistribution because their exclusivc rights have already been exhausted.
- The doctrine applies to all patented products, including both physical products and those obtained through patented processes.

**2. TRIPS Agreement and Parallel Importation**

- The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement emphasizes the importance of parallel importation.
- Article 28 of TRIPS grants exclusive rights to patentees, allowing them to prevent unauthorized third parties from engaging in acts such as making, using, offering for sale, selling, or importing the patented product.
- However, Article 6 of TRIPS clarifies that these rights are subject to the provisions of Article 6, which addresses the issue of exhaustion of intellectual property rights.
- The intention behind TRIPS is to promote parallel importation among World Trade Organization (WTO) member countries.

**3. Indian Patent Act and Parallel Importation**

If the subject matter of the patent is a product, Section 48 of the Indian Patent Act grants the patentee the exclusive right to stop other parties form manufacturing, using, selling, or importing that product in India.

- Under the Indian Patent Act of 1970, Section 107 A specifically addresses parallel importation.
- Clause(b) of Section 107 A allows for the Importation of patented products by any person from another person who is duly authorized under the law to produce sell or distribute the product.
- In simpler terms, if a patented product is first sold by the patentee or an authorized person, parallel importation is allowed by a third party, provided that the import is from someone who is legally authorized to produce, sell or distribute the product.

In summary, parallel importation strikes a balance between protecting patent rights and ensuring fair access to patented products across different markets. It allows for legitimate trade while respecting the rights of patent holders. On August 30, 2003, WTO members reached a formal agreement that would facilitate the import of less expensive generic medications produced under compulsory licensing for nations who are unable to produce the medications themselves, thus resolving the exporting countries issue. In actuality, the decision contains three waivers.

- Any member nation may export generic pharmaceutical products produced under compulsory licenses to satisfy the needs of importing nations; exporting countries' duties under Article 31(f) are waived.

- In order to prevent paying twice, importing nations forgo their duties to compensate patent holders under compulsory licensing. On the export side solely, compensation is necessary.
- When a regional trade agreement is in place and at least half of its members were classified as least-developed countries at the time of the decision, exporting restrictions are lifted for developing and least-developed nations, allowing them to export. In this manner, economies of scale can be utilized by developing nations.

The temporary nature of the waivers contained in the 2003 Decision, Decision called for the TRIPS Council to prepare a permanent amendment to the TRIPS Agreement based, where appropriate, on the 2003 Decision. Agreement on such an amendment, through the insertion of a new Article 31bis and Annex to the TRIPS Agreement, was reached on 6 December 2005 when the General Council adopted a Protocol Amending the TRIPS Agreement.

**Appreciating The Pro-Health Right Scenario in Developing Countries**

In 1996, a new National Drugs Policy was adopted by South Africa with the objective of "ensuring an adequate and reliable supply of safe, cost-effective drugs of acceptable quality to all citizens of South Africa" [48]. The South African Government following the principles of the Policy amended its existing Medicines Act for improvement of access to medicines [49]. In response, South Africa was placed on the United States Special 301 Watch List [50] and challenging the amendments, a suit was filed by 39 pharmaceutical companies contending that patent protections would be destroyed by them by giving the Health Minister overly broad powers for producing or importing cheaper versions of drugs still under patent [51], Global public outrage ultimately went ahead to a change in the position of United States and then in 2001, to the withdrawal of the law suit by the pharmaceutical companies. In 2002, for example, the U.S. Government pressured South Korea to refuse a compulsory license for Gleevec, a leukemia drug that costs around $27,000 per year per person.

Pressure was also faced by Thailand following its attempts to lower the prices of medicines through compulsory licensing. Compulsory licenses were issued by Thailand for HIV and heart disease medicines to meet its obligations to provide universal access to medicines. Thailand was also placed in 2007 on the Special 302 Priority Watch List [52]. The European Commission also did not welcome the measures taken by Thailand. Again in 2008, the Thailand Government issued compulsory licenses for three anti-cancer medicines noting the burden of cancer and the requirement for the Government health program for providing access to cancer medicines. For the use of this TRIPS flexibility, a worldwide campaign for supporting the Thai compulsory licenses led to several statements of support however growing pressure was continued to be faced by Thailand in response to its use of compulsory licensing.

In the 2008 case [1], Pfizer alleged that Cosmos had infringed its patent on a medicinal product known as "azithromycin dihydrate." Cosmos, however, contended that the patent was not in force between 2003 and 2006 (when the alleged infringement occurred) due to the failure of Pfizer to pay the renewal fees on the patent and it was entitled to import, manufacture, sell, and export the patented product without the authority of Pfizer by virtue of section 58(2) of the Industrial Property Act, which allows parallel importation. Section 58(2) provides that "the rights under the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya." However, in this particular case, the Kenyan tribunal took the view that the product was not a first-line treatment for HIV/AIDS patients and that even if this were the case, it would not entitle the respondents to exploit the patent without authorization.

Kenya was selected because it is a typical example of a developing country with significant public health challenges that also has obligations to protect patent rights. It has been estimated that about 1.6 million Kenyans are living with HIV/AIDS UNAIDS [2], and It has been estimated that cancer currently causes 7% of the total number of deaths in Kenya and cancer is ranked as the third highest cause of death in the country [3]. In 2001 Kenyan Industrial Property Act complies with the requirements of the TRIPS Agreement. It equally contains certain flexibilities such as provisions on compulsory licenses, research exception, and parallel importation. Pursuant to Article 43(1)(a) of the Kenyan Constitution, which provides that everyone has the right to "the highest attainable standard of health, which includes the right to health care services, including reproductive health care." Thus, individuals can institute legal proceedings to challenge any governmental action (including legislative enactments on patent rights and other IPRs) that potentially or actually infringes on their right to health [4]. In this case The court found that certain provisions of the Kenyan 2008 Anti-Counterfeit Act Section 2, 32 and 34 violated fundamental rights guaranteed under the Kenyan Constitution. Specifically, these provisions were in conflict with the right to life, human dignity, and health. a Kenyan High Court made landmark pronouncements on the relationship between the right to health and intellectual property rights.

In the English case. the plaintiffs (who held a license under a patent to exclusively sell certain drugs) sought to restrain the defendants from selling one of those drugs in the UK. However, the court refused to grant an injunction restraining the defendants from selling the drug because it was a unique, life-saving drug with no precise equivalent in the market as the plaintiffs were not yet selling the drug in the UK. Thus, the English court was clearly concerned about preserving access to this life-saving drug for patients in the UK.

In the Indian case [58] the Delhi High Court refused to grant an injunction sought by Roche against Cipla for the latter's production of the former's patented drug. The Delhi High Court noted that: The Court cannot be unmindful of the right of the general public to access life saving drugs which are available and for which such access would be denied if the injunction were granted. The degree of harm in such eventuality is absolute; the chances of improvement of life expectancy; even chances of recovery in some cases would be snuffed out altogether, if injunction were granted. Another way of viewing it is that if the injunction in the case of a life saving drug were to be granted, the Court would in effect be stifling Article 21 of the Indian Constitution, which provides for the right to life and which

forms the bedrock of the right to health in India so far as those who would have or could have access to Erloticip are concerned.

**Landmark Intellectual Property Cases Impacting Health Access In India**

Novartis AG, a pharmaceutical company based in Switzerland, filed a case [59] challenging the order of the Chennai-based Intellectual Property Appellate Board rejecting its claim for a patent for the beta-crystalline of imatinib mesylate, brand name Glivec (Gleevec), on the ground that patent qualifies as a "new product" which comes by through an invention that has a feature that involves technical advance over the existing knowledge and that makes the invention "not obvious" to a person skilled in the art, which is decided by the Supreme Court of India on April 1, 2013 as under: "In view of the findings that the patent product, the beta crystalline form of Imatinib Mesylate, fails in both the tests of invention and patentability as provided under clauses (j), (ja) of section 2(1) and section 3(d) respectively, the appeals filed by Novartis AG fail and are dismissed with cost." However, Glivec case is remarkable because it has gone beyond the specific technical and legal issues surrounding patents and has put the matter in a much larger political and economic perspective. What the judgment said and what it implied has tremendous significance for the patent regimes in developing countries beyond the secondary patenting issues. The judgment has a positive impact on affordability and accessibility of medicines.

Bayer Corporation v. Union of India [60], This landmark judgment is the first-ever case in India dealing with the granting of a compulsory license under an application made under Section 84 of the Patents Act, 1970. Natco, a drug manufacturer had approached Bayer for a grant of a voluntary license to manufacture and sell the drug at a much lower price of Rs. 10,000/- per month of therapy as against the price of Rs. 2,80,428/- per month of therapy charged by the petitioner. The request was denied and hence they made an application to the Controller under section 84 of the Act for a compulsory license on the ground that the petitioner had not met the reasonable requirement of the public in respect of the patented drug. It was granted on the condition that the applicant had to sell the drug at Rs 8,800/- per month and was directed to pay 6% of the total sale as royalty to the petitioner. Natco was also directed to sell the drug only in India and to make the drug available to at least 600 needy patients each year free of charge. Appeal in High Court, As per Section 84(7) of the Act, which provides that the reasonable requirement of the public is not satisfied, if the demand for a patented article is not met to an adequate extent in which regard the patent holder has failed in the present case [61].

**Suggesstion**

There is a key problem in the coexistence approach, as it is difficult to define the balance between incentives for innovation and access to medicines.

- No clear provisions exist in international conventions or domestic legislation to prevent the abuse of patent rights concerning access to health, even after the TRIPS Agreement and Doha Declaration.
- Before the TRIPS Agreement, many developing and least-developed countries struggled with patent monopolies, mostly controlled by developed countries like the US.
- The transitional periods for least-developed countries have been extended until July 1, 2034, by the WTO, meaning there is still a long way to go before patent rights and the right to health can coexist effectively.
- Developing countries need to devise strategies to limit the current expansion of international patent law and protect their access to medicines.
- While there are growing demands for stronger patent laws, the right to health can provide a framework for reclaiming policy space to shape national patent laws that prioritize access to medicines.
- Domestic courts have a vital role to play in disputes involving pharmaceutical patents, recognizing the tension between patent rights and the right to health, and resolving it by distinguishing between the instrumental role of patents and the fundamental importance of health rights.

**Conclusion**

In 2001, the pharmaceutical industry pipeline contained 402 new cancer medicines, 123 new treatments, and 176 new medicines for neurological diseases. The question is whether providing patent rights to the patentee might motivate them to innovate new medicines but till now it is hand fruit to the people, suffering from health crises Today the word patent is well known even to a layman and COVID-19 has made patents in Pharmaceutical industry all more popular. The tensions between the right to own intellectual property rights and the implications this could have on high prices for pharmaceutical products.

At the Sixty-First World Health Assembly on 24 May 2008, the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property attempts to balance the right to health with the right to own intellectual property. Accordingly, the WHO Global Strategy sought to achieve this balance by calling for more efforts to be made to implement States' obligations arising under applicable international human rights instruments with provisions relevant to health, while at the same time acknowledging that the Universal Declaration on Human Rights as interpreted by UN human rights organs, the right to health requires that countries progressively take positive steps towards facilitating access. Dismantling the 1970 regime may constitute a violation of India's obligations under the Covenant on economic, social and cultural rights.

**References**

1. The Patent Controversy, the Hindu Posted: 2004
2. Collins Dictionary. Definition, Thesaurus and Translations [Internet]. Collinsdictionary.com. 2019. https://bit.ly/2Lk3ZsB
3. Life Saving Drugs – Drugs Bank [Internet]. Drugs Bank. 2019. https://bit.ly/2LugWAk
4. Priority life-saving medicines for women and children 2012. World Health Organization. 2012. https://bit.ly/35eG1WC.
5. Vardhman Health Specialities Pvt. Ltd. Available at https://vardhmanhealth.com/life-saving-medicines/
6. Emergency Life Saving medicines and PHECC'S role in educating the public to use those medicines, available at https://www.phecit.ie/PHECC/Publications_and_Resou

rces/Newsletters/Newsletter_Itmes/2016_Summer/Emergency_life-saving_medicines.asp
7. National List of Essential Medicines (NLEM), 2002 available at https://main.mohfw.gov.in/newshighlights-104
8. Cf David P Fidler, International Law and Infectious /diseases (Oxford: Oxford University Press 1999).
9. Available at www.thehindu.com/2004/12/10/stories/2004121002361000.htm
10. The Right to Health, Fact Sheet No. 31, United Nations High Commissioner for Human Rights, Geneva, Switzerland.
11. World Health Organization, Globalisation. Trips and Access to pharmaceuticals (WHO) Policy Perspectives on Medicines No. 3), 2001.
12. Committee on Economic, social and cultural Rights, General Comment No.14, UN Doc E/C 12/2000/4(2000).
13. Article VII of the Declaration of Alma Ata, 12 /September 1978, in Report of the International Conference on Primary Health Care (Geneva: World Health Organisation, 1978)
14. World Health Assembly, HIV/AIDS: Confronting the Epidemic, Resolution WHA 53:14(20 May 2000)
15. Resolution 2001/33, Access to Medications in the context of Pandemics such as HIV/AIDS, UN Commission on Human Rights, 23 April 2001, UN Doc E/2001/23-E/CN 4/2001/167.
16. UN General Assembly, Report of the Special Rapporteur of the Commission on Human Rights, on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, 59th Session, 8 October 2004, A/59/422.
17. Commission on Human Rights, Access to medication in the context of pandemics such HIV/AIDS, Resolution 2001/33
18. UN General Assembly, Report of the Special Rapporteur of the Commission on Human rights, on the right of everyone to the enjoyment of the highest attainable standard of physical and mental Health. 61st Session, 12 Sep 2006. A/61/338.
19. The WHO Department of Medicines Policy and Standards is lead in Developing and setting medicines policies, norms and standards as wells as contribution to the overriding responsibility to provide information and guidance to Member states and other stakeholders in global health.
20. Hogerzeil, H.V. et. Al. (2006), 'Is access to essential medicines as part of the fulfilment of the Right to Health enforceable through the courts?', 368 The Lancet 22 July:305 at 311. This article was also considered in the Special Rapporteur's Report to the 61st General Assembly
21. UN Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines, Draft for Consultation 19 Sep 2007.
22. WTO Declaration on the TRIPS Agreement and Public Health, adopted on 14 Nov 2001, WT/MIN(01)/DEC/2 (Doha Declaration on TRIPS and Public Health)
23. Compulsory licensing, the Paragraph 6 system and other efforts to wards improving access are considered in detail in Part IV: Access
24. The Millennium Development Goals Report(2008), New York, United Nations.
25. United Nations organization. Millennium Development Goals. New York, 2000, Target 17 of Goal 8. Available from: http://www.undp.org/mdg/. Accessed on: 8 March 2024
26. (Francis Coralie Mullin vs The Administrator, Union Territory of Delhi AIR 1981 746)
27. 1986 AIR 180
28. AIR 1984 SC 812
29. (1996) 4 SCC 37
30. AIR 1989 S.C. 2039
31. AIR 1995 SC 922
32. AIR 1998 Cal. 121
33. AIR 1995 SC 922
34. AIR 2003 SC 664
35. AIR 1997 SC 568
36. (1998) 4 SCC 177: AIR 1998 SC 1703
37. Article 39(e) of the Constitution of India.
38. Article 39 (f) of Indian constitution.
39. Article 42 of the constitution of India.
40. Article 47 of the Indian constitution.
41. Article 48 A of the Constitution of India.
42. S. Joseph, "Trade and the right to health
43. WTO General Council, "Amendment of the TRIPS Agreement," Decision of 6 December 2005, WT/L/641.
44. The Right to Health, Fact Sheet No. 31, United Nations High Commissioner for Human Rights, Geneva, Switzerland
45. Mile Moore (2004), Doha and beyond : the future of the multilateral trading system.Cambridge: Cambridge University Press
46. Article 31(f) of the TRIPS Agreement
47. Maskus KE. The curious economics of parallel import. *WIPO J Anal Intell Prop Issues* 2010; 2: 123
48. National Drug Policy for South Africa, 1996, p.3. Available at http://apps.who.int/medicinedocs/documents/s17744en/s17744en.pdf
49. Medicines and Related Substances Control Amendment Act No. 90 of 1997. Available at www.gov.za/documents/download.php?f=70836
50. Office of the United States Trade Representative (USTR), Special 301 Report 1999. This list is maintained under the United States Trade Act, 1974, in respect of each country. It is a precursor to trade sanctions that the United States may impose on any country unilaterally. avaliable at http://www.keionline.org/ustr/1999special301
51. Department of Essential Drugs and Medicines Policy, WHO(2001). Essential Drugs in Brief: A bulletin on major WHO Country and Regional work in the field of Essential Drugs and Medicines Policy, issue No. 04, April 2001. Available at http://www.who.int/medicines/publications/brief/en/edb04.pdf
52. Office of the United States Trade Representative (USTR), Special 301 Report, 2007. Available at http://www.ustr.gov/sites/default/files/asset_upload_file230_11122.pdf

53. Pfizer Inc. v. Cosmos Limited (Case No. 49 of 2006, Judgment of the Industrial Property Tribunal at Nairobi, April 25, 2008).
54. "Kenya: HIV and AIDS estimates (2011)." Available at http://www.unaids.org/en/regionscountries/countries/kenya/.
55. S. Mojtehedzadeh, "Killer cancer still neglected in Kenyan health care system," *Daily Nation* (February 11, 2013). Available at http://www.nation.co.ke/Features/DN2/Cancer-The-elephant- in-the-room/-/957860/1689876/-/item/0/-/fcev4nz/-/index.html.
56. P.A. Ochieng, M. Atieno, and J. Munyo v. Attorney General (Petition No. 409 of 2009, Judgment of the Kenyan High Court, April 20, 2012). https://unctad.org/ippcaselaw/sites/default/files/ippcaselaw/2 · PDF
57. Roussel-Uclaf v. G. D. Searle & Co. Ltd & Another, [1977] F.S.R. 125 (Judgment of the English High Court of Justice – Chancery Division)
58. Hoffmann-La Roche Ltd. v. Cipla Ltd., I.A. 642/2008 in CS(OS) 89/2008 (Delhi High Court March 19, 2008)
59. Novratis AG V. Union of India & others Civil Appeal Nos. 2706-2716 of 2013 (Arising out of SLP (C ) Nos. 20539-20549 of 2009);.
60. AIR 2014 Bom 178
61. www.manupatra.com