

NAVIGATING THE INTERFACE BETWEEN WOMEN'S HEALTH AND INTELLECTUAL PROPERTY RIGHTS: A HUMAN RIGHTS APPROACH

B. Muthu Jeyakumari

Assistant Professor,

Government Law College, Tirunelveli

Abstract

Women's health is influenced by the broad spectrum of factors such as biological, social, economic, and environmental determinants, yet it has been historically overlooked with policy frameworks and healthcare systems. As a result, women face a higher burden of certain diseases and health risks compared to men which may be due to biological or gender differences. Since ancient time, women's primary duty has been viewed primarily on child birth and reproduction and the cost of women's health is often neglected. In the contemporary global order, intellectual property (IP) regimes particularly those governing pharmaceutical patents play a decisive role in determining the availability, affordability, and accessibility of healthcare products vital to women's well-being. Women's health is recognised in major international instruments such as Universal Declaration of Human Rights (UDHR), the International Covenant on Economic, Social and Cultural Rights (ICESCR), the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW), and the Beijing Platform for Action. These frameworks affirm women's entitlement to the best standard of health but they provide only limited protection due to weak enforceability and lack of specific obligations on states to prioritize access to affordable medicines for women when confronted with the realities of modern intellectual property IP regimes. TRIPS Agreement enable stringent patent protections that restrict access to essential drugs and life-saving treatments which often overshadow human rights commitments. In the contemporary global order, Intellectual property (IP) regimes particularly those governing pharmaceutical patents play a decisive role in determining the availability, affordability, and accessibility of healthcare products. This paper analyses how weaknesses within intellectual property systems such as poor implementation, weak accountability, and structural inequalities undermine international protections for women's health. It advocates for adopting to stronger human rights in IP rules so that women can obtain easily without difficulty to healthcare and essential medicines worldwide.

Keywords: Gender inequality, Human Rights-Based Approach, Intellectual Property, Pharmaceutical Patents, Women's health

INTRODUCTION

Many International Trade agreements are there to negatively impact women's health. World Trade Organization (WTO) is included among such institutions that impose detrimental policies. Agreements, for example, the Trade Related Aspects of Intellectual Property Rights (TRIPS) and the General Agreement on Trade in Services (GATS), negatively affect women in three ways; first by restricting access to essential medicines, they undermine women as users of health care systems; Secondly, by commercialization and privatizing services, they affect women in their role as care givers as providers of care; Finally, by patenting medicinal plants, they disrupts women's traditional roles as cultivators of these herbs.¹

Women's ability to obtain health services is predominately controlled by male family members and it was more pronounced during emergencies and disasters such as floods, earthquakes, or pandemics, when rapid medical attention is critical. Social norms often restrict women's mobility, decision- making power, financial autonomy preventing them to take treatment of their own. This dependence not only postpone timely care but also amplifies women's vulnerability to injury, infection, malnutrition, and psychological trauma. Women often conceal their illnesses from family members after disasters, largely because of the high cost of medicines and their increased household responsibilities, compounded by cultural norms that discourage them from prioritizing their own health.²

Pharmaceutical patents play a central role in shaping women's health outcomes where access to essential medicines becomes more critical after post-disaster. Patent monopolies often keep the prices of vital drugs such as antibiotics, contraceptives, antiretrovirals, cancer treatments, and maternal health medicines beyond the reach of low-income women. In remote areas, where women are already in struggle to access health care facilities, Patent-driven shortages and limited generic competition further restrict availability. Thus, the global IP system, while designed to promote innovation, often reinforces gender-based inequities which limit the timely and affordable access to life-saving medicines for women. It is therefore essential to analyse the intersection of patent laws and women's health for understanding how trade and IP

¹ Turshen, M. (2019). *Women's health movements: A global force for change*. Springer Nature Singapore. (p. 55).

² Rezwana, N. (2017). *Disasters, Gender and Access to Healthcare: Women in Coastal Bangladesh*. United Kingdom: Taylor & Francis.

regimes can either support or undermine women's right to the maximum achievable standard of health.

LITERATURE REVIEW

Women's health is shaped not only by biological factors but also by systemic gender inequalities, discriminatory laws, and social barriers that restrict access to essential healthcare is increasing recognised as a critical human right concern. Goldman and Hatch (2000) highlights that the reproductive health, violence, and structural inequities necessitating the need for gender-responsive legal and policy reforms as major issues affecting women's health.³

Similarly, Goldberg (1997) calls for rights-based policies and legal frameworks such as CEDAW to ensure accountability and equitable healthcare access and analyse how discrimination, limited autonomy, and structural inequalities adversely affects the woman's over-all wellbeing.⁴

Cook, Dickens, and Fathalla's, *Reproductive Health and Human Rights* (2003) harmonise medicine, public health, gender equality, and human rights obligations. Their work argues that women's reproductive health is shaped not only structural factors but limits access to health care. The authors also demonstrate that reproductive rights are inseparable from broader human rights principles such as dignity, equality, and non-discrimination through case analysis and discussions.⁵

Angela Sammarco's *Women's Health Issues Across the Life Cycle* (2017) offers a comprehensive understanding of how women's health needs evolved through the interplay of biological, psychological and social determinants from adolescence to old age, Her analysis shows that access to medicines is shaped not only by clinical availability but also affected by the socioeconomic status, cultural norms, health literacy, and structural inequalities that limit women's autonomy and timely use of healthcare.⁶

Advancing this perspective, Yamin (2025) provides a compelling human-rights argument for treating maternal mortality as both a legal and normative issue. Her work illustrates how international legal standards can be used to advance greater equity and hold states accountable.

³ Goldman, M. B., & Hatch, M. C. (Eds.). (2000). *Women and health*. Academic Press.

⁴ Goldberg, P. (1997). *Women, health and human rights*. *Pace International Law Review*, 9(1), Article 11. Retrieved December 4, 2025, from <https://digitalcommons.pace.edu/pilr/vol9/iss1/11>.

⁵ Cook, R. J., Dickens, B. M., Fathalla, M. F. (2003). *Reproductive Health and Human Rights: Integrating Medicine, Ethics, and Law*. United Kingdom: Clarendon Press.

⁶ Sammarco, A. (2017). *Women's Health Issues Across the Life Cycle*. United States: Jones & Bartlett Learning.

In the light of this analysis, they provide a solid conceptual and legal basis for analysing women's health from a human-rights perspective. Their perspectives are particularly valuable for studies exploring how laws, policies, or intellectual property regimes affect women's access to healthcare and shape broader health equity outcome.⁷

Roy Love's (2007) article, *Corporate Wealth or Public Health? WTO/TRIPS Flexibilities and Access to HIV/AIDS Antiretroviral Drugs by Developing Countries*, provides an important analysis of how patent regimes often prioritize corporate interests over public health needs which disproportionately affect vulnerable populations including women who face social and economic barriers in accessing the treatment. His work underscores the need for stronger public health safeguards within IP framework to ensure equitable access to life-saving drugs.⁸

S. K. Verma's (2019) article *Pharmaceutical Patents and Public Health*, provides a detailed analysis of how patent regimes of stronger patent protections led to higher prices and restricted the availability of generic medicines. Verma's work reinforces the need for balancing innovation incentives with public-health obligations and provides a foundational basis for evaluating how patent policy affects women's access to life-saving drugs and medicines.⁹

Collectively, these studies provide the conceptual foundation for analysing the intersection of women's health, intellectual property and human rights. They justify the need for a human-rights based approach to ensure that legal, policy and patent frameworks prioritise equitable access to essential health care and life-saving medicines for women.

OBJECTIVES

- 1) To examine the structural relationship between women's health needs and the international intellectual property (IP) regime, with specific attention to how pharmaceutical patents shape the availability, affordability, and accessibility of essential medicines for women.
- 2) To analyse the human rights framework particularly the right to health, non-discrimination, and gender equality in assessing the legitimacy and limits of intellectual

⁷ Yamin, A. E. (2025). Constructing maternal mortality as a human rights issue: Lessons for using international law to advance women's health and rights. In J. J. Dawuni & J. Cobbah (Eds.), *The Oxford handbook of women and international law* (pp. 345–367). Oxford University Press.

⁸ Love, R. (2007). *Corporate wealth or public health? WTO/TRIPS flexibilities and access to HIV/AIDS antiretroviral drugs by developing countries*. *Development in Practice*, 17(2), 208–219. Retrieved December 6, 2025, from <https://www.jstor.org/stable/25548200>

⁹ S. K. Verma, "Pharmaceutical Patents and Public Health," *Journal of the Indian Law Institute*, 61(2), 153–181 (2019). Retrieved December 6, 2025, from <https://www.jstor.org/stable/26915659>.

property protections that affect women's access to life-saving and life-enhancing medical products.

3) To identify the legal, policy, and socioeconomic barriers arising from patent monopolies that disproportionately affect women which are barriers to reproductive health commodities, maternal care medicines, cancer treatments, and chronic disease therapies.

4) To evaluate the international and national regulatory mechanisms (such as TRIPS flexibilities, compulsory licensing, price controls, and public-health safeguards) and their effectiveness in mitigating gender-based inequities in access to medicines.

5) To investigate how an IP regulation can be integrated with human rights-based approach (HRBA) ensuring that innovation policies harmonise with states' obligations to promote, protect, and fulfil women's health rights.

6) To propose legal and policy recommendations with evidence based for harmonising IP protection with women's health priorities, ensuring that patent regimes do not aggravate gender disparities in health outcomes.

7) To explore case studies illustrating how patented medicines, high-priced therapies, and market exclusivity have impacted women's health outcomes in different regions.

RESEARCH METHODOLOGY

This study adopts a qualitative and doctrinal research methodology supplemented by comparative analysis and case-based examination to examine how intellectual property regimes influence women's health in accessing the essential medicines from the human rights perspective. It relies on documentary analysis of primary sources including international instruments such as CEDAW, ICESCR, and the TRIPS Agreement, along with national patent laws, judicial decisions, and policy frameworks. Secondary sources such as scholarly reports of WHO and UN reports, and civil society publications are used to contextualise the gender specific health challenges under pharmaceutical patents. The research integrates thematic and comparative legal analysis to explore how patent protections shape women's real-life access to vital medicines for reproductive and maternal health, cancer care, and treatment of common infectious diseases, supported by case studies of high-priced patented drugs which are crucial to women's health. A human rights analytical framework helps to examine what governments are actually required to do to ensure equality, non-discrimination, and the right to health for women. Using this lens makes it possible to develop practical, gender-sensitive policy recommendations that better align intellectual property rules with women's real health needs.

RESEARCH PROBLEM

Despite global recognition of women's right to health, access to essential medicines remains a major challenge for women worldwide. Pharmaceutical patents often keep the prices of the drug very high and delay the availability of affordable alternatives, particularly for treatments related to reproductive health, maternal care, and gender-specific cancers. These barriers are compounded by social, economic, and cultural factors that disproportionately affect women's health. Existing intellectual property laws rarely account for women's unique health needs or incorporate human rights safeguards such as equality and non-discrimination. As a result, there is a widening gap between patent protection and women's right to affordable healthcare. The research problem is to examine how current patent regimes contribute to these inequalities and what reforms are necessary to better align IP policies with women's health rights.

HYPOTHESES

Main Hypothesis:

Current pharmaceutical patent regimes worsen gender-based inequalities in access to essential medicines, undermining women's right to health.

Sub-Hypotheses:

1. Implementing human rights framework on health grounded in the principles of availability, accessibility, acceptability, and quality of health facilities and services, together with participation, equality and non-discrimination, and accountability significantly reduce the barriers in accessing the essential medicines to women's health.
2. High prices and limited availability of patented medicines restrict women's timely access to reproductive, maternal, and gender-specific healthcare.
3. International and national regulatory mechanisms such as TRIPS flexibilities, Compulsory licensing, price health and public health safeguards significantly improve women's access to essential medicines in developing and under-developed countries.
4. Socioeconomic and cultural factors amplify the barriers created by patents.

ANALYSIS AND INTERPRETATION/FINDINGS

1. Integrating Human Rights Principles into IP Policy Can Mitigate Disparities

The findings conclude that integrating Human Rights Principles into health and IP policy directly strengthens the women's access to essential medicines and health services. WHO and the Office of the High Commissioner for Human Rights (OHCHR) articulated jointly the framework of the impact of a human rights-based approach on women's and children's health which rests on seven core principles: the availability, accessibility, acceptability, and quality of health facilities and services, together with participation, equality and non-discrimination, and accountability.¹⁰ When states integrate these elements into health and IP policy, mandates states to prioritize vulnerable groups and ensure health policies do not disproportionately harm women.

The grounding of health is contained in various international instruments. One of the earliest articulations of health as a human right is contained in the constitution of WHO, which defines health as "*a state of complete physical, mental and social well-being and not merely the absence of disease or infirmities.*" UDHR serves as the primary framework guiding present day conceptualization and articulation of human rights. Article 25 of the UDHR states that everyone has the right to a standard of living adequate for the health and well-being of himself and his family including food, clothing, house and medical care. Although the drafters use the term '*him and his family*', we may safely assume that this language was intended to mean all people and not just male people.¹¹ Human rights framework compels the state to redesign the IP laws in such a way that they do not restrict access to essential medicines for women.

Article 12 of the CEDAW also known as Women's Convention dictates that state parties "*shall take all the appropriate measures to eliminate the discrimination against women in the field of health care, to ensure on the basis of equality access to health services*". Thus, the Women's Convention does not establish a new right; rather, it positions health as an equality issue, emphasizing that women must be entitled to have access to health care and medical treatment on par with men. In 1993, the CEDAW Committee further affirmed that any form of gender-based violence that undermines women's enjoyment of their human rights or fundamental freedoms constitutes discrimination. These human rights and fundamental freedoms, as articulated in the recommendation, include the "*right to the highest standard attainable of physical and mental health*". Article 12 of the ICESCR also contains the same

¹⁰ World Health Organization. (2013). *Women's and children's health: Evidence of impact of human rights* (P. Hunt, F. Bustreo, & others). World Health Organization. Retrieved from <https://unicri.org/sites/default/files/2019-11/WHO%20Women%27s%20and%20Children%27s%20Health-%20Evidence%20of%20Impact%20of%20Human%20Rights.pdf> on 24 November 2025.

¹¹ Goldberg, P. (1997). *Women, health and human rights*. *Pace International Law Review*, 9(1), Article 11. Retrieved from <https://digitalcommons.pace.edu/pilraartic/vol9/iss1/11/> on 24 November 2025.

provision “*right to enjoyment of the highest attainable standard of physical and mental health*”. This provision defines the parameter of health as a protectable human right. There are many other documents without the legally binding force of a treaty or customary law, which addresses very particular issue relating to women’s health are rape, family planning and birth control. Women’s exclusion from access to essential medicines due to high prices, lack of availability, or discriminatory IP rules becomes a violation of *human rights*. Therefore, States that implement human rights standards will close these gaps and improve women’s access.

Paragraph 89 of the Beijing Declaration and Platform for Action is an influential document synthesizing various perspectives in articulating health as a human rights concern for women. It affirms that women are entitled to the maximum achievable standard of physical and mental health and reiterates that health encompasses complete physical, mental, and social well-being, not merely the absence of disease or infirmity. It further emphasizes that women’s health is shaped by their emotional, social, and physical well-being and is influenced not only by biological factors but also by the social, political, and economic conditions in which they live.¹² This further expands women’s access to essential medicines.

Goal 3 of the Sustainable Development emphasizes the importance of providing the widespread access to quality health-care services and guaranteeing that everyone can obtain safe, effective, high-quality, and affordable essential medicines and vaccines by the year 2030.¹³ Thus, it operationalizes the hypothesis at the global development level.

2. Impact of Pharmaceutical Patents on Women’s Health

a) HPV Vaccines and Cervical Cancer Prevention

Human Papillomavirus (HPV)¹⁴ is the most commonly sexually transmitted infection and is responsible for nearly all causes of cervical cancer. It is one of the fourth most common form of cancer among women worldwide. In 2020, there were 6,04,000 new cases and 3,42,000 deaths due to Cervical Cancer globally.¹⁵ The WHO has identified cervical cancer as a public health priority and set a goal to eliminate it by 2030. Cervical cancer remains one of the leading

¹² United Nations, *Beijing Declaration and Platform for Action* (1995), available at <https://www.un.org/womenwatch/daw/beijing/pdf/BDPfA%20E.pdf> (accessed on 25 November 2025).

¹³ World Health Organization. (n.d.). *Targets of Sustainable Development Goal 3 to ensure healthy lives and promote well-being for all at all ages*. WHO. Retrieved December 4, 2025, from <https://www.who.int/europe/about-us/our-work/sustainable-development-goals/targets-of-sustainable-development-goal-3> [who.int](https://www.who.int).

¹⁴ It belongs to the Papillomavirus family. The name “Papillomavirus” is derived from the Latin word *papilla*, meaning “nipple” or “pustule,” which reflects the appearance of the lesions it causes, and the Greek suffix *-oma*, denoting “tumour” or “swelling”. See, Guilfoile, P. (2019). *Human papillomavirus*. Infobase Publishing, p. 5.

¹⁵ *Cervical cancer: A global public health treatise*. (2021). IntechOpen.

causes of cancer-related mortality among women, with a disproportionately high burden in low-income countries where access to screening and preventive services is limited.

The HPV vaccines Gardasil and Cervarix which were protected by extensive patent portfolios plays a critical role in prevention. According to a study published in *Nature Biotechnology*, nearly 80 percent of cervical cancer deaths occur in lower-income regions. Despite being marketed in the USA for approximately USD 300, these vaccines have paradoxically been sold in several low-income countries even at higher prices, sometimes exceeding USD 500. As a result, the commercialization of HPV vaccines generates only modest public health gains when the populations most at risk face a de facto lack of access.¹⁶

b) Trastuzumab and Access Barriers in the treatment of Breast Cancer

Breast cancer is also prevalent among the women globally. According to WHO's 2018 data, approximately 2.1 million women were newly diagnosed, and nearly 630,000 lost their lives, largely because of late-stage detection and limited access to affordable, timely treatment.¹⁷ Trastuzumab is clinically effective for treating HER2-positive breast cancer but the cost is very high which creates substantial barriers to access. It was marked as an essential drug by WHO. In the United Kingdom, the full treatment cost can reach approximately GBP 90,000 per patient which place a heavy financial burden on both individuals and healthcare systems. As a result, affordability remains a major obstacle despite the drug's proven therapeutic benefits. Brazilian regulatory authorities approved the use of trastuzumab in HER-2 positive breast cancer in 2000. However, Trastuzumab is available only to privately insured patients and not available to the public till the year 2017. The increased cost of the drug, coupled with access challenges, has restricted its use.¹⁸ The Report of the WHO Expert Committee on Selection and Use of Essential Medicines, 2021 acknowledged that the trastuzumab is a high price medicine and making combination therapy with trastuzumab would be a great challenge for patients financially in health systems. It also highlighted that determining HER2 diagnostic tests were

¹⁶ Santos Rutschman, A. (2022). *Vaccines as technology: Innovation, barriers, and the public health*. Cambridge University Press, p. 99.

¹⁷ World Health Organization. (2019, December 18). *WHO prequalifies first biosimilar medicine to increase worldwide access to life-saving breast cancer treatment* [News release]. <https://www.who.int/news/item/18-12-2019-who-prequalifies-first-biosimilar-medicine-to-increase-worldwide-access-to-life-saving-breast-cancer-treatment>. (Accessed November 26, 2025).

¹⁸ Kristin, E., et al. (2022). *Does trastuzumab offer good value for money for breast cancer patients with metastasis in Indonesia?* Asian Pacific Journal of Cancer Prevention, 23(7), 2441–2449. <https://doi.org/10.31557/APJCP.2022.23.7.2441>. (Accessed November 26, 2025)

conducted in highly specialized laboratories and skilled technicians, which may not be widely available and affordable in many developing and under-developed income countries.¹⁹

c) Thalidomide Tragedy: Lessons on Patents, Regulation, and Ethical Oversight:

The thalidomide tragedy is considered as the worst catastrophic drug-related disasters in the world. It was patented in 1954 by the German Pharmaceutical company Chemie Grunenthal under the name Contargen, the drug was aggressively marketed as a safe, non-toxic remedy for morning sickness and insomnia in pregnant women. Despite these sweeping claims, without conducting any comprehensive human testing, patent was granted raising serious doubts about the scientific assertions in the patent specifications. It was subsequently licensed under 49 brand names and distributed across 79 countries.²⁰

Between the late 1950s to the early 1960s, thalidomide exposure during pregnancy resulted in the birth of nearly 10,000 infants worldwide with severe congenital deformities, only half of whom survived. West Germany alone reported about 6,000 affected children. Typical abnormalities included phocomelia (severely shortened limbs), genital and anal atresia, malformed reproductive organs, facial paralysis, sensory impairments such as deafness and blindness, and significant gastrointestinal and urinary defects. Thousands of additional foetal deaths are believed to have occurred due to the drug's toxicity.

This tragedy revealed grave lapses in both corporate ethics and governmental oversight. The regulatory systems failed to ensure adequate testing and monitoring but the manufacturers promoted thalidomide as completely safe. Compensation was extended only to victims who are alive, and no criminal accountability or full public inquiry was ever conducted for those who did not survive. The thalidomide disaster stands as a powerful reminder of the devastating impact of insufficient drug testing, misleading patent representations, and weak regulatory controls.²¹

The evidence clearly supports the hypothesis that *high prices and limited availability of patented medicines restrict women's timely access to reproductive, maternal, and gender-specific healthcare*. It also shows that patent-driven high prices, constrained supply, and

¹⁹ World Health Organization. (2022). *The selection and use of essential medicines: Report of the WHO Expert Committee on Selection and Use of Essential Medicines, 2021 (including the 22nd WHO Model List of Essential Medicines and the 8th WHO Model List of Essential Medicines for Children)* (p. 335). Switzerland: World Health Organization. (Accessed November 26, 2025).

²⁰ Martin, J. (2018). *Thalidomide catastrophe*. Onwards and Upwards.

²¹ Kim, J. H., & Scialli, A. R. (2011). *Thalidomide: The tragedy of birth defects and the effective treatment of disease*. *Toxicological Sciences*, 122(1), 1–6. <https://doi.org/10.1093/toxsci/kfr088>. Accessed December 5, 2025.

regulatory failures often hinder women's access to essential reproductive and gender-specific healthcare, thereby, the hypotheses is validated.

3. Balancing IPR with Human Rights to Health

In 1994, WTO adopted the TRIPS Agreement to work towards uniform recognition and global protection of IP rights. From the beginning, the TRIPS Agreement acknowledged the nexus of IP rights in public health. Article 8 of the TRIPS agreement, which applies to all Member states, must strike to balance patent rights and public health by permitting states to “*adopt measures necessary to protect public health and nutrition,*” as long as “*such measures are consistent with the provisions of this Agreement.*” Additionally, Article 30 states that Members may make limited exceptions to patent rights, “*provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent*”. Together, these provisions are intended to provide Member states the flexibility to draft patent laws that take public health interests into account. The Doha Declaration 2001 also affirms that TRIPS flexibilities can be used to protect public health without violating international patent obligations.

Allowing the manufacture and importation of patented medicines without the owner's permission is known as Compulsory licensing. A state can purchase the medicines at lower cost in other countries through parallel importation. During public health pandemics, TRIPS flexibilities allow countries to use Compulsory licensing and Parallel importation to bypass patents. For instances, nations like India issued compulsory license to cancer drugs like Nexavar, in 2012 to improve access. Similarly, During HIV crisis, South Africa used parallel importation to import generic drugs.²² Due to pricing and supply chain challenges, almost 50 percent of individuals lack access to essential medicines in Sub-Saharan Africa. This incident established the need to balance in the form of compulsory licensing and parallel importation. These regulatory mechanisms evidently support the hypotheses by mitigating the negative impact of pharmaceutical patents on women's health.

4. Socioeconomic and cultural factors amplify the barriers created by patents

Barriers in improving women's health is often rooted in socio-economic, cultural and other legal considerations. Affordability of patent medicines is restricted due to lower economic status of women, limited financial autonomy and disproportionate care giving roles. The burden of patent barriers is interrelated with socioeconomic cultural norms. The taboos in

²² Bharanitharan Rajendran, Neeraj Mishra, Nimisha Srivastava, & Sumel Ashique (Eds.). (2025). *Pharmaceutical regulatory affairs: Principles and practices*. CRC Press.

culture around reproductive health, gender norms restricting mobility and discriminatory health practices deepen the inequities. Women often lack access to patent-protected treatments necessary for self-care.²³

CONCLUSION

Women's health is often affected by socioeconomic constraints, structural inequalities and social norms which are discriminatory that restrict their access to afford the health care in a timely manner. This paper has reached the conclusion that pharmaceutical patent regimes while intended to incentivize innovation often exacerbate these inequities by limiting the availability of life saving treatments and medicines due to high cost of essential medicines. Patent monopolies, weak regulatory systems and limited generic competition can produce harmful consequences to women's health during pandemics and in ordinary circumstances is highlighted by the case studies of HPV vaccines, trastuzumab and through the historical thalidomide tragedy.

International human rights framework such as WHO-OCHR, CEDAW, ICESCR and the Beijing Action Plan right to health principles affirm the states' obligations to ensure equality, non-discrimination and universal access to essential medicines. However, these remain unrealised when IP rules are interpreted and implemented in a manner without adequate regard to gender-specific health needs. Integration of fundamental human rights standards into patent governance is necessary to guarantee the development of innovative solutions does not come out at the expense of women's health.

The findings further conclude that socioeconomic and cultural barriers of women limit the access of high cost of patent medicines and deepen the gender inequities. Therefore, a comprehensive, gender- responsive approach which includes UHC, targeted public investment, gender-sensitive innovation policies, and TRIPS flexibilities is addressed to women's health rather than the legal reform of patents.

Ultimately, harmonising Intellectual property rights with women's right to health is both a legal and moral obligation Governments, global health institutions, and regulatory bodies should implement policies that encourage equitable access, strengthen accountability, and prioritise women's health needs in innovation and patent systems. Only through such coordinated action the international community can guarantee that the protection of patents

does not undermine the fundamental right of women to the highest attainable standard of physical and mental health.

SUGGESTIONS AND RECOMMENDATIONS

1. Human Rights Principles into Patent Governance

Policymakers should integrate fundamental human rights principles such as equality, non-discrimination, participation and accountability into international and national IP frameworks. Before pharmaceutical patent is granted, they must consider the impacts on women's health particularly when they relate to access to reproductive, maternal and gender specific medicines. Human-rights impact assessments must be adopted in all patent offices before granting pharmaceutical patents which are likely to affect women's health.

2. TRIPS Flexibilities must be strengthened for Women's Health

When patent-protected medicines compromise the health of women, Governments should more proactively use TRIPS flexibilities such as compulsory licensing, parallel importation, and government use licences for reducing the price of essential medicines for cervical, breast cancer, HIV/AIDS, and reproductive health needs supported by clear national guidelines.

3. Promote Gender-Responsive Innovation Policies

R&D funding should be prioritised for diseases and conditions which affect women's health. To prevent monopolistic of pricing, publicly funded research is essential. By investing in technologies designed specifically for women such as contraceptives, menstrual health products, and vaccines, can help to close the gaps left by years of neglect in the patent-driven market and make sure women's genuine health needs they deserve receive the attention.

4. Enhance Affordability Through Differential Pricing and Patent Pooling

To reduce the cost barriers in assessing the medicines, different pricing strategies, Voluntary licensing through the Medicinal Patent Pool and public-private partnerships must be adopted.

Adopting differential pricing strategies, voluntary licensing through the Medicines Patent Pool (MPP), and public-private partnerships can substantially reduce cost barriers. Patent pools for women's health products, including HPV vaccines, HIV prevention technologies, and therapies for reproductive cancers must be negotiated by the state and world health institutions.

5. Address Socioeconomic and Cultural Barriers That Deepen IP-Driven Inequalities

Patents intensify the existing access barriers which are created by social norms restricting women's mobility due to limited financial autonomy and persistent gender-based discrimination. Legal reform alone is not effective. Policies must be framed to integrate IP reforms with gender-equity measures such as insurance coverage, cash transfer schemes, community-based health programs and awareness campaigns which are culturally sensitive to make it effective.

6. Expand Universal Health Coverage (UHC) with Gender-Sensitive Benefit Packages

Women's health services and medicines which are protected by patent and costly must be included as full coverage in Universal Health Schemes. Government must negotiate bulk purchasing of patented drugs to ensure affordability for the women living in poverty.

7. Improve Transparency in Pharmaceutical Pricing and R&D Costs

To improve transparency in Pharmaceutical Pricing, Government and international agencies should mandate disclosure of R&D expenditures, clinical trial funding and price-setting mechanisms. This will help to determine whether monopoly pricing is justified and the accountability is strengthened when women's health is compromised due to excessive pricing of patented drugs.

8. Build Capacity of Health Systems to Navigate IP Barriers

Public health officials, legal experts and Procurement officers must be given training to utilize the TRIPS flexibilities more effectively and negotiate equitable licensing terms. Legal-technical units must be institutionalized in every States within ministries of health to handle IP-related access challenges.

9. Strengthen Regulatory and Antitrust Oversight

Generic medicines must be encouraged and Competition authorities must monitor and act against anti-competitive practices such as evergreening and patent thickets which limit the market entry for women's health. Regulatory bodies must approve the high- quality generic medicines without delay.

10. Strengthen International Cooperation and Global Solidarity

Global health institutions, donors, and UN bodies should collaborate to:

- finance manufacturing capacity in developing and under-developed income countries,

- support technology transfer for women's health technologies,
- promote equitable access during pandemics or health crises affecting women disproportionately.

REFERENCES

- Bharanitharan Rajendran, N., Mishra, N., Srivastava, N., & Ashique, S. (Eds.). (2025). *Pharmaceutical regulatory affairs: Principles and practices*. CRC Press.
- Cook, R. J., Dickens, B. M., & Fathalla, M. F. (2003). *Reproductive health and human rights: Integrating medicine, ethics, and law*. Clarendon Press.
- Cervical cancer: A global public health treatise. (2021). IntechOpen. Retrieved December 5, 2025, from <https://www.intechopen.com/chapters/77058>
- Goldman, M. B., & Hatch, M. C. (Eds.). (2000). *Women and health*. Academic Press.
- Goldberg, P. (1997). Women, health and human rights. *Pace International Law Review*, 9(1), Article 11. Retrieved December 4, 2025, from <https://digitalcommons.pace.edu/pilr/vol9/iss1/11>
- Guilfoile, P. (2019). *Human papillomavirus*. Infobase Publishing.
- Kim, J. H., & Scialli, A. R. (2011). Thalidomide: The tragedy of birth defects and the effective treatment of disease. *Toxicological Sciences*, 122(1), 1–6. <https://doi.org/10.1093/toxsci/kfr088> (Accessed December 5, 2025)
- Kristin, E., et al. (2022). Does trastuzumab offer good value for money for breast cancer patients with metastasis in Indonesia? *Asian Pacific Journal of Cancer Prevention*, 23(7), 2441–2449. <https://doi.org/10.31557/APJCP.2022.23.7.2441> (Accessed November 26, 2025)
- Love, R. (2007). Corporate wealth or public health? WTO/TRIPS flexibilities and access to HIV/AIDS antiretroviral drugs by developing countries. *Development in Practice*, 17(2), 208–219. Retrieved December 6, 2025, from <https://www.jstor.org/stable/25548200>
- Martin, J. (2018). *Thalidomide catastrophe*. Onwards and Upwards.
- Rezwana, N. (2017). *Disasters, gender and access to healthcare: Women in coastal Bangladesh*. Taylor & Francis.
- Sammarco, A. (2017). *Women's health issues across the life cycle*. Jones & Bartlett Learning.

Santos Rutschman, A. (2022). *Vaccines as technology: Innovation, barriers, and the public health*. Cambridge University Press.

Turshen, M. (2019). *Women's health movements: A global force for change*. Springer Nature Singapore.

Verma, S. K. (2019). Pharmaceutical patents and public health. *Journal of the Indian Law Institute*, 61(2), 153–181. Retrieved December 6, 2025, from <https://www.jstor.org/stable/26915659>

World Health Organization. (2013). *Women's and children's health: Evidence of impact of human rights* (P. Hunt, F. Bustreo, & others). Retrieved November 24, 2025, from <https://unicri.org/sites/default/files/2019-11/WHO%20Women%27s%20and%20Children%27s%20Health-%20Evidence%20of%20Impact%20of%20Human%20Rights.pdf>

World Health Organization. (2019, December 18). WHO prequalifies first biosimilar medicine to increase worldwide access to life-saving breast cancer treatment [News release]. Retrieved November 26, 2025, from <https://www.who.int/news/item/18-12-2019-who-prequalifies-first-biosimilar-medicine-to-increase-worldwide-access-to-life-saving-breast-cancer-treatment>

World Health Organization. (2022). *The selection and use of essential medicines: Report of the WHO Expert Committee on Selection and Use of Essential Medicines, 2021* (including the 22nd WHO Model List of Essential Medicines and the 8th WHO Model List of Essential Medicines for Children). Switzerland: World Health Organization.

World Health Organization. (n.d.). *Targets of Sustainable Development Goal 3 to ensure healthy lives and promote well-being for all at all ages*. Retrieved December 4, 2025, from <https://www.who.int/europe/about-us/our-work/sustainable-development-goals/targets-of-sustainable-development-goal-3>

United Nations. (1995). *Beijing Declaration and Platform for Action*. Retrieved November 25, 2025, from <https://www.un.org/womenwatch/daw/beijing/pdf/BDPfA%20E.pdf>

Yamin, A. E. (2025). Constructing maternal mortality as a human rights issue: Lessons for using international law to advance women's health and rights. In J. J. Dawuni & J. Cobbah (Eds.), *The Oxford handbook of women and international law* (pp. 345–367). Oxford University Press.