Exploring Intellectual Property and Access to Medicines from a Gender Approach

Sama Resource Group for Women and Health

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I.

Introduction

The system of intellectual property rights such as patents is designed to support the commercialization and marketing of innovations, business activities, and associated rights. When this system is allowed to operate unchecked with limited or no regulation, it affects and violates human rights. These violations have a far more severe effect on women because of the systemic discrimination and biases entrenched in the functioning of big pharma and other profiteering corporations all chasing the bottom line. Additionally, the effects of these centralised neo-liberal efforts interact with the systematic and structural limitations faced by women in everyday life to enhance the constraints on women's access to healthcare and health rights (see also Sen and Ostlin, 2007).

Further, the impacts of capitalism are also disproportionately felt by women. Indeed, the impacts of the extractive commercialized agricultural activities exacerbate the tensions of the limited ownership of women on cultivable land, exclude women from decision-making processes regarding the use of their own land and breach their rights of compensation for lost land.[1] The detrimental ends of the industrial processes and emissions from fossil fuel consumption due to commercial agricultural activities have reportedly contributed to 78 per cent of the total greenhouse gas emission increase between 2000-2010.[2] The impact of such climate change is seen in the form of river floods, water scarcity, depleting groundwater resources, food insecurity, and shifts in food production across the world. These events have a disproportionate impact on women and girls thus recycling gender inequality. For example, polluted water imposes an added responsibility on women and girls, compelling them to walk long distances to fetch potable water, resulting in severe exhaustion and ill health.[3] The impact of climate events impacted the personal hygiene and sanitation of women has also been well documented.[4]

Ecofeminists have emphasized the connections between natural exploitation and women's oppression. In this regard, it is pertinent to remember the Chipko movement in the 1970s in India. When government authorities threatened to alter the ways trees and forest resources were treated as 'commons' by ceding control to corporations through

contracts, rural women in the area resisted vehemently. Theirs was a non-violent ecofeminist resistance against not just the government order but also against male dominance, the denial of women's rights, and the silencing of women's voices. "They wanted to protect the environment, preserving its state and simultaneously, they questioned the status quo, biased in favour of men, and demanded a say in decisions which affected them."[5]

Decades later, indigenous agricultural systems faced an attack with the push for genetically modified (GM) crops, seeds, and chemical farming. Large corporations like Bayer/Monsanto monopolized the market as the world's largest Genetically Modified (GM) seeds company. Driven by their agenda of monopolizing seed production and with the power of patents, these mega-corporations have exerted pressure on states to push small farmers into penury by forcing them to buy GM seeds. Ecofeminist arguments assert that the intellectual property rights in this case not only lead to environmental degradation, thanks to toxic GM seeds and technology sold solely for royalty collection and corporate profiteering, but also pushed farmers into the vicious cycle of poverty, indebtedness, ill-health, and suicides because of debt. This had grave repercussions for women who comprise 20–30 per cent of the agricultural workforce, and are used to seed-saving and sharing.

Additionally, the increasing control and patenting of traditional knowledge have had a deep impact on traditional agriculture and on those who depend on it. In India, women producers are significantly affected by this development, as they usually depend more on traditional systems of cultivation, for example, traditional ginger cultivation in Sikkim and West Bengal, subsistence agriculture in Wayanad, Kerala, and traditional agriculture in Kolli Hills, Tamil Nadu.[6] The role of women in the practice and preservation of traditional knowledge is well documented in many areas such as biomass-related activities and traditional agriculture (for example, seed preservation) and the practice and use of traditional medicine, especially for gynaecological treatment.

These shifts resulted in exacerbated economic inequality widened occupational gaps and deepened job insecurity for women, and pushed women into poverty. According to a report, "the social role ascribed to women in the agricultural system has also influenced this knowledge to some extent. The immediate impact of seed conservation is the reduced dependency on the market for the purchase of seeds as well as food".[7] These developments affect women much more than men, because women, being far less well integrated into the mainstream economic

structure, sustain themselves and their families on such basic systems.

Women, far less well integrated into the mainstream economic structure, sustain themselves and their families on basic systems. The intellectual property regime reveals the gendered effects of how 'businesses' are conducted and how corporations use the entitlements and private rights granted to them. It is essential to carefully examine the impact of such profit-driven systems on the lives, livelihoods, health, and well-being of women, particularly women from marginalized communities. Further, the system of intellectual property rights is designed to exclude marginalized and racialized women of benefits, even when it is their knowledge that aids innovation and invention.

The trade liberalization resulting from these agreements can alter economic inequality between men and women, and increase occupational gaps and job insecurity for women.[8] It also lays bare the need to be cautious about the gendered effects of how businesses are conducted, and how they use the entitlements and private rights granted to them. It is important to carefully peruse the effects of such systems on the lives, livelihoods, health and well-being of women.

A gender analysis of patent law in the context of drugs and neoliberal capitalist biopolitics reveals how women's bodies are controlled, governed, exploited, and devalued. Feminist scholarship has interrogated capitalist medical institutions to reveal their gendered and racialized foundations. Patents and gender, thus, have a close association. Time and again, women's bodies, including cells and DNA, have been used for commercial research in an illegal and unethical manner.

The life story of Henrietta Lacks of Baltimore, Maryland, in the United States, is one such example.[9] Born into an economically poor black family, Henrietta engaged in the tedious and back-breaking tobacco field in Virginia, exposing her to multiple health risks. Under economic constraints, she had to marry young. She discovered a lump in 1950 after the birth of her youngest child. Henrietta, complaining of vaginal bleeding in 1951, approached the Johns Hopkins Hospital for examination. At that time, the Johns Hopkins Hospital was one of the few hospitals providing medical care to poor black people. On finding a malignant tumour, she was administered radium treatment. At this time, a sample of her tissue was sent to a nearby lab working on tissue culture and hence collected the cells of all patients affected by cervical cancer visiting the Johns Hopkins Hospital. While all other cells thus collected survived only for a few days and died quickly, the lab found that Henrietta's cells not

only survived but multiplied every 20–24 hours. These cells were named ‘HeLa’(based on the first two syllables of her first and last names). They became the backbone of research in several fields of biological sciences. Sadly, cancer spread across Henrietta’s body, and she died within a year of seeking treatment.

However, her cells, HeLa Cells, were commercialized and sold worldwide for research that has formed the basis of modern medical research in the areas of cancer, infectious diseases, and polio, through which many establishments and pharmaceutical companies have made huge profits. For decades, her cells were used for research by third parties without the knowledge or consent of her family members. The continued use of the HeLa cell lines without attribution and consent reveals the persistence of racial inequity, discrimination, and colonialist biases in healthcare and research. The difficult lives of women such as Henrietta, struggling to access the fundamental right to life, are the subject of debate and discussion in policies and practices on the ethics of using biological material. This raises serious concerns about the abuse and exploitation of women based on inherent prejudices related to their lifestyles, race, ethnicity, and social background. The absence of gender in conversations on intellectual property rights is evident in how women’s contributions as inventors, knowledge producers, and ‘subjects’ of research and experimentation are denied or ignored.

Hence, the gendered nature and effects of such experiments and how innovators and inventors use the entitlements and private rights granted to them are of great concern. Commercialization and exploitation of natural resources, bodily resources (body fluids, genetic material), healthcare tools and related products (medicines, contraceptives) have a direct and indirect impact on women, exacerbating their struggle for equality and their search for a better and more equitable world. Furthermore, the patent regime governing pharmaceutical products has exacerbated the adverse impact of private rights in the form of intellectual property rights on women and vulnerable communities. The rights and needs of these marginalized groups need a closer analysis and discussion.[10]

It is this larger socio-economic context within which we place our argument towards gender-sensitive and rights-based interrogation of intellectual rights. We make a case for the urgent deconstruction of the IP regimes and move away from taken-for-granted centralised and institutionalized frameworks towards a “ground-level” understanding of their impacts.

II.

Situating a Gender-Based Analysis: Access to healthcare

Gender is a key social determinant of health that affects health outcomes for people identifying with all genders. It intersects with other social determinants like poverty, education, caste, race, sexuality, sexual orientation, ethnicity, age, disability, migratory and refugee status, and occupation. It is essential to address the role of restrictive gender norms and gender inequality both within and outside health systems. Years of intersectional feminist efforts in the field of health have led to the incorporation of gender into the discourse of health, however, it is time that these efforts be recognized by the healthcare system vis a-vie policies and programmes to move away from rhetoric towards action. The lack of accessibility to basic health services, diagnostics, and treatments that women and people within the LGBTQIA+ spectrum face are the results of traditional forms of gender-based inequity and socially sanctioned roles. They face discrimination and exclusion in access to healthcare, including inaccessibility to health and medical facilities, prohibitively priced medicines, and inadequate sexual and reproductive health (SRH) services.

This situation is particularly serious in low- and middle-income countries where patriarchy determines and shapes the traditional role of women and where women face various barriers in accessing their fundamental rights to healthcare. In such societies, women lack decision-making power because they are denied control over resources. In households with limited resources, men have a larger share of, and a larger claim to, healthcare than women. Their healthcare needs are neglected and ignored while those of men are accorded priority and importance.

The neglect of women's health must also be seen as a structural issue within the context of an unequal, underfunded, and inadequate public health system where basic standards of care are often not met. India spends only 1.3 per cent of its gross domestic product (GDP)[11] on healthcare whereas the 2017 National Health Policy (NHP) of India aims for 2.5-3 per cent GDP in health expenditure. The inadequate public health

infrastructure, which is often absent altogether in some countries, forces women to resort to the private sector, leaving them vulnerable to exploitation given the weak regulatory framework for private hospitals. In India, the cost of treatment in private hospitals is unaffordable for poor households which incur catastrophic health expenditures. In a study in Gujarat, around 75 per cent of women delivering in private institutions had a health expenditure of more than 10 per cent of the total annual family income, which amounts to catastrophic health expenditure.[12] Similarly, the out-of-pocket healthcare expenditure for the treatment of reproductive health-related diseases in private facilities in India is 5.4 times higher than the expenditure in public health facilities.[13]

The state has an obligation to ensure equal access to healthcare for women and to make provisions that do not impede access to medicines, diagnostics, or related technologies particularly related to sexual and reproductive health. This requires the state to exercise all available mechanisms and provisions in the policy, legislation, and international agreements to ensure that women, the LGBTQIA+ community, indigenous communities, people with disabilities, migrants, with refugee status, sex workers, informal workers and frontline health workers (FLHWs) have timely, affordable, and access to quality healthcare.

III.

Contextualizing Intellectual Property

Scientific, technological, and medical advancements and innovations have helped address serious global public health challenges, such as HIV/AIDS, Ebola, influenza, and, more recently, COVID-19. In general, innovations are almost always accompanied by intellectual property rights, a system designed to incentivize and encourage such breakthroughs and to regulate their manufacture. The patent owner is granted exclusive rights to make or use the patented invention for 20 years. By setting limits on ownership, usage, and access to the said technology, knowledge, service, or product, the structure is framed for maximizing the commercialization potential. The challenge is to find an optimal balance between the patent owner's rights and the needs of the

beneficiaries of the said innovation. The challenge is more complex regarding intellectual property rights over public health-related technologies.

On the one hand, it is often argued that developing new technology requires a significant investment of resources. On the other hand, a system of ownership may also lead to private profiteering at the cost of denial of public health innovations to the people most in need. When misused, the intellectual property system jeopardizes survival and well-being, making access to treatment difficult.

This issue briefly argues that intellectual property rights are not an inherently objective and neutral terrain. Like the law in general, the intellectual property system is also determined by the existing social, political, and economic contexts and is shaped by prevailing inequities and hierarchies. The brief argues that the entire patent system is also far from being gender-neutral. Paternalistic, capitalist and colonialist biases and discriminations remain entrenched in this system and disproportionately affect women and other marginalized groups.

IV.

International regime and the changing contours of access

The establishment of the World Trade Organization (WTO) and, with it, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1995 imposed an obligation on member states to provide minimum protection for intellectual property. This meant that the members of the WTO would have to change their national laws in compliance with the TRIPS Agreement. This would result in a major shift in the national regime, even affecting public health.

The TRIPS Agreement required countries to protect intellectual property within their borders for a particular period, granting the innovator monopoly rights. Such rights allow the intellectual property holder to impose restrictions on and control the trade of the product. An analysis of the TRIPS Agreement through a feminist lens reveals that TRIPS

emphasized trade-related and monetary aspects of compensation on investments made by the innovator while completely ignoring the value of the moral, ethical, and non-monetary recognition of the innovator.[14] Historically women have been denied education with limited access to avenues for developing their knowledge. Women who made pathbreaking inventions have been regarded as 'trespassers'.[15] While different types of intellectual property have been recognized under the TRIPS Agreement, including patents, copyright, industrial designs, geographical indications, trademarks, layout design of integrated circuits, and undisclosed information, this brief will deal with the impact of pharmaceutical patents on public health, particularly on the health of women. In doing so, we also question the monolithic understanding of knowledge itself and argue that it needs to be inclusive of the work and lived experiences of women and indigenous communities. The system of intellectual property rights and patents has a systemic way of keeping women and gender minorities out of the realm of benefits, even when their knowledge and invention aid the patent. As feminists working on public health, we emphasize the need to take into account the social history of the production of knowledge.

In the post-TRIPS period, WTO member states are required to introduce product and process patents. This has prompted several discussions on the impact of such changes on access to pharmaceuticals. The countries that had tailored their patent regimes for more competition in the pharmaceutical market by granting only process patents now have to grant product patents to pharmaceutical products as well. This means that in the post-TRIPS period, most pharmaceuticals have 20-year patent protection, thereby giving the patentee a market and price monopoly. Generic pharmaceutical manufacturers, therefore, have to wait for the expiry of the patent term to introduce pharmaceuticals at competitive prices. This has resulted in decreased access to medicines and inequity in access to timely and affordable therapeutics for all.

The HIV/AIDS pandemic showed the importance of breaking the barriers of patents to allow affordable HIV drugs. Countries like South Africa and Brazil took steps such as importing cheaper versions of medicines and imposing mandatory local manufacturing of drugs. These actions were challenged by developed countries representing pharmaceutical interests at national and international adjudicatory levels. These challenges were withdrawn following massive backlash and criticism at the international level. However, developing countries were left fearing sanctions if they took measures to safeguard public interest that might harm corporate interests. This soon led to a public outcry over political pressures that

discouraged developing countries from exercising rights like the grant of compulsory licences to safeguard public health.

Developing countries pushed for an interpretation of the TRIPS Agreement that would uphold the right of the WTO members to use provisions such as the grant of compulsory licences and the parallel import of drugs in the public interest. This led to the signing of the Doha Declaration on the TRIPS Agreement and Public Health in 2001, which reinforced the understanding that the TRIPS Agreement and the rights granted therein cannot trump the right to health. The Doha Declaration states: "Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency."[16]

Even though it has been accepted that the TRIPS Agreement should be read in a manner that protects public health, WTO members have been hesitant to use this interpretation, mostly because they fear a backlash in the form of trade sanctions by developed countries. It is argued that the patentee can issue voluntary licences to third parties to increase production and enhance access. However, such licences are difficult to negotiate and are issued at the discretion of the patentee. The patentee is not obliged to ensure greater affordability and accessibility. Indeed, there have been instances where the patentee has imposed licence agreement terms disallowing sales of pharmaceutical products in certain countries. Patent monopolies, therefore, allow access to critical therapeutics and diagnostics to only those who can afford to pay the monopolistic price.

V.

Access to medicines in international instruments

The issue of access to medicines in the context of pharmaceutical patents has been the subject of many international debates. Accordingly, the patent over pharmaceuticals and the manner of exercise of such patent raise concerns about the right to health, particularly in the quest to

access essential medicines. It is within this ongoing debate about pharmaceutical patents and public health that this paper argues for women's increased access to medicines within the framework of human rights law and standards. Access to medicines is identified as part of the fundamental human right to health, given that the right to health cannot be achieved without access to essential medicines for the effective treatment of ailments. Health as a human right is enumerated in several human rights instruments.[17]

International conventions, including the International Covenant on Economic, Social and Cultural Rights (ICESCR) (1966) and the Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW) (1979), recognize the obligation of member states to recognize the right of everyone to enjoy the highest attainable standard of physical and mental health. Article 25.1 of the Universal Declaration of Human Rights (1948) states that everyone has the right to a standard of living adequate for their health and well-being, including food, clothing, housing, and medical care.

Similarly, General Comment 14 of the Committee on Economic, Social and Cultural Rights (CESCR) iterates that the right to health comprises four interrelated elements—availability, accessibility, acceptability, and quality. The element of accessibility identified herein includes access to affordable healthcare. General Comment 14 specifically notes that health facilities, goods, and services provided privately must be affordable for all, including socially disadvantaged groups. It also states that "poorer households should not be disproportionately burdened with health expenses as compared to richer households". It is noteworthy that the CESCR comment adds that the private business sector also has the responsibility towards the realization of the right to health. The CESCR also provides that the state has an obligation to ensure that health facilities, goods, and services are within the physical reach of the population, especially vulnerable and marginalized groups such as women and children.[18]

The right to health refers to the right to the enjoyment of a variety of goods (medicines), facilities, services and conditions necessary for its realisation (OHCHR, 3). Linkage to trade and universal access to health was also addressed in one of the Sustainable Development Goals (Goal 3). SDG 3.8 states, "Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all." Similarly, 3. B of SDG mentions, "Support the research

and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all."

States also have the obligation to ensure equal access to healthcare for women, including access to family planning. It is the state's obligation to make provisions that do not impede access to medicines, diagnostics or related technologies related to sexual and reproductive health. This requires the States to exercise available mechanisms in the policy, legislation, and international agreements to ensure that women, children, the LGBTQIA+ community, women with disabilities, migrants and other vulnerable groups have timely, affordable, quality access to healthcare.

It is known that the existing discriminatory norms and values have resulted in biases in health research, leading to a lack of understanding of the impact of disease and medicines on women's bodies. Such biases in health research have in turn exposed women to more vulnerability to disease and subsequent harm/injury.[19]

In light of the above discussion, the issue of access to medicines is an issue of human rights, not least because such a correlation is a guarantee of the moral and legal entitlement afforded to all individuals. The human rights approach also places the accountability on the state to uphold, guarantee and implement human rights including the right to health.

Furthermore, the international rights regime imposes an obligation on the private sector as well to take into consideration the needs of women, children, and vulnerable communities during the course of their 'business'. In the context of intellectual property, the need to bridge the gender gap in recognizing women as inventors has also been acknowledged.[20] However, the impact of private rights in the form of intellectual property rights on women, LGBTQIA+ and other vulnerable communities, and on their rights, needs a closer analysis and discussion.

While the international instruments provide a framework for the states to ensure the protection and promotion of the human rights of patients,[21] in India, the right to health is recognized as a part of the constitutionally

recognized right to life. The Constitution of India, under the Directive Principles of State Policy, directs the state to improve public health, nutrition, maternity relief etc. as part of state responsibility.

VI.

Pharmaceutical Product Patents: Barriers to Access to Healthcare

Economic inequity and the high market price of patented drugs have resulted in a global health crisis, particularly affecting low-income nations. For instance, in India, in 2015–16, pharmacies accounted for at least half of the out-of-pocket expenditure of households.[22] A committee set up in India in 2007 to suggest a system of reference pricing and price negotiation stated that the prices of patented medicines, even after negotiation, would remain unaffordable for the majority of the population.[23] Sadly, this continues to be the situation even today.

Below we discuss the impact of intellectual property rights on accessibility to some essential medicines for women, and the global campaigns and movements by treatment activists and women, that have brought about some changes in accessibility. In particular, the most vulnerable and marginalized women in low-income nations suffer the most because of the poor availability of much-needed healthcare services and medicines.

The global order has accepted the right to patent, but still, these rights remain a significant factor in poor treatment and health outcomes for women. Patented drugs are an additional burden on women, along with multiple other constraints that prevent women from meeting their healthcare needs and demands. Financial and structural factors such as patent rights and corporate profiteering that curtail women's right to health and medical treatment need to be addressed. In the following section, we examine the relationship between drugs, patents, and gender, based on the case studies of some specific drugs.

VI.I.

Nevirapine

In the 1990s, several developing countries struggled to protect their people from the HIV/AIDS pandemic. Women were disproportionately affected from the beginning of the pandemic. Even as recently as 2019, women comprised more than half of all people living with HIV in South Africa.[24] AIDS-related illnesses were one of the leading causes of death for women between 15 and 49 years in the region.[25] In sub-Saharan Africa, women had a higher incidence of HIV/AIDS as compared to men.

A gendered analysis of HIV/AIDS shows that it is the systemic disempowerment of women over their bodies and their sexual lives, reinforced by their social and economic inequality, that puts them at higher risk for HIV/AIDS. Women living with HIV face greater stigma and discrimination but they also face the overwhelming burden of family care and domestic chores. Women are more susceptible to the disease, especially in low-income countries, since they lack decision-making power in sexual interactions and face financial stress that weakens their bargaining capacity, including the use of contraceptives like condoms.[26] Women face difficulty in negotiating their agency for safe and healthy sex since the repercussions are as grave as domestic abuse, exclusion from children, desertion, abandonment, and divorce. Physical violence, the threat of violence, and the fear of abandonment are significant deterrents for women who have to negotiate the use of a condom or leave relationships that they perceive to be risky. Violence against women contributes directly and indirectly to women's vulnerability to HIV and their ability to cope with infection.

Stigma surrounding HIV/AIDS also exists within the gay community and has a negative effect on the physical and mental health of men who have sex with men (MSM) and of people living with HIV. Stigma is associated with increased levels of anxiety, loneliness, depressive symptoms, and a history of suicidal ideation. Along with the high vulnerability of women, mother-to-child transmission (MTCT) of the virus during pregnancy or in the post-partum period through breastfeeding is a huge challenge for mother and child. MTCT can be significantly reduced if antiretroviral medicines are made readily available and easily affordable to poor women and women at high risk. To increase the survival chances of babies, the United Nations General Assembly on HIV/AIDS called for efforts to increase HIV prevention and treatment in a multisectoral and gender-sensitive manner.[27]

The drug Nevirapine is used to prevent MTCT of HIV. In South Africa, around 90 per cent of HIV infections in children resulted from the parent-to-child transmission.[28] Nevirapine was made available only in public sector hospitals ostensibly on the grounds of safety. Around 2001, the Treatment Action Campaign (TAC), a coalition of South African AIDS-related organizations, initiated a suit against the government of South Africa, on the grounds that the policy of making the drug available only in the public sector imposed a barrier to accessibility and impeded the right to health of pregnant women living with HIV and their children. The court ruled that limiting accessibility to Nevirapine "is not reasonable and is an unjustifiable barrier to the progressive realization of the right to health care". This ruling was also upheld by the Constitutional Court of South Africa.[29]

The adverse impact of patents on pharmaceutical products was seen during the HIV/AIDS epidemic. Most drugs for HIV were patented by multinational companies, thus preventing the generic production of the medicines. Monopolies granted for medicines led to an escalation of prices, unaffordability, and unavailability of medicines for those who really needed the drugs. Low and middle-income countries, were thus, unable to provide medicines to their people. In 2001, just the sub-Saharan region had more than 28.1 million people living with HIV.[30] It was when South Africa took the lead in amending its law to procure affordable medicines that some generic manufacturers like Cipla started producing medicines that treated HIV, and the prices dropped steeply. This also led to the increased availability of HIV medicines in the developing world. Cipla offered a cocktail of three HIV drugs—Nevirapine, Didanosine, and Zidovudine—at one-thirtieth of the then-market price, making the drugs available at less than one dollar a day.[31]

In India, Boehringer Ingelheim (BI) filed applications for patenting the paediatric form of the anti-AIDS drug Nevirapine. It should be noted that granting a patent to this application would have resulted in granting a monopoly to Nevirapine, a drug that was already known before the patent application was filed by BI in India. A group of women living with HIV in India, the Positive Women's Network (PWN), along with the Indian Network for People Living with HIV/AIDS (INP+), filed an opposition before the Indian Patent Office against the grant of a patent to BI's application. Accepting the arguments made by PWN and INP+, the Indian Patent Office rejected the grant of a patent to BI's paediatric form of Nevirapine.[32] The intervention ensured that the drug remains available to women and children at affordable prices, and the government HIV programme is not affected by monopolistic prices.

VI.II.

Cancer drugs

Women are more likely to experience severe side effects of chemotherapy, immunotherapy, etc. and therefore had a 34 per cent higher risk of adverse events (AEs) from chemotherapy than men.[33] Additionally, the sex disparity for women is drastically high while receiving immune therapy, since nearly 50 per cent of women have an increased risk of serious side effects compared to men.[34] The Lancet Commission working report on gender and cancer adopted the intersectional feminist approach to ascertain how the varying positioning of women can affect their treatment, diagnosis, and mortality rates.[35] Further, more than 300,000 women die from cervical cancer each year; nine in ten of these women live in a low- or middle-income country.[36]

Low literacy levels among women, competing health needs in the family, limited resources, poorly developed health services, and limited information on cancer prevention contributes to the inequity faced by women living with cancer.[37] Gender-based roles, amounting to a different threshold of illness for women based on cultural values and patriarchal norms to ensure the continued functioning of the household, further skew the access to healthcare for women in developing countries. In India, for example, women below 30 and above 60 reportedly face extensive discrimination in gaining access to healthcare.

Women are highly vulnerable to various forms of cancers such as breast, uterine corpus, colorectal, endometrial, lung, cervical, skin, and ovarian cancers have relatively high mortality rates for women.[38] Increasing the accessibility of diagnostics and medicines for women, therefore, is an ethical concern. In addition, the WHO Model List of Essential Medicines (also known as the Essential Medicines List or EML) has identified cytotoxic medicines such as carboplatin, cisplatin, capecitabine, methadone, cyclophosphamide, fluorouracil, gemcitabine, among many others, for the treatment and management of various cancers commonly associated with women.[39] These drugs in addition to the other essential treatments for such cancers are both expensive and inaccessible to women in developing and low-income countries due to the patent regimes.

VI.III.

Trastuzumab

Trastuzumab is an important drug for women living with human epidermal growth factor receptor 2(HER2) breast cancer, which affects about one in four patients diagnosed with breast cancer.

In India alone, about 100,500 new breast cancer cases are reported every year, of which 70,000 succumb every year.[40] In some states, breast cancer is the leading cause of death in women.

Trastuzumab was granted a patent in several countries in the late 1990s and early 2000s, and was introduced in India in 2002. This meant that the patentee enjoyed a market monopoly for 20 years in the country where the drug was patented. During this period, the cost of one year's course of Trastuzumab was as high as about INR 2,426,507.64, placing it out of the reach of millions of women who suffered immature deaths because they could not afford the drug.[41] The patentee also filed secondary patent applications in several countries, including India. This meant the continued unaffordability of Trastuzumab beyond the initial 20-year period of the original patent term. When such essential drugs remain expensive and out of reach for women, it creates an additional burden on women who already suffer from poor treatment, inadequate diagnosis, and abandonment by their families.

In 2012, the Campaign for Affordable Trastuzumab wrote to the prime minister of India, asking that Trastuzumab be made available for free at public cancer treatment facilities and at an affordable price in the private market.[42] The group noted that while the drug was exorbitantly priced, no other company other than the patentee, Roche, could make the drug available in the market. As a result, the patentee had a complete price and market monopoly over the drug. Roche's Trastuzumab, marketed as Herceptin in India, was the first such drug made available in the country at a price of around INR 110,000 per vial. In March 2012, after the Indian Patent Office issued a compulsory licence on another cancer drug, Sorafenib tosylate, Roche cut the price of Herceptin from INR 100,800 per dose to INR 92,000 per dose. Due to its prohibitive price, the Indian government in 2013 considered issuing a compulsory licence on the patent for Trastuzumab.[43] In March 2013, the Campaign for Affordable Trastuzumab again urged the Minister of Commerce to take action and issue a compulsory licence on Roche's patent. Faced with the threat of a compulsory licence, Roche's licensee started offering Trastuzumab at a

lower price of INR 75,000 per dose, which was still unaffordable to many. Eventually, in 2013, Roche stated that it would not pursue some of its patents related to Trastuzumab in India.[44] Although biosimilar treatments provide some respite for women in developing countries who cannot afford patented medicines, biosimilar medicines also remain highly expensive and unaffordable for poorer women.

The expiry of the original patent on Trastuzumab in India would have meant that other companies could manufacture the drug, leading to competition and a reduction in the price. However, Roche, the company that owned the patent, kept engaging in tactics to delay the entry of other players by citing non-compliance with regulatory pathways by other companies. For instance, in India, Biocon Ltd. and Mylan Inc. sold Trastuzumab under the brand names Canmab and Hertraz, respectively. Canmab and Hertraz were proposed to be launched at a 50 per cent lower price than that of Herceptin.[45] Roche sued these companies in India, claiming that they were misrepresenting their drugs to be 'biosimilar Trastuzumab' and that their biosimilar versions were not approved in accordance with the Guidelines on Similar Biologics.[46] The threat of legal suits by Roche against any potential manufacturers of the drug dissuaded the latter from manufacturing the drug, thereby affecting the availability and affordability of the drug for women not only in India but also in other countries that relied on drug imports from India. In these conditions, women are forced to resort to costly medical treatments to fight cancer. Later, in India, the government put a price cap on Trastuzumab at INR 55,800 per injection. This was much lower than the price offered by Roche, viz. INR 75,000.[47] But even at this price, it was unaffordable to most women with cancer in India.

Disputes related to breast cancer have strongly recognized the issues around patenting and the need for increased access to modern medicines for women. Regarding these disputes over patent rights and human rights to health, we must accept that for overall development and innovation in medicine, women's healthcare services should not be compromised. Women's health and medical needs—including prevention, screening, diagnosis, and treatment— must be placed at the centre, for health is a crucial indicator of human rights.

VI.IV.

Sorafenib tosylate

Sorafenib tosylate is a crucial drug for the treatment of kidney and liver cancer. It is marketed under the brand name Nexavar by Bayer Corporation and was patented in India in 2008. Bayer's Nexavar, priced at INR 284,000 per patient per month, was unaffordable for most patients in India. In 2011, as against the demand of 8,842 patients, only 200 patients were able to procure the drug from the patentee Bayer. In 2014, about 17,000 patients needed the drug.[48]Consequently, the first-ever compulsory licence in India was granted for this drug so as to market a more affordable generic version of Nexavar. This allowed the drug to be sold at INR 8,800 per person per year.[49]

To facilitate faster approval of medicines in other countries, India's patent law allows the export of patented products (including by persons other than the patentee) for uses that are reasonably related to the development and submission of information required in India or any other country. This means that Indian generic pharmaceutical companies can export the product that may be patented in India to other countries for conducting studies for marketing the drug. This, in turn, allows for the faster approval of the drug and allows third parties to commence selling the medicine as soon as the patent expires in the country.

Using this legal exception to patent rights, when an Indian generic pharmaceutical company started exporting the patented product, Bayer initiated legal action, resulting in a lawsuit that dragged on for over five years.[50] The court eventually held that such export was allowed. However, the use of such tactics by the patentee, that is, of taking generic pharmaceutical companies to court, not only resulted in fear among potential manufacturers of being embroiled in legal disputes but also delayed the availability of drugs in other countries.

VI.V.

Bedaquiline

Tuberculosis (TB) is a major public health issue in India. The country is home to about 26 per cent of the global TB population.[51] India accounts for about 34 per cent of global TB deaths, and 40 per cent of the TB cases reported in India are among women.[52]

Women in India are disproportionately affected by TB. Women living with TB suffer discrimination not only at their place of employment but also within their families; they are separated from their children and are pushed out of their homes. Unmarried girls may delay approaching a health centre for TB-related care to hide the illness from neighbours, or at times may prefer marriage over TB treatment. In the case of married women, household responsibilities, neglect of women's health unless they are seriously ill, limited financial resources, women's lack of agency, restrictions on women's movement, patriarchal norms, etc. lead to delays in seeking TB-related care. Additionally, there are gender differences in access to healthcare, diagnosis, and stigma associated with the disease. The inequities in access to healthcare particularly for infectious diseases such as TB for women were exacerbated during the COVID-19 pandemic.

In cases of severe forms of TB, traditional drugs do not work and the patient can be resistant to as many as more than two drugs. This is called Multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB). Hence, only a limited number of medicines work for people affected by MDR-TB or XDR-TB. In 2020, about 49,679 people were reported to be affected by MDR-TB in India. MDR-TB and XDR-TB-related treatment is very painful, including injectables and medicines that cause severe side effects, including hearing loss and psychosis. In the past six or seven years, new medicines have been developed to treat MDR-TB and XDR-TB. WHO also recommends an all-oral treatment regimen for treating MDR-TB and XDR-TB. This means no more painful injectables and increased access to safer medicines with fewer side effects. The drug Bedaquiline forms the backbone of the all-oral regimen recommended for treating MDR-TB.[53]

In India, Bedaquiline is only available through the National Tuberculosis Elimination Programme (NTEP). Its sale is not permitted in the private market. However, a response to an RTI (Right to Information) query revealed that Bedaquiline is priced (procured) at about INR 20,000 for a six-month course per patient. That is, the NTEP has to spend this amount per patient for just Bedaquiline, which is to be taken in combination with several other medicines. Bedaquiline has been patented in India by Janssen Pharmaceutica N.V. The patentee enjoys a market monopoly till 2023. Consequently, the NTEP is unable to procure this drug from any other supplier nor can it purchase it at a cheaper price. This has led to the rationing of the drug and placed it beyond the reach of those who need it the most.

The patenting regime has created barriers to the accessibility and affordability of medicines for people who need these drugs for their

health and well-being, if not their very survival. The generic pharmaceutical industry in India has exported inexpensive drugs to other countries in the past. However, patent-related restrictions prevent countries that could have imported inexpensive versions of Bedaquiline from doing so. Cognizant of the impact of the patent monopoly, a TB survivor and a civil society organization filed a petition before the High Court of Mumbai, asking that a compulsory licence be issued allowing third parties to produce Bedaquiline and offer it at an affordable price.

While intellectual property rights continue to pose a barrier to access to Bedaquiline, there were also policy barriers that came to the fore when women affected by TB challenged those issues. In 2017, Bedaquiline was available in India in less than ten government centres across the country. An 18-year-old woman suffering from XDR-TB travelled more than 1,000 kilometres to Delhi from Bihar because the lifesaving Bedaquiline was not available in her home state.[54] Bedaquiline, a drug that was important for her survival, was not available in her home state.[55] However, on reaching Delhi, she was denied access to the drug on the grounds that the drug was available only to the residents of the area. In the absence of any alternative treatment, the woman challenged the discriminatory practice before the High Court of Delhi. The government thereafter clarified that the policy would not discriminate in terms of accessibility to the drug based on domicile, and Bedaquiline was provided to the woman.

For women, their socially inferior position influences their health-seeking behaviour, adherence to treatment, and experience of stigma. TB and its treatment are strongly influenced by gendered cultural norms and socioeconomic factors like poverty and backward social position. Also, pregnancy plays a critical role in spiking the rates of TB infection for women and in increasing mortality rates among adolescent and young adult women.[56] In some cases, when men are required to commit to supervising the health status of their female partners, they have instead restrained the women and even turned abusive and violent towards them. There is a vast gender-based differential in TB morbidity, and it points to the persistence of gendered differences and culturally and socially sanctioned discrimination.

A study by Sama conducted in Odisha and Jharkhand in 2018 revealed that young girls with TB face particularly severe stigma. Unmarried girls and women prefer the diagnosis of TB to be kept confidential to avoid being labelled 'TB patients'.[57] Having TB can affect their marriage prospects, lead to the breaking off of engagements, or even to the ending of marriages. The study also highlighted that women with TB are the

worst sufferers, especially during seasonal migration. A respondent who had migrated to work at a brick kiln in another state said, “Men can take out time and visit the local hospital, but we hardly get to visit a hospital and may not get permission from the Bhatti [brick kiln] managers either.” Gender and financial barriers are major obstacles preventing women from seeking access to medical treatment, with higher chances of developing XDR-TB and other co-morbidities.

Women, from marginalized communities, are especially vulnerable due to economic constraints and gender-based disparity. They suffer from TB, anaemia, and malnutrition.[58] A cross-sectional study in Uganda comparing average 24-hour nutrient intakes between wasted and non-wasted TB patients found that nutrient intake among men was higher than that among women regardless of wasting and the severity of the disease.[59] The study showed the effect of disease severity on nutrient intake and the gender differences in nutrient intake among individuals with or without TB. The gender differences in the magnitude of nutrient intake are explained by cultural factors that compromise intake among women. These factors include unequal distribution of food within the household (in favour of men). The gendered distribution and consumption of food within the household is the result of the socialization of women to show restraint in eating which deprives them of nutritional intake, to give the best servings of food to men, and to allow others in the family to eat first.

VI.VI.

COVID-19 vaccines

The absence of gender discourse in conversations on intellectual property rights is also manifest in the ways in which women’s contributions as inventors, knowledge producers, subjects of clinical trials suffering exploitation, and more, are denied. We have also seen how the COVID-19 pandemic has exacerbated health inequities between countries and worsened the living conditions of marginalized communities such as women, persons with disabilities, the elderly, migrant workers, with refugee status, sex workers, indigenous communities, frontline health workers (FLHWs) and LGBTQIA+ communities.

COVID-19 revealed the gaps in the health system and revealed that big pharma and big corporations continue to base their work and production on profit-making. Even during the pandemic, companies are investing their time and resources in enforcing their intellectual property rights,

instead of supporting an arrangement or agreement whereby such rights may be waived temporarily to ensure greater access to COVID-19 vaccines, diagnostics, and therapeutics for everyone in the world.

Further, the Covid-19 pandemic and related lockdowns have had a disproportionate impact on women. The already existing responsibilities of childcare and household chores were added extra burdens resulting from lockdowns, not less the responsibility to take up the informal care of infected family members. Women also faced a heightened risk of sexual and domestic violence and reduced access to reproductive health services. Outside of their homes, their risk of contracting COVID-19 was much higher because they constitute 70 per cent of the global healthcare workforce while also performing the bulk of unpaid care work at home.[60] COVID-19 posed huge risks to the survival of pregnant women, including acute respiratory syndrome.[61] Inequities in access to healthcare for women have been further exacerbated during the COVID-19 pandemic. The pandemic has not only affected women's sexual and reproductive health, but also women's susceptibility to other infectious diseases such as tuberculosis, with a greater number of women than men being affected by the disease during the pandemic.

Women's varying contextual situations shape their accessibility to and affordability of vaccines. Most women face restricted mobility and limited finances in reaching vaccination sites. Further, information is disseminated generally in a language that is difficult to understand easily and gaining access to correct and relevant information is also an issue. The gender gap in information accessibility is also present in the vaccination roll-outs. Globally, there are disproportionate and varying levels of vaccination availability and accessibility for different groups based on gender identity. In India, for example, around 954 women out of 1,000 men had been fully vaccinated by January 2022.[62]

In India, the COVID-19 vaccines currently being used are Covishield (Serum Institute of India and AstraZeneca), Covaxin (Bharat Biotech), and Sputnik V (Gamaleya Research Institute of Epidemiology and Microbiology, Moscow) with approvals for other vaccines such as Corbevax (Biological E Limited). Covishield has been granted or has pending patent applications in over 30 countries, including India. In the case of Covaxin, it is unclear who owns the intellectual property rights. Covaxin is an indigenous vaccine developed in collaboration with public-funded research institutes like the Indian Council of Medical Research (ICMR) and its subsidiary, the National Institute of Virology (NIV), Pune. These intellectual property-related barriers not only determine the

accessibility of COVID-19 vaccines in India but also accessibility in several other low- and middle-income countries that have secured life-saving drugs from generic pharmaceutical companies in the past, at competitive prices.

In early 2021, Covishield was procured at about INR 200 per dose in India, while it was procured by the European Union at nearly Euro 1.78 per dose (at about INR 157).[63] The prevailing patent barriers make it difficult for generic manufacturers to offer these vaccines at competitive prices. In May 2021, the ICMR, which had co-developed Covaxin, announced that it would share the technology related to the vaccine with other countries.

A proposal for waiving the intellectual property-related provisions of the TRIPS Agreement placed before the WTO Council for COVID-19-related tools faced much resistance from the rich countries. In June 2022, the Ministerial Council (MC) of the WTO agreed to a text that is a far cry from the original text proposed for the waiver of the TRIPS Agreement provisions.[64] This acts as a major barrier to the dissemination of, and appropriate access to, COVID-19-related scientific advancements.[65]

By refusing to support the proposal on the TRIPS waiver, the countries opposed to the move are not only furthering private intellectual property rights, but are also neglecting their duty to protect the rights of women, children, persons living with disabilities, the LGBTQIA+ community, and other marginalized groups, as mandated under various international treaties. There have already been calls to develop a response to the COVID-19 pandemic from a women's rights perspective,[66] one that ensures disability-specific measures,[67] and one that mitigates the sufferings of the LGBTQIA+ community.

The developed countries and patent holders have responded with cynicism to these calls for the sharing and transfer of technology, even though the developing countries have time and again proven that they have the capacity to manufacture and scale up these essential health tools.

VII.

Conclusion

The COVID-19 pandemic once again reminded us that health results from and is inextricably linked to social, economic, and environmental justice. The health and human rights crises exacerbated in these times were the undeniably-a result of the structures of discrimination, and inequities globally, rooted in the controlling interests of the few private players/corporate capitalists class including the big corporations. Policies such as TRIPS further enabled the consolidation of these powerful, and profiteering agendas; failing the needs and interests of the people at large, in particular those who are made marginalised on the basis of their race, class, colour, gender identity, disability, sexual orientation, caste, including the indigenous people, refugees, migrant workers amongst others, situated globally across regions.

As has been noted in this brief, the gender differential in accessibility to and affordability of medicines is the result of the primacy accorded to private rights like intellectual property rights. A global public health approach to dealing with pandemics such as COVID-19 is necessary to protect women's human rights globally, and, in particular, in countries in developing countries. The stances on safeguarding intellectual property rights need to be examined, like any other laws, or policies, about their direct and indirect impacts on the denial of women's equal enjoyment of their rights and must be revisited and amended or repealed accordingly.

A situation where the power of big pharma and other profit-driven companies to inappropriately exercise private rights—to the detriment of the larger public good—remains unchallenged, and deepens gender-based marginalization and discrimination. International trade law, including the IP law, perpetuate racialized and gendered forms of discrimination in access to medicines, and vaccines as they reproduced the transnational inequities in access to COVID-19 vaccines, treatments, and other technologies.

A gender analysis of intellectual property rights is an opportunity to question the existing norms of monopoly and private rights and to assess their effects on health and their gendered impact. The market monopoly of such technologies, particularly health technologies, affects women and

marginalized gender communities disproportionately. For women, particularly marginalized women, excessively priced medicines due to patents not only limits access to healthcare but also lead to poorer health outcomes and impose huge constraints on those countries' contexts coping with highly limited budgets. High out-of-pocket payments on medical care push families to the brink of poverty.

Access to equitable and affordable essential and life-saving medicines is intrinsically linked to the ideals of social justice and equality. The realization of the interlinkage between the right to health and the accessibility of essential drugs seeks to guarantee individual freedom and entitlements as an ethical and legal right. Approaching the issue from a human rights perspective provides a clear outline of the spheres of duties and responsibilities of the state regarding the rights of women, particularly within the context of patent law and rights.

Advocating equal accessibility of essential drugs for all from a human rights perspective aims to promote and uphold the right to health, particularly within the context of patent law and rights. In light of the catastrophic economic impacts of patented drug and vaccines that intertwines with the systemically underprivileged and economically disenfranchised position of women, a human rights approach to health is of paramount importance. Further, the intersectionality between the social, economic, and political determinants of health highlight that the patent regime has become an umbrella environment which governs women’s access to life-saving technologies. The discussion on the relationship between patents and women’s health with special case studies makes it urgent that an intersectional approach be afforded to the study of patents and a human rights approach be brought into the conversation.

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