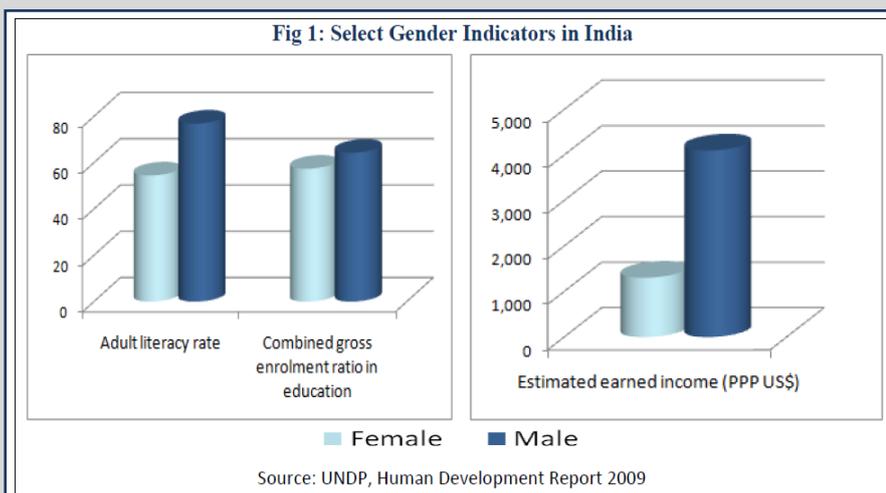


Trade, Intellectual Property Rights (IPRs) and Gender Issues in India

"The idea of a better-ordered world is one in which medical discoveries will be free of patents and there will be no profiteering from life and death.." Indira Gandhi

Trade Liberalisation and Gender Equality

Trade and policies governing trade have far reaching implications for the development of a country. In fact, both play decisive roles in designing or redesigning the property relationships in an economy. They have been major factors in defining the rules of access to resources such as land, education and capital. As gender related development is closely linked to these factors, the gender dimensions of trade policies have come under the critical scrutiny of researchers as well as women's groups. This is especially so because the current global trade framework does not affect all equally. Gains and losses are determined by an individual's relative position within the economy, society and politics. Several recent studies have found evidence that present trade policies and practices are gender insensitive, and coupled with systemic gender inequality, these policies have often deprived women of developmental opportunities as well as benefits (UNCTAD 2009, Fontana 2003, Van Staveren et al 2007). For instance, The Beijing Declaration and Platform for Action (1995) noted that macroeconomic policies were not gender Sensitive. The declaration also urged the states and organizations to increase women's participation in and access to new technologies as a tool for strengthening women's economic capacity and democratic processes.



Though India is projected as the next 'global super power', it has a poor track record on gender related development indices such as literacy rate (54.5%), enrolment ratio in education (57.4%) and income earned which on an average is only 1/3rd of what men earn in India (see fig.1). India is ranked 134th in United Nation's Human Development Index (HDI), way below Sri Lanka (102nd) and far from its 'economic role model', i.e. the United States (19th).

Similarly the other development indices such as sex ratio and maternal mortality rates are among the worst in South Asia. The Provisional 2011 Census in India reveals a sex ratio of 914, the lowest sex ratio in India's history. It has to be noted that this is happening in a country with a projected GDP growth of over 8 percent. The stark reality represented in these statistics underscores the importance of understanding the linkages between trade and gender in the Indian context. This policy brief is an attempt to present gender impacts of trade especially with a focus on intellectual property rights (IPR).

Since the 1990s, changing political and economic contexts and the introduction of a rules-based multilateral trading system through the World Trade Organisation (WTO), a new set of global policies and global processes is now determining entitlements and disentanglements in India. In the backdrop of the social, cultural, religious, political and economic inequities enmeshed in Indian society, this new global economic order is impacting women's lives in India directly and indirectly. Women in India, while seeing an increase in opportunities in some sectors of the economy, are also facing a new set of disentanglements. In order to integrate the Indian economy into the global system, the government has initiated a wide range of policy level changes that are related to trade, including the lowering of border tariffs on both agricultural and industrial products and exposing India's producers and workers, including women, to global competition. More recently, the government has started liberalising the services sector

and investment norms (in services and other sectors), and strengthening intellectual property rights. With the increase in bilateral or plurilateral free trade agreements (FTAs), this process is being expedited.

Trade, Intellectual Property and Gender Dynamics: Why Does IP Matter?

Box 1

Intellectual Property Rights (IPR): The right to possess or control the use of intellectual property, such as trademarks, copyrights, patents, design and trade secrets.

World Trade Organisation (WTO): An inter-governmental body where member countries develop and enforce rules for international trade.

IP rights represent exclusive economic rights for an innovator over his/her ideas or 'creations of the mind' for a certain period; be it a technology, a product, a design and other forms of innovation. These may take different forms (see Box 1). Surprisingly, IP has come to occupy a significant position in global trade agreements, both at the WTO and in FTAs which are otherwise supposed to promote a non-restrictive global trading system. Including norms on intellectual property which offer protective rights has been argued for by developed countries on the ground that these norms are necessary for encouraging innovation and a global trading system requires the recognition of IP for the free flow of goods and services across country borders.

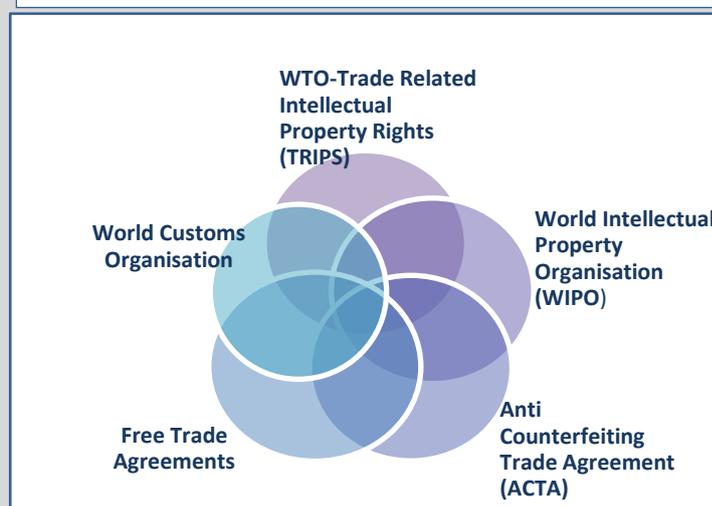
What has, in effect, happened is that there is now increased control across the globe over knowledge and technology in fields such as pharmaceuticals, traditional medicines, traditional knowledge and agriculture. Instead of encouraging innovation, strong protection of IP in the field of medicines has been found to have failed in delivering medicines for diseases and conditions affecting developing and least developed countries. Where medicines do exist, IP rights have often reduced competition resulting not only in the decreased availability of both products and technology, but also in exorbitant prices. Of late, many scholars and policy makers have convincingly argued that IP rights inhibit the diffusion of scientific knowledge. Of these, patents have had a more devastating impact on access to knowledge and technology especially for developing countries.

Moreover, IP rights benefit only those with significant material resources and those who already have access to knowledge. For example, only companies or individuals with high technical and material resources can hope to get IP rights in terms of patents, copyrights, designs etc. The IP regime tends to bypass those who do not have such resources. Women in India and in most of the developing world lag behind both in resource ownership (capital, land) as well as in educational attainments. On the other hand, they are often the most affected by the rise in prices and lack of availability of products, medicines and healthcare. Starting with the WTO, the IP regime has become increasingly stronger under bilateral trade agreements.

Even products, systems and technologies which are imperative for basic sustenance such as traditional knowledge and medicines, seed and food, cultivation systems and bio diversity are all increasingly controlled by this regime. These affect women much more compared to men, because women, not being so much integrated into the mainstream economic structure, sustain themselves and their families off such basic systems.

In addition to rules on IP mandated by the WTO and those negotiated in FTAs, global IP standards are being increased and are being pursued through parallel and additional mechanisms such as the World Intellectual Property Organisation (WIPO), World Customs Organisation (WCO) and the Anti Counterfeiting Trade Agreement (ACTA) (see fig. 2). These sometimes overlap and supplement each other and reinforce the IP system. Some of the effects of these systems and their particular gender concerns are discussed below.

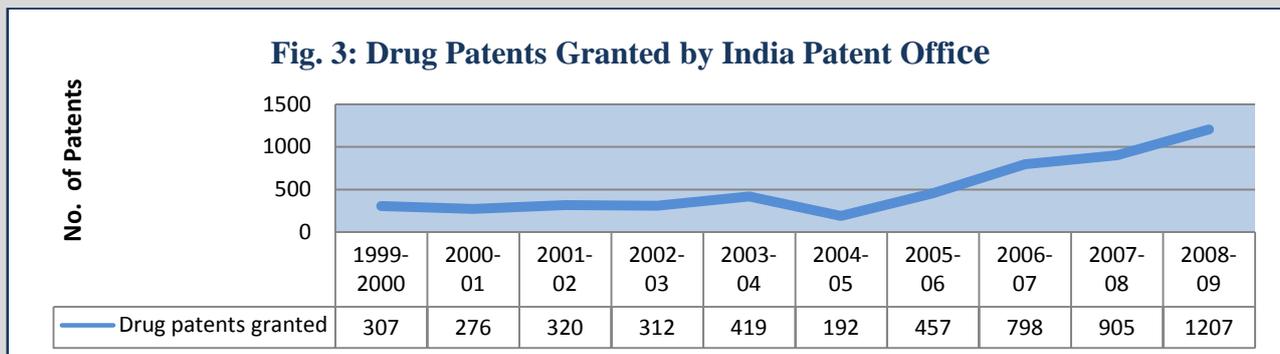
Fig. 2: Institutions/Mechanisms Affecting IPRs



WTO and IP: The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement)

The WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights, also known as the TRIPS Agreement, is supposed to "strike a balance between the long term social objective of providing incentives for future inventions and creation, and the short term objective of allowing people to use existing inventions and creations. The agreement covers a wide range of subjects, from copyright and trademarks, to integrated circuit designs and trade secrets. Patents for pharmaceuticals and other products are only part of the agreement" (WTO: 2006).

The TRIPS Agreement globalised rules related to intellectual property and required countries to amend their legislation accordingly. For instance, TRIPS requires countries to grant 20 year patents for products and processes. At the time the Agreement was being negotiated no country in the world provided such long patent terms and many countries, including India provided extremely limited rights in sensitive areas like food and pharmaceuticals. Recognizing the differences in development among the WTO members, the TRIPS Agreement specified different time periods for compliance with the Agreement. For developed countries it was within one year, for developing countries, the last date was 1 January 2005 and for Least Developed Countries (LDCs) it is 2013, except in the case of pharmaceuticals where the deadline for LDCs is 2016.



Source: Annual Reports, India Patent Office

India's deadline to comply with the TRIPS Agreement was 2005. The Indian Parliament was forced to amend India's Patents Act, 1970, once heralded by UNCTAD as a model for developing countries. According to data from the Indian patent office, the changes in Indian law brought about due to the WTO have triggered product patenting to a large extent with foreign multinational companies being primary players. Similarly, the number of drug patents granted by the India patent office has gone up since 2005 (see Figure 3).

In 2001, a little over five years after the TRIPS Agreement was signed, the effects of patents on medicines were starting to be felt across the globe. As the HIV epidemic swept through Africa, Asia and Latin America, medicines protected by patents in the US and Europe were available only at exorbitant prices. The crisis led to the WTO members issuing the important 'Doha Declaration on TRIPS and Public Health' (see box 2) that also recognized the rights of member countries to use so-called "TRIPS-flexibilities" to safeguard public health.

In order to strike a balance between the right holders and the end users of patented technology, WTO-TRIPS allows flexibilities with regard to; 1) the method of implementing TRIPS obligations ; 2) substantive standards of protection; 3) mechanisms of enforcement; and, 4) areas not covered by the TRIPS Agreement. The first category includes concepts such as novelty and inventiveness; or of situations of extreme urgency

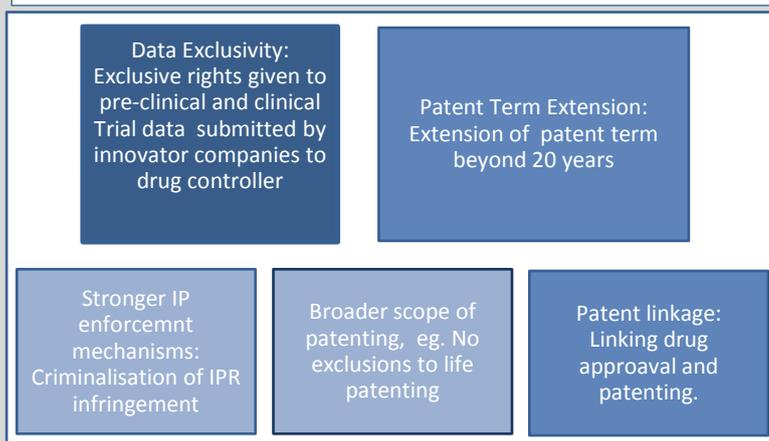
Box 2: Importance of the Doha Declaration

In 2001, **World Trade Organization (WTO)** in its Doha ministerial meeting reached an agreement, known as 'the Doha Declaration', which interpreted TRIPS "in a manner supportive of WTO members' right to promote public health and...promote access to medicines for all." The Doha declaration recognized member countries' rights to make use of TRIPS flexibilities that would safeguard public health measures.

for the purposes of compulsory licenses. In the case of compulsory licensing, a government may allow someone else to produce the patented product or process without the consent of the patent owner. The second category of flexibilities include introduction of exceptions to rights conferred such as experimental use and the "Bolar" exceptions (to obtain regulatory approval for a product). In the third category, members can resort to their own legal system and practices to implement enforcement obligations.

Free Trade Agreements and TRIPS-plus Provisions

Fig. 4: TRIPS plus IP Provisions in Free Trade Agreements



Free Trade Agreements typically expand obligations of governments in relation to the liberalisation of trade and investment far in excess of what countries have agreed to at the WTO. Developing countries had the advantage of negotiating as a block in the WTO to protect their interests. But as the FTAs are negotiated country by country, developing countries have lower bargaining power when negotiating on their own with a stronger trade partner or a developed country. Like the WTO, FTAs are extremely broad in scope and cover several sectors including trade, services, and intellectual property. In fact FTAs are often seen to go way

beyond WTO rules as it includes provisions on investment, government procurement and competition, which were originally kept out of WTO by developing countries during the Uruguay round of negotiation.

Recent studies on FTAs have shown that developed countries push through so called ‘TRIPs-plus’ provisions on the national policies of developing and least developed countries (see Fig.4). In the policy parlance, “TRIPS-plus” is an informal term used to denote the protection of intellectual property that goes beyond the requirements of the TRIPS Agreement i.e. any protection of IP that surpasses the standards and requirements spelt out in TRIPS provisions can be termed as TRIPS-plus.

Fig. 5: Data Exclusivity in FTAs and Implications: Some Examples

<p>Medicines: Parallel protection to IP, prevents generic producers from supplying, increases prices taking medicines out of reach of vulnerable groups like women.</p>	<p>Clinical Trials: Encourages additional trials, often on women and poor, increases health risks. This is against the Helsinki declaration on medical research.</p>	<p>Agro chemicals: Encourages additional clinical trials; delays the introduction of generic pesticides and agrochemicals; leads to price increase; threat to small scale industry.</p>
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However, in the garb of IP protection, the TRIPS flexibilities discussed above are gradually being made unusable. For instance, data exclusivity is an example of a TRIPS-plus measure which can have a huge impact on developing countries as it can bring extended protection for off-patent medicines. (See Fig. 5). Under the data exclusivity period, even if compulsory licensing (license to manufacture and market patented products without the permission of the patent holder) is issued companies will not be able to get the marketing approval for the licensed drug. Prolonging the term of patent protection beyond 20 years, drug marketing approval-patent linkages are other examples of TRIPS plus IP provisions. According to experts most of the TRIPS plus provisions delay or hamper generic competition thus enabling big pharmaceutical companies to extent their monopolistic rights in the market. The control over the use of knowledge and technology is also becoming stronger.

Impact of IP: A Sector Specific Look and Associated Gender Concerns

Pharmaceuticals

Under the Indian Patents and Designs Act of 1970, there are two kinds of patents, product and process patents, that have a life of fourteen years. It also kept drugs and agro-chemicals away from product patent regime. The important provision of the Act is that process patents used for food, medicine or drug have a term of only five years from the date of sealing of the patents or seven years from the date of the patent whichever is shorter. The policy inputs of 1970s, especially, the absence of product patent regime played a decisive role in the development of the Indian pharmaceutical industry in the post-1970. In fact, it also ensured reasonable domestic competition in the pharmaceutical industry as well as access to medicines compared to other developing countries. Over the years, India has become the main supplier of essential medicines for developing countries. According to MSF, 67 percent of medicine exports from India go to developing countries. Main procurement agencies such as UNICEF (approx. 50% of their distribution), International Dispensary Association (IDA), Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) and the Clinton Foundation purchase their medicines from India.

This policy induced self reliance in access to medicines is now under threat from stronger patent regimes. As the growth of Indian generic companies is seen to be a threat to global big pharmaceutical companies, there is a concerted effort by them to curb the growth of the Indian domestic industry through various measures. Stronger patent regime is one of the tools of multinational pharmaceutical companies in this wrangle over markets. In this entire politics, the access to medicines to the poor and needy is severely affected.

The prices of drugs have skyrocketed in the recent past especially after the introduction of the product patent regime. The patented medicines are sold without any price control and price monitoring as it does not come under National Pharmaceutical Pricing Authority (NPPA). As a result, the pharmaceutical companies are free to charge as they wish. The exorbitant prices of drugs (see table 1) charged by innovator companies related to forms of cancer specific to women are detailed below.

Table 1: List of Select Cases of Costly Branded Medicines

Brand Name of the Drug	International Non-proprietary Name	Company	Indication	Package	Price (Rs.)
Herceptin	Trastuzumab	Roche	Breast cancer	440 mg x 50 ml x 1's	1,24,000
Tykerb	Lapatinib ditosylate	Glaxo	Breast cancer	250 mg x 70's	46,025
Arimidex tab	Anastrozole	Astra Zeneca	Breast cancer	1 mg 2x14	3,272
Gardasil	Vaccine	Merck	Cervical cancer	0.5ml	2,800

Source: CIMS website- <http://www.mims.com/index.aspx>

In India, access to treatment and healthcare has a clear gender differential. In addition, women incur lower expenses on medicines and hospitalisation facilities compared to their male counterparts. So the moment there is an increase in the price of medicines and a fall in availability, women tend to reduce treatment. This is also apparent from the case studies of couples living with HIV, where, if the supply of medicines is hampered, the woman tends to give up treatment, allowing the man to continue treatment. The effect of patents on prices of medicines is already being felt by women living with cancer. Trastumazab, a key medicine for breast cancer has been patented in India and is available at the price of Rs. 124,000 per month per person. Therefore, an average Indian would not even dare to imagine the cost of treatment for the required 52 weeks.

Box 3: TRIPS-plus Provisions Relating to Medicines

1. Data exclusivity
2. Ever-greening of medical patents
3. Patent linkage
4. Blocking compulsory licenses
5. Restricting parallel importation
6. Border measures
7. Restriction on the preferential treatment enjoyed by the domestic private and public pharma companies in government procurement.

Traditional Knowledge and Medicines

The importance of traditional knowledge is growing every day as it encompasses a wide range of areas such as food and agriculture, the environment especially conservation of biological diversity, health, including traditional medicines, human rights and indigenous issues and aspects of trade and economic development. In the recent past, due to its ever-increasing commercial potential, the issue of access and control over resources of traditional

Box 4: Traditional Knowledge (TK)

is a broad term referring to knowledge systems, encompassing a wide variety of areas, held by traditional groups or communities or to knowledge acquired in a non-systemic way. These knowledge systems have significance and relevance not only to its holders but to the rest of the humanity. There are two major Systems of traditional knowledge protection. 1) Positive protection, i.e. giving traditional knowledge holders the right to take action or seek remedies against any misuse of traditional knowledge. 2) Defensive protection, i.e. safeguarding against illegitimate intellectual property rights acquired by third parties over traditional knowledge.

knowledge systems, and especially the role of IP systems in relation to traditional knowledge (TK), has been under critical scrutiny (see box 4 for an explanation of TK). The question of how to preserve, protect and equitably make use of TK is still a controversial one. Similarly, of late, there have been many instances of bio-piracy and patenting of products that emerged out of traditional knowledge (see the box 5). In fact, the patenting on the "use of turmeric in wound healing" is the first controversial case in this regard.

The Convention on Biological Diversity (CBD), an international agreement established by the United Nations in 1992 to preserve biological diversity around the world took up the issue of Traditional Knowledge. CBD has become controversial as it failed to reach consensus on the matters relating to access and benefit sharing. According to Article 8(j) of the CBD, each Member State shall, as far as possible, where appropriate, and subject to national legislation to: respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying

traditional sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices. However, several instances have come to light where companies or patent obsessed 'innovative' scientists have impinged upon the rights of the practitioners of traditional knowledge through various policy loopholes and policy aides.

The role of women in the practice and preservation of TK is well documented in many areas such as seed preservation, bio mass related activities, traditional agriculture, and the practice as well as use of traditional medicines, especially for gynaecology related treatment. Traditional knowledge is recognised as a 'gendered science'.

Bio diversity in areas such as Western Ghats, the northeast region, the Jeypore tract of Orissa and coastal ecosystems are already under threat in India. In order to deal with the current problems in the access, practice and commercialisation of TK, there is a need to bring in alternative development models which will make the communities self reliant and also protect their rights against corporate takeovers.

Agriculture

There are several IP issues related to agriculture as well, the most important of which is related to

the access to seeds. Under the TRIPS Agreement, countries are not obligated to grant patents on plants and animals

Box 5: Examples of Patents Granted over "Inventions" Based on Biological Resources

- Use of *Turmeric* in Wound Healing, (USPTO later revoked the patent)
- Composition of *jamun*, bitter-gourd, *gur-mar* and eggplant for treatment in diabetes.
- Various products obtained from the neem tree.
- Varieties of *basmati* which have the characteristics of growing in temperate climate in the absence of sunlight.
- Composition of *methi* as a tonic to bring down blood glucose levels.
- Compositions comprising of *kala jeera* or *kalonji* for increasing immune functions, and in the treatment of diabetes, hepatitis, and asthma.

but must grant what is known as plant *variety* (plant categories, usually a cultivar or hybrid, say a variety of seeds) protection. However, they are allowed to come up with their indigenous or *sui generis* protection system in conformity with their local conditions. Accordingly, India passed its own Plant Varieties Protection (PVP) Act in 2001 to protect IP rights of breeders. However, this Act gives precedence to farmers' rights as opposed to breeders' rights and allows farmers to freely save, use, and exchange seeds, and therefore protects an agricultural system which is traditionally practiced by Indian farmers, especially smaller ones.

The FTAs that India is negotiating with developed countries, for example with the EU, has the potential to reverse this gain. These usually include demands that India should join the International Union for the Protection of New Varieties of Plants (UPOV 1991). This is an international convention that provides a framework for plant variety protection. But, in contrast to India's PVP Act, it gives precedence to breeders' rights over that of farmers and can prevent farmers from saving, using and freely exchanging seeds. It also prevents the use of protected plant varieties for research. Women have traditionally played the role of 'seed keepers' in India and in other developing countries, for example among the *Apatanis* of Arunachal Pradesh and the *Garhwalis* of the Western Himalayas. But their ability to save, exchange seeds for production and for sustaining families by saving seeds for future use can get undermined by such provisions.

Strong IPR provisions in FTAs with developed countries can also threaten present legal provisions such as the registration of extant and farmers' varieties. Benefit sharing provisions to compensate farmers for their innovations can also be threatened by FTA provisions by the undermining of domestic laws governing access to and the equitable sharing of benefits from genetic resources such as India's Biodiversity Law or rules related to disclosure of origin of materials. The international negotiations on access and benefit sharing (ABS) under the Convention on Biological Diversity (CBD) may also be undermined by these provisions.

As described before, the increasing control of traditional knowledge by big firms based in foreign countries can threaten India's traditional agriculture and those who depend on it. Women producers may be significantly affected

by this 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 diverse traditional agriculture in Kolli Hills, Tamil Nadu.

Box 6: TRIPS-plus Provisions Relating to Agriculture

1. Extension of standards of protection,
 - Patentability for life forms
 - Requirement to accede to the Budapest Treaty, which obliges parties to recognise the physical deposit of samples of microorganisms, in lieu of full written disclosure of the invention, through an international depository authority-
2. Data Exclusivity for agro-chemical products
3. Compulsion to align with the International Union for the Protection of New Varieties of Plants (UPOV)

In addition, India had taken a strong stance at the WTO to include a strong definition of micro organisms as patenting of life is sensitive from a development perspective. This was left out of the purview of TRIPS. However under the FTAs, this exclusion may no longer be an option if developing countries are pressurised by developed FTA partners to ratify the Budapest Treaty, which allows lax rules in the IP rights of micro organisms.

Geographical Indications (GIs) are another form of IP protection pursued with vigour by developed countries. Under GIs, products from a certain region get certain IP rights and cannot be produced and sold by other regions. EU's champagne, scotch whiskey are prime examples. However, this is to the disadvantage of developing countries, especially their small and women farmers who are much weaker in registering such GIs as these require complicated documentary proof, processing fees and knowledge of procedures. A mutual recognition system of such GIs is currently being negotiated at the WTO. In addition, EU, in its proposed FTA with India, has demanded that its agricultural GIs be automatically recognised by India. Such demands pose a threat to India's agriculture in general and to weaker farmers in particular.

Agro chemicals earlier exempted are now included under the Indian Patent Act of 2005, already raising their costs. The data exclusivity clause in FTAs can now add on an extended system of protection and monopoly which will bar producers from introducing low cost generic agrochemicals even after the expiry of patents. Patent term extension by five years under some FTAs will also affect agro chemicals. All these provisions can affect prices and availability of generic fertilisers, pesticides, insecticides, fungicides etc.

Conclusion

Due to various political, economic, and historical reasons women and men are differently placed on the development trajectories. Though, the trade policies are supposed to be gender neutral, in practice, the present policies are grossly gender biased. The proliferation of FTAs and WTO-plus instruments in the field of IP would completely undermine whatever little progress we have achieved on gender-related development indicators. As these policies have a direct impact on the entitlements of women and the other marginalized sections, government should carry out comprehensive impact assessments in order to study the social and economic costs inflicted on the vulnerable sections of the Indian population. The government should regain as well as retain its domestic policy space in order to safeguard the interests of weaker constituencies. It should also make sure that the gender component is addressed and incorporated into the policy decisions after having consultations with gender experts.

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