Access to essential medicines is an integral component of the Right to Health, which has been explicitly enunciated in a number of international instruments. However, it has been most elaborated under article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR). The right to health under article 12 is elaborated by the Committee on Economic, Social and Cultural Rights in General Comment No. 14 (United Nations, 2000). It provides for the right of everyone to the highest attainable standard of physical and mental health. States have an obligation to respect (not interfere with the right itself), protect (prevent interference by others), and fulfil (take all administrative measures) the right to health. It also provides that all health services, goods, and facilities, including medicines, are to be made available, accessible, acceptable, and of good quality. Furthermore, the provision of essential medicines to all persons in a non-discriminatory manner is a core obligation of the state, which would also include ensuring availability and access to quality affordable medicines.

The role of the law in saving lives is evident from the time HIV was wreaking havoc all over the world. Before the mid-1990s there was no treatment for HIV. The mid-1990s saw the advent of triple-combination antiretroviral therapy (ART), which became available in the West immediately, while millions of People Living with HIV (PLHIV) in the developing world could not access ART till much later. During this period, the drugs were priced about US$10,000 per patient annually, denying access to life-saving ART to PLHIV in most developing countries. It was only when developing countries like Brazil took initiative to provide better health care that the movement to make ART more accessible in developing countries began.

When at the turn of the century Indian generic companies announced that they would provide ART at US$350 per patient per annum, accessibility of ART became more possible in the developing countries (McNeil, 2001). The resulting increased competition in the generic market thereon led to a 99 per cent drop in the prices of ARV drugs from 2000–10, to about US$10,000 per patient per annum, providing affordable access to ARVs to millions of people across the world.

Indian generic companies were able to sell ARVs at low prices because the Indian patent law at the time did not recognise product patents on pharmaceutical products. Before 1972, the original Patents Act, 1911 in India, allowed patent protection for both products and processes, allowing the patent holder to exercise absolute monopoly rights and control on both the availability of the drug and its price. One of the main consequences of the 1911 Act was that drug prices in India were amongst the highest in the world. Realising the need to prioritise the public health agenda, after a lot of study, the Patent law in India
was amended in 1970, but in a very simple manner. Patent only for process was protected but no patent for pharmaceutical products was allowed. This simple measure allowed generic companies to manufacture drugs through alternative processes. Competition amongst drug companies flourished, and by the 1990s, Indian generic industry was offering the lowest medicine prices in the world. Thus, by the late 1990s, 90 per cent of the ARVs in the developing world were provided by the Indian generics (Waning, et al., 2010). India became the pharmacy of the developing world.

In the early days of the fight for access to ART, Brazil had a major role to play. The 1996 policy of the Brazilian government to provide free ART to PLHIV was instrumental in improving health and providing access to medicines to thousands of Brazilians. This was possible, partly because of the expertise of the Brazil's domestic pharmaceutical industry, which allowed the country to produce generic versions of ARV drugs. Thus, Brazil provided a shining example to the rest of the developing world. Unfortunately, unlike in Brazil, in India the free ARV support for PLHIV was introduced only in 2004, almost ten years after its introduction in Brazil, despite the fact that India had the largest pool of generic companies in the developing world.

At the global level, the Brazilian policy of free access to ART was regularly used as an example to demonstrate that goal of access to medicine is achievable. The ‘3 by 5’ initiative from the WHO, implemented in 2003, is one such instance. In fact, the Doha Declaration, which emphasised on TRIPS flexibility for better access to medicine, is often seen as an acknowledgement of Brazil’s policy of free ART. Because of Brazil, the rest of the developing world started free ART thanks to the Global Fund on HIV, TB and Malaria, PEPFAR and UNAIDS.

While protection of pharmaceutical product patent could be excluded earlier, as in India, the TRIPS agreement of 1995 changed all that. Under TRIPS, protection had to be provided to both product and process patents. India and the developing countries agreed to the TRIPS Agreement because of the flexibilities that could be used in their domestic IP Laws. The flexibilities in the TRIPS Agreement were fought for on the basis of public health interests. These flexibilities, amongst others issues, aided the objective of making medicines available at affordable prices. These include allowing members to define their own patentability criteria; the opportunities to challenge patent applications by pre- and post-grant oppositions; revocation; to provide for issuing of compulsory licensing; amongst others.

Exercising this facility provided under TRIPS, in 2005, India used all the flexibilities and amended its patent laws and, amongst other amendments, added a higher standard of patentability to address the evergreening of patents. India found that the experience in the US and EU showed that over 76 per cent of pharmaceutical patents were for new forms of known drugs without any additional therapeutic effect. Such evergreening also allowed for increasing the patent period for the originator companies. So, India amended its patent law and inserted Section 3(d) in the Patents Act. Section 3(d) does not allow patents on new forms of known drugs unless there is significantly more efficacy in the new form as compared to that of the known drug.

Section 3(d) was challenged by Novartis when its patent application on cancer drug ‘Gleevec’ was rejected by the Madras High Court on the ground of 3(d). Novartis claimed that Section 3(d) violated the TRIPS Agreement and the equality provision in the Indian Constitution. The Madras High Court (2007) rejected the contentions of Novartis and upheld Section 3(d). It held that Section 3(d) was to promote the fulfilment of the right to health obligations of the government. Section 3(d) is crucial for promoting generic competition and reducing the prices of costly drugs by not allowing patenting of new forms of known drugs.

Later, again in the Novartis case, the Supreme Court (2013) clarified the scope of Section 3(d) making it clear that it does not apply to physical properties but applied to other properties relating to therapeutic efficacy and the Patent Applicant would have to show in each case that the efficacy was significantly more than that of the known substance.

However, developed countries and powerful multinational corporation (MNC) blocs such as ‘Big Pharma’ are increasingly focusing on furthering their narrow industry agenda of super profits, forcing
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developing countries to do away with their laws, which would ensure access to affordable medicines. India, for example, had been facing immense pressure from the US to dilute Section 3(d) of the Patents Act. The pressure is also on countries not to introduce provisions, like Section 3(d). Though it would stand to reason that provisions like 3(d) should be introduced in developing countries, till date only the Philippines and Argentina have introduced provisions similar to Section 3(d) in their patent laws.

Today, access to affordable medicines is under threat from a variety of fronts. The primary danger, as always, is the pressure that the US, the EU, and Japan are exerting on developing countries to dilute their IPR (intellectual property rights) regime through threats of trade sanctions such as US 301, and the introduction of Free Trade Agreements (FTAs) like the North American Free Trade Agreement (NAFTA), the Trans Pacific Partnership Agreement (TPPA), the Regional Comprehensive Economic Partnership (RCEP), and so on. Though the US has withdrawn from negotiations in the TPPA, the deal is being pursued by other countries like Japan, Australia, and South Korea.

All the so-called FTAs have common provisions which seek to extend patent monopolies and restrict competition from generic companies that ultimately allow exorbitant profits to be reaped by the MNCs. These include patent for new or second use, patent term extensions, data exclusivity, limiting oppositions to grant of patents, limiting conditions for issuing compulsory licenses, data exclusivity, patent linkage, enhanced enforcement measures, all of which enhance monopolies and restrict introduction of generic competition in the market and thereby allow the reaping of exorbitant profits by the Patentees.

Most problematic in these FTAs is the inclusion of Investor State Dispute arbitration tribunals. This allows only the private corporations to sue states for doing any act, which would potentially adversely impact on the potential profits of the corporation. It is a one-way street. Pertinently states are not allowed to sue the private corporations. The tribunals are not accountable to any communities and are only a boon for lawyers, who appear for the states and private corporations on a regular basis. There are no appellate procedures. Proceedings, unlike domestic courts, are held in closed door hearings. There are a huge number of disputes pending in the private arbitral tribunals which are set up. These tribunals are totally outside the domestic legal system and are totally unaccountable to the members of the public. A number of awards have been rendered against states, mostly developing countries, awarding millions of dollars against them. Developing countries are now realising the negative impact of such tribunals. States need to review such arbitration agreements and refuse to enter into them.

The access to the new drugs like sofosbuvir for hepatitis C and bedaquiline and delamanid for TB are good examples with which the problems of access to medicines can be illustrated in the present-day scenario.

Sofosbuvir is an effective drug for hepatitis C. Apart from the fact that there is a dispute about the actual entity, which ‘invented’ sofosbuvir, in respect of which there is an ongoing dispute in the US, the drug does not deserve to be patented. It has been disallowed a patent in Egypt, in Ukraine, and host of other countries. Where it has been granted a patent, like Malaysia, the government rightly issued a compulsory license to make it available to the patients who need the drug. Unfortunately, in India, which boasts of the best patent law for access to medicines, it was patented, but no compulsory license has been issued. Instead Gilead, the patentee in India, has issued voluntary licenses to at least 11 generic companies, making the drug available at about US$900 for a 12-week treatment (Pillai, 2015). There is no genuine competition but controlled access through voluntary licensing.

Voluntary license granted to the generic players in India is the latest tool of the big pharma companies influencing accessibility and affordability of medicines. Because of this, the generic companies are not filing patent oppositions or demanding compulsory licenses. For example, in the case of sofosbuvir in India, the generic companies who filed patent oppositions withdrew them and did not even demand a compulsory license because of the voluntary license offered to them. Though the countries in Latin America and the Middle East and North Africa are most in need of drugs like sofosbuvir, they have not been included in the list of countries to which Indian generic companies having voluntary licenses can export the drug.
Voluntary licenses have passed on the initiative from the state to the private sector and have put the MNCs in the driver’s seat to control the accessibility and affordability of medicines. Though this challenge has to be met internationally, unfortunately civil society organisations, which were united at the turn of the century, are now divided over voluntary licenses.

There is a worse story to tell with respect to Multi-Drug Resistant (MDR) TB. India also has the largest number of people living with TB, estimated at 2.7 million. It also has the largest number of people living with MDR TB, at 147,000 (Central TB Division, 2018). New drugs bedaquiline, with the combination of another drug, delamanid, has shown a lot of promise as a new and effective therapy for MDR TB. Bedaquiline and delamanid for adult formulations were added to the WHO Essential Medicines List (EML) for TB in 2015 while delamanid was added to the WHO EML for children in 2017. In India, bedaquiline and delamanid have been patented by Janssen (a division of Johnson and Johnson) and Otsuka respectively. Despite the patent having been granted for both the drugs, they are not available to People Living with MDR TB (PLDTB) in India who desperately need them. They are being given as donations to the Government of India through USAID who get it from Johnson and Johnson, and Otsuka. However, these drugs are made available to only about 1,000 PLDTB when according to independent estimates about 20,000 PLDTB are in need of those drugs in India.

Donations are likely to stop sometime next year. Then, if at all available in the market, the price for a six-month course of bedaquiline in India will be US$900 and an exorbitant US$1,700 for a six-month delamanid course, the price of which is not expected to decrease substantially.

What can the government do? It can issue a `government use license’ under Section 92 of the Indian Patents Act and then invite generic companies to manufacture them. With generic competition, drug prices will fall dramatically and become available to the PLDTB in India who need them at affordable prices. This will be in accord with the TRIPS Agreement, the DOHA Declaration, and the UN High Level Panel on Access to Medicines. However, because of the US government pressure, this is not seen as an option. This would be detrimental to the government’s own programme to eliminate TB by 2025, five years ahead of the deadline under the Sustainable Development Goals.

Conclusion

The framework on the right to health makes it clear that medicines must be available, accessible, acceptable, and of good quality, and reach ailing populations without discrimination throughout the world. Affordable access to medicines cannot be achieved sustainably without sufficient market competition. The need of the hour is for developing countries to utilise and preserve the flexibilities embodied in the TRIPS Agreement in their national laws and prioritise the right to health above all.

In the case of patenting of drugs, which makes the drugs unavailable, inaccessible, or affordable, compulsory licenses, in accordance with law, should be resorted to. This will also cut into the strategy of voluntary licenses which Big Pharma has adopted. For this, the civil society again needs to be united across continents, from Latin America to Europe, Africa and Asia, to challenge the agenda of MNCs of the voluntary license regime, FTAs, and bilateral agreements. This is required so that the state can be back in the driver’s seat to make medicine accessible and affordable for its own people.

Note

1 Though the TRIPS Agreement was entered into 1995, different countries were given different time lines for full compliance depending on their development, and they were categorised into developed (which had to comply with TRIPS one year after 1 January 1995), developing (which had to comply within ten years of 1 January 1995, that is 1 January 2005), and least developed (which had to comply initially in 2006, which was extended to 1 January 2016, and later to 2033).
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