LAW *vision*

Trips Agreement and patenting of pharmaceutical products

MD. MAHBOOB MURSHED

MY Ph.D. Supervisor Professor Shah Alam drew my attention to a news item published on February 10, 2006 in the front page of The Daily Star. The gist of the news is that the foreign pharmaceutical companies obtained as many as 40 patents on their drug formulas in the last couple of months. Bangladesh Association for Pharmaceutical Industries opposed the said action of the patent office, which went in vain.

The news disclosed the following consequences:

i.The waiver of the WTO for not patenting the pharmaceutical products in the Least Developed Countries (LDCs) has been ignored;

ii.The reverse engineering of the multinationals products used by the local pharmaceutical companies would be obstructed;

iii.Marketing and exporting of local pharmaceutical products using reverse engineering would be challenged by the multinational companies, which would cripple the local pharmaceutical companies;

iv.The price of the pharmaceutical products in local and international market would be 15 to 20 times higher than the present one;

v.WHO Council's waiver of exclusive marketing right of new pharmaceutical products by its manufacturer would be affected;

vi.The local parent officials are ignorant about the consequences and impacts of patent rights and the latest development in the TRIPS; and

vii.Failure of government to reap the full benefit of the TRIPS.

The President of the Bangladesh Association for Pharmaceutical Industries (BAPI) claimed that as per the TRIPS, the LDCs including Bangladesh are supposed to manufacture and export patented drugs until 2016.

In this article I would try to highlight the present legal position of Bangladesh in patenting pharmaceutical products, how far the aforementioned consequences or impacts of patenting pharmaceutical products by the multinational companies are real, the provisions of the TRIPS in this regard, the WTO and Doha agreement and what role can be played by the Government of Bangladesh in the prevailing situation.

Legal position of Bangladesh

The way in which the Patents and Designs Act, 1911 defines invention, it seems that there is no bar to patent pharmaceutical inventions in Bangladesh. Let us examine the definition of invention given in the Act in order to justify the statement made above. Clause (8) of Section 2 of the Act defines 'invention' as any manner of new manufacture and the term includes an improvement and an alleged invention. Clause (10) of the same section provides that the term 'section' provides that the term 'manufacture' includes any art, process or manner of producing, preparing or making an article, and also any article prepared or produced by manufacture. If we read both the definitions together we would find that the words 'new manufacture' include pharmaceutical inventions. Since there is no provision regarding patentable invention and exclusion from patentability, therefore, it is very difficult to come to a straight forward conclusion that any particular invention is not patentable in Bangladesh.

Provisions of the TRIPS

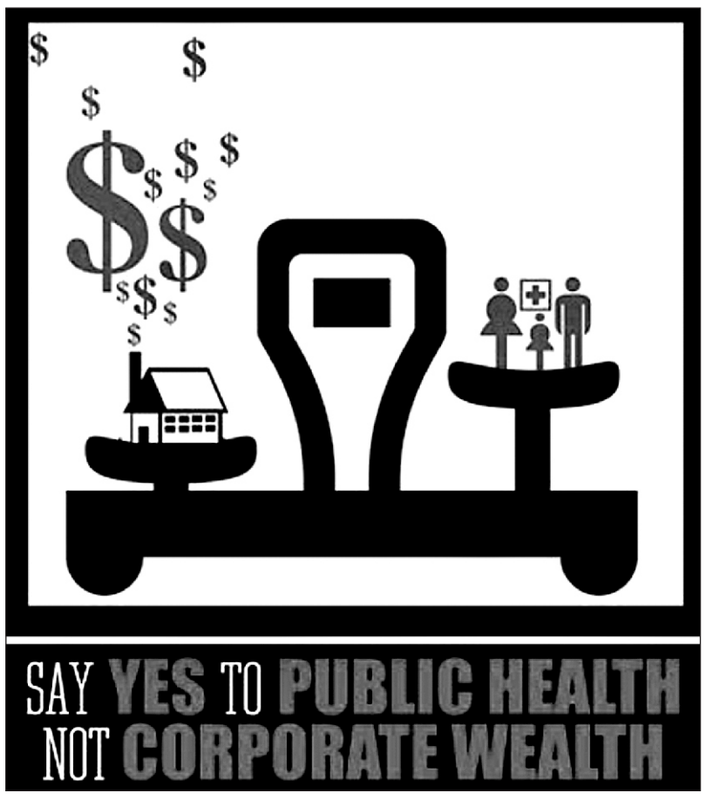
The TRIPS Agreement requires member countries to make patents available for any invention, whether products or processes, in all fields of technology without discrimination, subject to the normal tests of novelty, inventiveness and industrial applicability. It is also required that patents be available and patent rights enjoyable without discrimination as to the place of invention and whether products are imported or locally produced (Article 27.1).

There are three permissible exceptions to the basic rule on patentability. One is for inventions contrary to ordre public or morality; this explicitly includes inventions dangerous to human, animal or plant life or health or seriously prejudicial to the environment. The use of this exception is subject to the condition that the commercial exploitation of the invention must also be prevented and this prevention must be necessary for the protection of ordre public or morality (Article 27.2).

The second exception is that Members may exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals (Article 27.3(a)).

The third is that Members may exclude plants and animals other than micro-organisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. Plant varieties, however, must be protectable by patents or by a special system (such as the breeder's rights provided in the conventions of UPOVthe International Union for the Protection of New Varieties of Plants). Moreover, the whole provision is subject to review four years after entry into force of the Agreement (Agreement Article 27.3(b)).

The agreement says patent protection must be available for inventions for at least 20 years. Patent protection must be available for both products and processes, in almost all fields of technology. Governments can refuse to issue a patent for an invention if its commercial exploitation is prohibited for reasons of public order or morality. They can also exclude diagnostic, therapeutic and



surgical methods, plants and animals (other than microorganisms), and biological processes for the production of plants or animals (other than microbiological processes).

The agreement describes the minimum rights that a patent owner must enjoy. But it also allows certain exceptions. A patent owner could abuse his rights, for example by failing to supply the product on the market. To deal with the possibility, the agreement says governments can issue "compulsory licences", allowing a competitor to produce the product or use the process under licence. But this can only be done under certain conditions aimed at safeguarding the legitimate interests of the patent-holder.

If a patent is issued for a production process, then the rights must extend to the product directly obtained from the process. Under certain conditions alleged infringers may be ordered by a court to prove that they have not used the patented process.

A much-talked issue of the present time is ensuring patent protection for pharmaceutical products to provide incentives for research and development into new medicines protecting people's right to access to medicine in the LDCs. Flexibilities such as compulsory licensing, transfer of technology by the developed countries to the LDCs and a grace period to implement the provisions of the TRIPS Agreement for the LDCs etc. are provided in the TRIPS Agreement for LDCs to implement the TRIPS standard of patent protection. But due to lacking of infrastructure and technology the use of the provisions of compulsory licence would be difficult for the LDCs. For example if the Government of Bangladesh issues compulsory licence to produce essential medicine for HIV treatment, antiretrovirals (ARVs), the local pharmaceutical industries may not be able to produce the drug due to the lack of technological know how and infrastructure. The developed countries are yet to show their sincerity in transfer of technology to the LDCs according to the provisions of the TRIPS Agreement.

It is clear from the aforementioned provisions of the TRIPS Agreement that member States must provide patent protection for the pharmaceutical products.

Doha Declaration

In the Declaration of the 4th Ministerial Conference in Doha, the Ministers emphasised on the implementation and interpretation of the TRIPS Agreement in a way that supports public health by promoting both access to existing medicines and creation of new medicines. The ministers referred the matter to a separate declaration. The separate declaration on TRIPS and Public Health was to address concerns on the possible implications of the TRIPS Agreement for the access to medicine.

According to article 65 (1) and article 66 (1) of the TRIPS Agreement the LDCs are to implement the provisions of the TRIPS Agreement within 1 January 2007. Therefore, Bangladesh is to amend the Patents and Designs Act, 1911 in order to incorporate the provisions of the TRIPS within 1 January 2007. This provision is modified by the declaration regarding patenting pharmaceutical products. WTO ministers issued a special declaration at the Doha Ministerial Conference in November 2001. They agreed that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. They underscored countries' ability to use the flexibilities that are built into the TRIPS Agreement. And they agreed to extend exemptions on pharmaceutical patent protection for least developed countries until 2016.

Impacts of patenting drug formula

Therefore, from the analysis of the legal provisions mentioned above it can be concluded that by providing patent protection to the drug formulas of the multinational companies the patent office of Bangladesh failed to utilise the waiver given by the WTO ministerial conference, the highest-level decision-making body of the organisation. We cannot straight way come to a conclusion that the patent office deliberately ignored the waiver of the Ministerial conference. We have already seen the legal provision of Bangladesh is in favour of patenting pharmaceutical products. The patent office is legally bound to grant patent on a valid application.

When patent protection is provided for a pharmaceutical product or a drug formula in such a case local manufacturers cannot use the method of reverse engineering in order to manufacture the product commercially or use the drug formula for commercial purpose. At best the local manufacturers can use such products or formula to invent a better product or formula by using reverse engineering. Since Bangladesh is an LDC it is not in a position to provide its local manufactures the technological or logistic support to conduct research on the patented products or formula of the multinational companies in order to produce better product or formula and in this way reap the benefit of patenting pharmaceutical products or drug formula.

The existing practice of using reverse engineering of the pharmaceutical products or drug formula would be definitely challenged by the multinational companies for the reverse engineering of their patented product and formula. The local manufacturers would loose the legal battle and will be compelled to withdraw their products or formula from national and international market and have to pay a huge compensation to the multinational company concerned. When the local manufacturers would require to use the patented product or formula of a multinational company they must get licence from the company by paying huge foreign currency. Due to this the price of the essential drugs may shoot up to several times than the existing price.

Since the Doha Declaration extended the time for providing patent protection to the pharmaceutical products by the LDCs till 1 January 2016, the exclusive rights for a new pharmaceutical product i.e. making, using, offering for sale, selling and importing for these purpose and for a new drug formula i.e. for use of the formula and the product obtained directly from the formula need not be provided by the LDCs. Therefore, Bangladesh is not required to provide exclusive rights to a multinational company for its new pharmaceutical product or a new drug formula. But once patent protection is given by the patent office for such a product or formula then the government is bound to provide and ensure the exclusive rights of such a company.

We cannot outright say that the local patent officials are ignorant about the consequences of the patent rights and the new development in the TRIPS Agreement due to the grant of patent for the drug formulas of the multinational companies as mentioned in the news. But we can emphasise the need of awareness of the patent officials about the latest development in the TRIPS Agreement and WTO's latest development and the WIPO's programmes regarding patent law.

At this point of time we cannot make such comment that government has failed to reap the full benefit of the TRIPS Agreement regarding the relaxation given by the TRIPS and the Doha declaration for providing patent protection to the pharmaceutical products. But right now government must act positively to reap the full benefit of the TRIPS and the Doha Declaration regarding protection of right to public health and access to medicine.

Required role of government

In order to stop patenting pharmaceutical products and drug formula by multinational companies the government must take step to amend the Patents and Designs Act, 1911 within the shortest possible time in order to exclude pharmaceutical products and drug formula or process by providing express provision regarding patentable subject matter in the Act which will expressly exclude that pharmaceutical products and process or drug formula from patenting till 1 January 2016. This is the easiest and convenient way of reaping benefit of the TRIPS and the Doha Declaration. Government may grant compulsory licenses for patented pharmaceutical products, process or drug formulas or provide provision for parallel import of such patented product, process or formula.

But such solution is a temporary one. The government also can strengthen its patent officials by providing them better training on WTO, TRIPS Agreement and WIPO's role on protecting the interest of LDCs. The government should take appropriate step to be treated as most favoured nation by the developed countries as per article 4 of the TRIPS Agreement. The government may take step to modernise its WTO cell of the Ministry of Trade and Commerce and open a special wing at the Ministry of Law, Justice and Parliamentary Affairs to oversee the legal consequences of the TRIPS Agreement and WTO Ministerial Conferences on Bangladesh. Such an effort would give Bangladesh a better footing to protect and exploit benefit from such ministerial conferences and any negotiations on WTO Agreement. Bangladesh should exploit the provision of article 66 (2) of the TRIPS Agreement to get better technology by way of technology transfer from the developed countries to create a sound and viable technology base.

Conclusion

Bangladesh cannot keep itself isolated from the international treaties, particularly from the WTO Agreement and the TRIPS Agreement in the present era of globalisation. Bangladesh is a signatory and a party to both WTO Agreement and the TRIPS Agreement. Therefore, full governmental and non-governmental efforts are needed to reap highest benefit from such agreements. The technology base of Bangladesh is very weak to compete with the products of the developed countries, even with the products of emerging regional economic power like India. So Bangladesh must achieve required development in science, technology and industrial sectors in order to provide the TRIPS standard patent protection particularly to the pharmaceutical products, process and drug formula within the grace period given by the WTO Ministerial Conference.

Bangladesh has already achieved a good progress in manufacturing life saving medicines by its local pharmaceutical industries. We expect that Bangladesh government would give special attention to the sector of pharmaceutical industries so that by 1 January 2016 it can compete with the multinational companies and patent protection can be enforced in this field as per the provisions of the TRIPS Agreement.

The author is Joint District Judge, Dhaka.

HUMAN RIGHTS *monitor*

Indigenous peoples' human rights

KHANDAKER FARZANA RAHMAN

INJUSTICE suffered by the victims of minority discrimination and related intolerance is well known in the world including Bangladesh. Limited employment opportunities, segregation and endemic poverty are only a few. The disadvantages faced by them in society are also familiar: lower pay for work of equal value; high illiteracy rate; and poor access to health care, etc.

The minority, immigrant, and ingenious people having limited employment opportunities are at the bottom of the labour market. Maurice Gledle-Ahanhanzo, the special investigator on the subject of the UN Commission on Human Rights, studied the situation of indigenous women in the labour market when he visited Brazil in 1995. He concluded that, "black women receive the lowest salaries (four times lower than that of a white one), are employed in the most unhealthy locations, work a triple working day and face threefold discrimination."

Who are ingenious people?

Indigenous people are the people living in an area prior to colonisation by a state or the people living in an area within a nation state, prior to the formation of the nation state, but who do not identify with the dominant nation or the descendants of either of the above.

The UN Commission on Human Rights has provided the following definition: "Indigenous people are composed of the peoples who inhabited the present territory of a country wholly or partially at the time when persons of a different culture or ethnic origin came there by conquest".

Indigenous peoples in New World

In the New World, the White European colonizers arrived and settled suddenly, with drastic results. The indigenous people were pushed aside and marginalised by the dominant descendants of Europeans. Modern estimates place the 15th century, or pre-Columbus, population of North America at 12 to 15 million. By the 1890s, it had been reduced to approximately 3000000. In parts of Latin America, the results were similar; in others, there are still majority indigenous populations. They still face the same obstacles as indigenous peoples elsewhereprimarily, separation from their lands.

Indigenous people in Bangladesh

In Chittagong Hill Tracts, the term indigenous people or Adivasi(in Bengali) applies to eleven montagnard or hill peoples: Bawm, Chak, Chakma, Khumi, Khyang, Lushai, Marma, Tanchangya, Tripura. They are mainly known as Pahari. In the central and north-western parts of Bangladesh, the Koch, Rajbangshi, Munda and Santhal live.

Steps taken by United Nations

- UN Universal Declaration of Human Rights 1948 states the rights for indigenous people: All human beings are born free and equal in dignity and rights. And all are equal before the law and are entitled without any discrimination to equal protection of law.
- ILO Convention No. 107 of 1957 provides the promotion of improved social and economic conditions for indigenous peoples.
- In 1970, the Sub-Commission on Prevention of Discrimination and Protection of Minorities (a subsidiary body of the Commission on Human Rights) commissioned special Rapporteur Martinez Cobo of Ecuador to undertake a study on "The Problem of Discrimination against Indigenous Populations".
- The report found that some governments denied indigenous peoples existed within their borders. Other denied existence of any kind of discriminationin contradiction to the reality encountered. It described cases where the government authorities unwittingly betrayed their badly discriminatory thinking.
- The establishment of the UN Working Group on Indigenous Populations in 1982 was a direct result of the Cobo Study. Consisting of five independent experts, the Working Group meets annually in Geneva, and until now, has been the only arena in the United Nations system in which indigenous people could state their views.
- The United Nations International Decade of the World's Indigenous Peoples (1995-2004) has helped to focus efforts in the United Nations system on two primary goals: The creation of a Permanent Forum on Indigenous Issues, and the drafting of a Declaration on the Rights of the Indigenous People.

The ECOSOC and the United Nations Charter body to which the commission on Human Rights reports took steps to establish the Permanent Forum on Indigenous Issues, which will consist of eight governmental experts and eight indigenous representatives.

Indigenous peoples' rights in Bangladesh

The Constitution of the People's Republic of Bangladesh provides the similar rights as fundamental rights stated in UN Universal Declaration of Human Rights of all citizens in Bangladesh and article 28(4) of the Constitution enables the state to enact special provisions for advancement of any backward sections of citizens.

On 9August 1993, the Bangladeshi Indigenous peoples while celebrating the International year of the World's Indigenous Peoples, demanded constitutional recognition of their cultural integrity. The impact of the international events was realised within this country in various ways.

- The UN events led to the forging of greater unity among the country's indigenous peoples.
- It instilled a greater sense of pride in their indigenous identity.
- It led to the growing currency of the term "indigenous" and "adivasi".

Though the indigenous peoples constitute a considerable part of the country's population they are denied to play a role in state-formation and nation building. They cannot exercise their rights in the case of land alienation. Again they are suffering from the non-acknowledgment of their right to self-determination and the district and regional councils are indifferent in this respect.

What can be done?

To protect the rights of the indigenous people and to resist the discrimination against them, some recommendations must be adopted, such as

- Good governance plays a vital role in involving minorities in society and protecting their rights and interests. Through recognition, dialogue and participation, all the citizens of a diverse society can form a greater understanding of one another's concerns.
- Education and the media have important roles to play in this regard, as do political representatives and community leaders.
- Positive action by states can include legislative measures that introduce higher maximum penalties for minority motivated crimes.
- State authorities need to ensure that minorities enjoy the fundamental right to equality both in written legislation and in society at large. The roles of local government, civic organisations and non-governmental organisations are important in this respect.
- The government should take some effective initiatives to increase the employment of persons of minority origins in fields where they are under-represented, and establish human rights institutions.
- Other recommendations include monitoring hate speech, promoting empowerment through education, and ensuring adequate housing and access to health care for the indigenous people.

The author is in 4th year LL.B. (Hons), University of Dhaka.