Do not trade away our lives

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We see today a shift in the terrain of trade agreements from the World Trade Organisation (WTO), and the binding trade rules that it imposes on member countries, to bilateral and regional trade agreements. From 1990 to 2007, the number of such agreements notified to the General Agreement on Tariffs and Trade (GATT) or the WTO increased from 20 to 159 (1). At present, it is estimated that over 250 regional and bilateral trade agreements govern more than 30% of world trade.

A principal reason for this shift of terrain and the huge increase in bilateral/regional trade agreements has been the inability of the WTO to govern global trade. To a great extent, this has been a result of the unwillingness of powerful trading blocs (the United States, the European Union, Japan, etc) to accommodate the legitimate concerns of developing nations; and also because of differences between the EU and the US in some major areas (especially related to agricultural subsidies). As a result, ever since the WTO ministerial meeting in 1999 in Seattle, no WTO ministerial meeting has concluded with a clear global consensus on the way forward for global trade.

For countries such as India, it is important to understand another major reason why trade negotiations are being conducted bilaterally, rather than through the multilateral forum of the WTO. The EU, Japan, and the US view bilateral agreements as means to extract concessions that go beyond the agreement in the WTO. Thus, for example, these agreements do not include the flexibilities available under the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement (part of the WTO agreement of 1994) and can impose additional obligations. Since 2001, every trade agreement signed or under negotiation by the US has increased the scope of intellectual property right protection of pharmaceuticals, including patent terms beyond the 20 years provided for under the WTO. Protection of knowledge and genetic resources is another area in which regional and bilateral trade agreements could affect health. Several agreements ease restrictions on patenting life forms and the protection of plant varieties.

Free trade agreements: understanding the real motives

The history of the negotiations in GATT (the precursor to the WTO), which led to the formation of the WTO, shows how the US has always combined negotiations in multilateral and bilateral fora in order to ensure that its writ finally prevails. For example, during the 1980s the US set the scene for the inclusion of an agreement on intellectual property in the Uruguay Round of GATT negotiations (1986-1994) through a series of strategic bilateral negotiations on intellectual property with countries like Brazil, Singapore and South Korea (2). The purpose of these was to break the resistance of those developing countries that were leading the opposition to the US agenda on intellectual property within the Uruguay Round of negotiations, as well as to set precedents for the kind of standards that the US wanted to see included in a multilateral agreement (in the WTO) on intellectual property.

In the US, the Trade Promotion Authority Act of 2002 directs the US trade representative to seek to ensure "that the provisions of any multilateral or bilateral trade agreement governing intellectual property rights that is entered into by the United States reflect[s] a standard of protection similar to that found in United States law". Clearly, thus, what is demanded by the US in free trade agreements (FTAs) as regards intellectual property rights(IPRs) is informed by the domestic laws of the US, and not by the internationally negotiated TRIPS agreement.

The EU has been no less blunt in making explicit its intentions as regards FTAs. The EU's trade policy aggressively advances issues which it has not been able to pursue adequately in the multilateral forum of the WTO. They focus on five major areas : 1) market access for European business through elimination of tariff and non-tariff barriers; 2) the so-called Singapore issues (investment, government procurement, competition and trade facilitation) which were rejected in the Cancun ministerial meeting of the WTO in 2003 by a combined front put up by governments of developing countries; 3) intellectual property rights; 4) the service sector which is a stronghold of the EU economy; 5) reference to sustainable development including rhetoric about social and environmental standards, core labour rights and decent work (which are euphemisms used to put at a disadvantage enterprises located in developing countries) (3).

Given the very large number of FTAs being negotiated (or those that have already been signed) it is often difficult to track specific developments. There is a set of common demands that are contained in most FTAs that involve the EU, US and Japan, though there are differences in emphasis. The US, for example, is keen in its FTAs to push for stronger intellectual property rights measures that go beyond the TRIPS agreement. The EU is especially keen on pushing agreements that require greater liberalisation of the service sector (including the health sector) and for tariff reductions on goods. These specific demands are in line with the strengths of the respective economies. The US economy depends significantly on sectors that are IP dependent – pharmaceuticals, software, etc. The EU's economic health depends significantly on its service sector.

How FTAs and the WTO co-exist

There is a curious story which explains how FTAs and the WTO exist side by side. The cornerstone of the WTO is the most-favoured-nation treatment among the member-countries. This clause means that member countries of the WTO cannot discriminate in their treatment of other member countries, i.e. in any WTO member country, all WTO member countries (operating through corporations, etc. located within their territories) must be provided with the same facilities and be subject to the same rules. Logically, this should bar all FTAs, because these agreements can have provisions that are different from the WTO and thus do discriminate between countries who are part of an FTA and those who are not (even if both sets are members of the WTO). The catch lies in the fact that when the WTO agreement was signed in 1994, many countries were already bound by bilateral agreements that eliminated customs-related regulations between contracting parties. Thus, the WTO agreement issued a waiver on "custom unions", taking recourse to Article 24 (8b) of GATT), which says:

> A free-trade area shall be understood to mean a group of two or more customs territories in which the duties and other restrictive regulations of commerce (…) are eliminated on substantially all the trade between the constituent territories in products originating in such territories.

While FTAs today use the cover of this waiver, substantive parts of almost all FTAs have very little to do with customs regulations, but deal with other aspects of global trade (for example, IPRs are not part of customs related issues).

Immediate cause for concern: EU-India FTA

In June 2007, the European Commission and the Indian government started negotiating the EU-India FTA. One of the most ambitious negotiations, the FTA will mean a massive slashing of India's import duties (up to 95% of all goods produced) and include trade in services, investment, intellectual property rights, competition policy and government procurement. The FTA will have far-reaching consequences on national, state and local laws and policies that are seen to restrict free trade of European imports and therefore, on the lives and livelihoods of Indian citizens.

Given the veil of secrecy that shrouds the negotiations, no authoritative text is available as regards the respective negotiating positions of the EU and India. The analysis presented below is based on "leaked" texts and dribbles of information that activist organisations have managed to access. Though all sectors of the Indian economy are likely to be affected, the comments in this essay are limited to the possible impact in the health sector.

Government procurement: The estimated value of goods procured by central and state governments in India is estimated to be about US$ 35-50 billion. The EU has been prominent in pushing for an agreement on "government procurement" in FTAs. This was one of the "Singapore issues" that were rejected by developing countries in the Cancun ministerial meeting of the WTO in 2003. In a government procurement agreement (GPA) whatever the government of a member country of and FTA procures, all other members have equal right to bid for tenders. So, for example, if the EU-India FTA is signed incorporating a GPA clause, India will have to allow companies to bid for contracts for all government procurements. This could mean that when tenders are floated to procure medicines for public health facilities, companies based in the EU would have the right to bid for such contracts. Such a situation can also affect the ability of the Indian government to determine how food for public distribution systems would be procured. In addition to such direct impact on the health sector, a GPA affects different sectors of the economy, and hinders the efforts by developing country governments to plan for the growth of its domestic industry.

Appropriation clause in investment chapters: FTAs have different chapters dealing with different areas, such as IP, manufacturing, services, investment, agriculture, etc. A major area of concern related to investment chapters in most FTAs is that they allow private companies to file cases against governments. So they subject countries to the risk of litigation by corporations based in another country. This might be related to a company's objections to the host government's environmental, health, social or economic policies, if these are seen to interfere with the company's "right" to profit. The biggest issues relate to the provisions for compensation for "expropriation", which can be direct (as in cases of nationalisation) or indirect (policies or actions that impinge on the profitability of the company concerned) (4).

These are not imagined consequences. For example, in November 2000 the multinational water infrastructure company AdT filed for arbitration and sought $25 million from the Bolivian government as compensation for its lost investment including expected profits, after the government was forced to reverse a disastrous water privatisation attempt in Cochabamba. Similarly, in 2010 Philip Morris International -- the world's second largest cigarette company and manufacturer of brands such as Marlboro and Red and White -- sued the Uruguayan government for its regulation that requires tobacco companies to cover 80 per cent of their cigarette packs with pictorial tobacco-warning labels (5).

Liberalisation of health services: The General Agreement on Trade in Services (GATS) under the WTO is negotiated through a system where countries have the option to open areas of their service sector (water services, education, health, banking, insurance, tourism, etc) based on their own requirements. So, countries can choose not to open up certain areas as well. In this, the GATS agreement is different from other agreements in the WTO that require similar degrees of compliance from all member countries.

However, FTAs can try to get around this by providing for opening up the service sector. For developing countries with failing health systems, foreign investment may seem an attractive source of capital and medical technology. Yet involvement of the foreign private sector in health care has the potential to marginalise the poor even further. Companies seek markets in which they can be assured sufficient returns, and this typically concentrates investment in more affluent areas.

FTAs are also known to target specific government schemes that are designed to safeguard public health and rational use of medicines. The Australia-US FTA made Australia's Pharmaceutical Benefit Scheme a prime target. Under the scheme, low drug prices are negotiated by the combination of stringent cost-benefit (or "pharmacoeconomic") analyses and the market power of a centralised buying system that the government oversees. The FTA now allows US pharmaceutical manufacturers to ask for an independent review if the Pharmaceutical Benefits Advisory Committee decides not to list their drug.

Data exclusivity: From various news reports it is clear that "data exclusivity" (DE) has been one of the major areas of contention in the FTA negotiations between the EU and India. Data exclusivity refers to the practice where a company which introduces a new drug is provided with a monopoly for a certain period (usually 5-10 years) over the data that it submits to regulatory authorities. If such a provision is in place, it acts as a barrier to the introduction of generic versions of new medicines. As regulatory agencies are not allowed to use the data (data related to safety, efficacy, dosage, etc) provided by the originator company, each generic version has to be preceded by clinical trials to generate this data afresh. Data exclusivity, thus, adds to the cost of generic medicines, delays their introduction and also is unethical because it requires clinical trials to be done for medicines for which data is already available.

Data exclusivity is not a TRIPS requirement and the present Indian law does not provide for it. It must also be understood that DE and patents can coexist, or DE can exist in a situation where there is no patent. Thus, DE acts as an additional instrument, to promote monopoly and to delay introduction of generic drugs.

There is clear international evidence that pushes up treatment costs and promotes monopoly. In Jordan, where data exclusivity was introduced as part of the US-Jordan FTA, a study found that of 103 medicines registered and launched between 2001 and 2006 that had no patent protection in Jordan, at least 79% had no competition from a generic equivalent as a consequence of data exclusivity (6). A study on the effects of DE in another free trade agreement negotiated by the European Commission showed that in Colombia alone, the introduction of a 10-year period of data exclusivity would lead to an increase in medicines expenditure of US$340 million by 2030 (7).

IP enforcement measures: The other major area in the negotiations, where the EU has been particularly insistent, relates to "IP enforcement measures". There are several IP enforcement provisions in the India-EU FTA negotiations (8) including:

Injunction provisions: These provisions can undermine the independence of the Indian judiciary by requiring courts to grant injunctions, in the case of a patent dispute, even before the validity of the disputed patent is established. This means that generic companies can be asked to stop production or even destroy stocks, even before a final settlement of an IP-related dispute is arrived at.

Border measures: In December 2008, customs authorities in the Netherlands detained the generic version of losartan potassium, used to treat high blood pressure, manufactured in India by the generic company Dr Reddys and in transit to Brazil. According to the Brazilian government, 300,000 patients in Brazil were awaiting this medicine (8). In this case, the drug was legally produced in India and was legal in Brazil, i.e. in neither the exporting or importing country was there a patent violation. Yet the drugs were seized on the ground that there was a patent violation in the port of transit. There have been several other such cases, where Indian generic drugs, in transit to developing countries, have been seized at European ports.

In the EU-India FTA negotiations, it is understood that the EU has reluctantly agreed to remove patents from "border measures", but it continues to seek the detention of goods including pharmaceuticals if companies allege trademark infringement even if it is a civil trademark dispute. If accepted, this can increase border searches and can interfere with cross-border transit of legitimate generic medicines

Third party liability: This will place "third parties" at risk of severe penalties for an alleged patent infringement. Third parties can mean suppliers of active pharmaceutical ingredients used for producing generic medicines; distributors and retailers who stock generic medicines; not-for-profit organisations which use generic medicines to treat patients, etc. This can act as a major deterrent for anyone involved in the production, sale and distribution of affordable generic medicines.

Can the government negotiate away our rights?

The government has yet to articulate its medium- to long-term strategy behind negotiating FTAs, let alone share any concrete details about the content of each FTA negotiation. For example, the India-ASEAN FTA was signed without even chief ministers

of different states seeing the offer of goods to ten ASEAN countries. In the case of the EU-India FTA, both the Indian government and the European Commission have consistently refused to share information with civil society groups and the general public. Repeated calls for transparency and accountability have been ignored, thereby undermining the basic tenets of democratic process, policy making and law.

Given the wide range of impact that the Indo-EU FTA is likely to have -- not just in the health sector but in almost all areas of peoples lives (agriculture, industry, livelihoods, trade and commerce, financial and other services, etc) – it is unacceptable that the agreement be signed without any informed discussion in the country. Transparency is the hallmark of good governance, and it is only to be hoped that a modicum of good sense shall prevail and the government of the day shall heed calls from different quarters to at least discuss the implications of the agreement.

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