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Implications of bilateral FTAs on access to medicines

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The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)[1] of the World Trade Organisation (WTO) mandated the introduction of protection of intellectual property rights (IPRs), notably patents, for pharmaceutical products.

While the implications of the TRIPS Agreement for access to medicines raised significant concerns, a recent new wave of free trade agreements (FTAs), negotiated outside the WTO, requires even higher levels of intellectual property protection for medicines than those mandated by the TRIPS Agreement.

The measures involved include the extension of the patent term beyond 20 years; prohibition of use of test data on drug efficacy and safety for certain periods for the approval of generic products; linkage between drug registration and patent protection; and, in some cases, limitations to the grounds for granting compulsory licences.

This paper reviews some of these measures that further limit the competition of generic products and discusses their possible implication for access to medicines.

INTRODUCTION

Medicines, like any other products, can be protected by IPRs such as patents. Such protection means that their production, importation and commercialisation are subject, for a given period, to exclusive rights that allow title-holders to charge prices above marginal costs.

The resulting higher prices may mean, especially for poor people living in developing countries, that a large part of the population is deprived of access to the medicines they need.

With the adoption of the TRIPS Agreement, most countries have accepted to provide a minimum level of IPR protection, including patent protection for 20 years (calculated from the date of filing of the patent application).

The TRIPS Agreement has generated a massive change in the legislation of developing countries, which now provide patent and data protection (that is, protection on clinical data against unfair commercial use) for pharmaceutical products. Only the least developed countries were permitted to delay the introduction of such protection until 2016.[2]

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While developing countries were adapting to the new intellectual property rules mandated by the TRIPS Agreement (which generally entered into force in these countries in 2000) and implementing measures to manage the foreseeable increase in the cost of medicines, a further wave of international agreements, in this case of a bilateral nature, has emerged.

These new free trade agreements, negotiated outside the WTO, require even higher levels of intellectual property protection for medicines than those mandated by the TRIPS Agreement, and in some cases go beyond what is required in the developed countries that are promoting them.

This paper reviews certain clauses contained in some of the FTAs that may have an important impact on access to medicines, since they delay or restrict competition from generics. The focus will be on the FTAs negotiated by the USA, which are more comprehensive and elaborate than those negotiated by the European Union (EU) and European Free Trade Association (EFTA) countries.

FTAs AND "TRIPS-PLUS" STANDARDS

The requirements imposed by the TRIPS Agreement on medicines, and the flexibilities left for their implementation, have been extensively studied by scholars and non-governmental and international organisations, such as the World Health Organisation (WHO).[3]

Since 2001 the USA has initiated 11 bilateral and regional free trade agreements with 23 countries. In this respect, agreements with Chile, Jordan, Morocco, Singapore and the countries of Central America (plus the Dominican Republic) have been ratified by the US Congress (see endnote *a*), while six FTAs with 13 additional countries have been initiated and are under negotiation (see endnote *b*). Other FTAs have been signed by or are under negotiation between developing countries and the EU or EFTA (see endnote *c*).

A common feature of these agreements is that they include "TRIPS-plus" standards, i.e., they require protection of IPRs beyond what was agreed upon in the TRIPS Agreement.

It is to be expected that the longer and stronger IPRs required by such TRIPS-plus standards will reduce access to medicines in low- and middle-income countries considerably more than in high-income countries.

Although these FTAs have only started to be implemented (or are yet to enter into force), there is a growing body of literature critically examining their likely impact, particularly on public health.[4-12]

In contrast, there is still a dearth of studies on the reasons why developing countries opt to enter into FTAs, as well as on the extent to which the associated expected commercial benefits (which may be ephemeral as competitive situations change) might outweigh the higher public health costs they are likely to bear.

Substantial health-related costs were estimated in the context of the FTA negotiations between Andean countries and the USA[13, 14], but the governments of Peru and Colombia accepted a broad set of TRIPS-plus standards despite the adverse opinion of their public health authorities.

This paper is based on an extensive review of the literature, including some studies that estimate the possible public health costs of introducing TRIPS-plus protection for pharmaceuticals.[13, 14]

DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

The TRIPS Agreement obliged all WTO Member states to provide patent protection for pharmaceuticals, defined the exclusive rights conferred to patent owners, limited the possible exceptions to such rights and determined the conditions for the granting of compulsory licences. It also introduced, for the first time in an international agreement, the obligation to protect data against unfair competition.[15]

Soon after the adoption of the Agreement, serious concerns were raised about its possible impact on public health.[3] As a result of strong tensions arising from its implementation (as illustrated by the case initiated by a number of pharmaceutical companies against the government of South Africa)[16], the

Fourth WTO Ministerial Conference (held on 9-14 November 2001) adopted the Doha Declaration on the TRIPS Agreement and Public Health.[17]

The Declaration recognised the "gravity" of the public health problems afflicting many developing and least developed countries, especially – but not limited to – those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

While acknowledging the role of intellectual property protection "for the development of new medicines", it affirmed that the TRIPS Agreement "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all".

The Declaration confirmed a number of flexibilities that Members can use to implement the Agreement, including the adoption of an international principle of exhaustion of rights (under which parallel imports may be accepted) and the granting of compulsory licences (under which the government or a third party can, subject to certain conditions, use a patented invention without the consent of the patent owner).

The adoption of this Declaration and, subsequently, of a Decision aimed at facilitating the importation of medicines by developing countries without manufacturing capacity in pharmaceuticals[18], was an attempt to ensure, through the effective use of the permitted flexibilities, some balance in the implementation of the TRIPS Agreement and, in particular, that public health be given priority in case of conflict with intellectual property rules.

The wave of FTAs referred to above represents a drastic setback in this respect, since they not only erode such flexibilities but also impose a number of additional obligations on states that can further restrict their access to medicines.

TRIPS-PLUS PROVISIONS IN FTAs

Analysis of the FTAs already signed and those under negotiation indicates that the inclusion of a number of TRIPS-plus provisions is a common feature.

Although there are differences, all these FTAs increase the term and scope of protection for pharmaceuticals, on the general argument that the current levels of protection (even if TRIPS-compliant) do not permit adequate recovery of research and development (R&D) costs.

Some of the additional standards that are likely to have significant implications for access to medicines are examined below.

Patent term extension

Under the TRIPS Agreement, patents must last for 20 years from the date of application. Economists have for a long time debated about the optimal patent life, only to come to the conclusion that it depends on each particular invention or class of inventions, and that determining it *a priori* would be costly and in some cases simply impossible.[19, 20]

Using the argument that in the case of pharmaceuticals, the need to obtain marketing approval of new chemical entities reduces the effective term of patent protection and the possibility of recovering R&D costs, the pharmaceutical industry has in some countries (e.g., the USA and the EU) obtained the right to extend the patent term to compensate for delays in the examination of the patent application and in the process of marketing approval.

The FTAs promoted by the USA oblige the partner countries to extend the patent term to compensate for "unreasonable" delays beyond a certain period (a) in the procedures for the marketing approval of a medicine and (b) in the examination of patent applications.

As far as the delays in procedures for the marketing approval of a medicine are concerned, most agreements do not mention whether the extension shall apply only to delays in the country where it is sought (although it would be legitimate to interpret it this way) or whether the delay in the country where the first approval was obtained should also be taken into account. This has been clarified, however, in the case of Bahrain, which has been obliged to take into account the delays also in a foreign country (FTA Article 15.6.(b)(ii)).

No maximum period is provided for the extension. Paradoxically, this constitutes a remarkable difference between these FTAs and the current law in the USA, where provision is made for some time limits. The extension in the USA to compensate for delays in the marketing approval process does not exceed five years, and in no case should exclusivity exceed 14 years from the date of approval by the US Food and Drug Administration (35 U.S.C. S. 156 "Extension of patent term"). In addition, the extension applies to only one patent per product. Due to the shortening of the marketing approval time in the last few years[21], the extension provisions in the USA are not applied in practice.

Data exclusivity

The TRIPS Agreement requires WTO Members to protect undisclosed test data on pharmaceutical (and agrochemical) products against unfair competition (TRIPS Article 39.3). Under this rule, correctly interpreted, Members are not obliged to grant exclusive rights over data, as is done under the *sui generis* regimes established in the USA, the EU and in other countries.[22]

The FTAs negotiated by the USA drastically depart from the TRIPS standard. They oblige the parties to grant exclusive rights for at least five years counted from the date of approval of the product, irrespective of whether it is patented or not and, in most cases, of whether the data are undisclosed or not. Such exclusivity will apply irrespective of whether the national health authority requires the submission of the data or not (i.e., even in cases where it relies on the approval made in a foreign country) and covers chemical entities that are not "new", as they may have been previously approved in other territories.

In addition, in the case of the Central America-Dominican Republic FTA, a waiting period of five years is provided for. According to Article 15.10.1(b) of this agreement, a party may require that the person providing the information in another territory seek approval in the party within five years of obtaining marketing approval in the other territory. Thus, the originator of the test data enjoys a full 10 years of exclusivity during which no other individual would be able to use, without his consent, directly or indirectly, the relevant test data.

Linkage between drug registration and patent protection

The US FTAs require a linkage between drug registration and patent protection which is absent in the TRIPS Agreement. As a result, the national health authority must refuse marketing approval to a generic version of a product if a patent thereon is in force, unless by consent or acquiescence of the patent owner. In addition, such authority must inform the patent owner about applications for the approval of generic products.

Other standards

In addition to the TRIPS-plus standards mentioned above, some FTAs restrain the WTO Members' freedom, confirmed by the Doha Declaration, to determine the grounds for compulsory licences. Thus, in the case of the FTAs agreed between the USA and Australia, Jordan and Singapore, such grounds are limited to cases of anti-competitive practices, public non-commercial use, national emergency or other circumstances of extreme urgency. This limitation, which openly contradicts the Doha Declaration, does not appear in other FTAs that the USA has entered into with developing countries after the adoption of the Declaration.

The possibility of parallel importing of medicines and other products (i.e., importing a patented product which has been legitimately put on the market abroad, without the consent of the patent owner) has also been limited in some FTAs (those between the USA and Australia, Morocco and Singapore) that permit the patent owner to prevent parallel imports through the use of contract or other means.

Finally, some FTAs (e.g., that with Morocco) require the recognition of patents over the "second indication" of a pharmaceutical product. This obligation unnecessarily expands the scope of patentability and ignores the right, recognised by the TRIPS Agreement, to exclude the patentability of therapeutic methods.

IMPLICATIONS

Extension of patent term

There is no sound justification for the extension of the patent term as required by these FTAs. First, in the case of commercially successful medicines, the R&D costs may be recovered by several months of sales at the prices that can be charged in isolation from competition, under the exclusive rights enjoyed by the patent owner. Second, the time necessary to comply with marketing approval procedures has shortened. Third, only a few patents protect new active ingredients; the great majority cover logical extensions of existing knowledge or developments that are patented with the deliberate aim of delaying competition.[23]

The extension of the patent term to compensate for delays in the process of examination of patent applications overlooks the fact that in many developing countries patent offices are under-staffed and delays are common.

In addition, an extension is unnecessary where patent laws, as is often the case, confer rights to applicants before the patent has been granted, as soon as the application has been published. This would effectively exclude competitors for at least 18.5 years, since such publication normally takes place 18 months after filing.

The possibility of such extension creates uncertainty for generic producers and, when effected, will have obvious consequences on public health: it delays the introduction of competing products, with the ensuing loss of consumer welfare and increased barriers to access to medicines, especially by the poor.

Since the grounds for the extension of the patent terms under the FTAs are independent and cumulative and involve no maximum period, nothing seems to prevent a patent from being extended for x years due to a delay in its granting process, and for y more years due to a delay in the marketing approval process.

Thus, patents on pharmaceutical products may last for several months or years after the 20-year term required by the TRIPS Agreement. These mechanisms will have the effect of making the public pay for any eventual administrative delays, and generate an increased flow of payments to pharmaceutical companies that can hardly be justified by any additional benefits to patients in developing countries.

Since the revenues obtained from such countries contribute only a small extent to the profits of drug companies, the amounts involved have only a small effect on the R&D decisions made by them.[24] Similarly, longer patent rights (depending upon various factors such as administrative delays) are unlikely to increase foreign direct investments or transfer of technology, which in any case are only weakly related to the level of intellectual property protection.[25]

Data exclusivity

Particularly in countries that have only recently introduced patent protection for pharmaceutical products, the implications of data exclusivity will also be significant, since medicines that are off-patent may then become subject to exclusive rights.

These provisions create an effective barrier to competition from generics, since even where a product is off-patent, no marketing approval can be granted to generic manufacturers unless they replicate the full set of test data necessary to obtain approval, which is costly, time-consuming, and questionable under the Declaration of Helsinki.[26]

A study in Peru relating to 43 products that could have been subject to data exclusivity estimated that their average price would have been between 94.3% and 114.4% higher than in the absence of these provisions.[27]

Patent-registration linkage

The linkage between drug registration and patent protection ignores that patents are private rights – as stated in the Preamble to the TRIPS Agreement. It shifts to states the responsibility of preventing possible infringement.

States also assume any liability for unduly preventing the approval of a generic product, if it is finally determined that the patent is invalid or that there is no infringement. Health authorities

do not have the knowledge or experience to assess the claims of a patent and/or its possible infringement.

Pharmaceutical patents cover not only the active ingredients but a wide range of other aspects (such as salts, esters, ethers, polymorphs, formulations, active metabolites, isomers).[23] Under a linkage system, such patents – in many cases, susceptible to validity challenges – may erect a formidable barrier to legitimate generic competition.

The patent-registration linkage goes beyond the standards applied in the USA and the EU. For example, the US Food and Drug Administration does not substitute patent owners in enforcing their rights. It must only inform them about the existence of a third party's application on the same drug, provided that the relevant patents have been registered in the so-called "Orange Book". It is the patent owner's responsibility to act before the courts if an alleged infringement exists. A report of the US Federal Trade Commission reveals, however, that in most cases patent owners failed to prove such infringement.[28]

Moreover, in the EU there is complete independence between patent protection and registration. Health authorities limit their function to ensuring compliance with the relevant standards of safety, quality and efficacy of medicines and do not assume any role in enforcing patent rights.

Other standards

Compulsory licences and parallel imports have been widely recognised as important instruments for promoting access to medicines at affordable prices.[29, 30]

However, data exclusivity and the patent-registration linkage can make illusory the granting of compulsory licences and non-commercial government use, since prospective compulsory licensees are unlikely to replicate test data, and governments cannot normally wait until a new set of test data has been developed.

In some cases, "side letters" or "understandings" have been signed suggesting that the FTAs' provisions are compatible with the Doha Declaration and, in particular, that the use of compulsory licences to protect public health would not be impeded. However, these letters or understandings – which contain language that is inconsistent with the right to adopt measures to protect public health recognised under the Doha Declaration – only have interpretive value. In the event that a pharmaceutical company that has a brand-name drug decides to challenge a decision to approve a generic drug produced under a compulsory licence, the conflict will only be "informed" by the letter and will have to be resolved on the merits of a particular case.[12]

CONCLUSIONS

A number of developing countries have agreed, or are in the course of negotiating, FTAs in order to attain perceived commercial advantages. As a result, they have been bound to accept standards of protection of intellectual property rights for medicines that go well beyond what they had already consented to at the multilateral level. (Editor's note: Recognising the adverse public health effects of the provisions of the FTAs signed by the US government with Peru and Panama, a bipartisan agreement reached in June 2007 between the Republican and Democratic parties in the US Congress made concrete suggestions to amend provisions relating to the extension of the patent term, data exclusivity and the linkage between drug registration and patents.)

Although the FTAs that have been discussed here are too recent to enable a full assessment of their effects on public health, their higher standards of protection will, by their very nature, delay or restrict generic competition and thereby reduce access to medicines.

Accepting those standards negates the letter and spirit of the Doha Declaration, and will limit the capacity of states to progressively realise the human right to health.

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Endnote ***a***: United States-Jordan free trade agreement (2001). United States-Chile free trade agreement, signed in Miami, 6 June 2003; entered into force 1 January 2004 (Chile FTA). United States-Singapore free trade agreement, signed in Washington, DC, 6 May 2003; entered into force 1 January 2004 (Singapore FTA). United States-Morocco free trade agreement, signed in Washington, DC, 15 June 2004; entered into force 1 July 2005 (Morocco FTA). United States-Dominican Republic-Central America free trade agreement, signed in Washington, DC, 28 May 2004 and 5 August 2004; parties: Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Nicaragua and the United States (CAFTA). United States-Bahrain free trade agreement, signed in Washington, DC, 14 September 2004 (Bahrain FTA).

Endnote ***b***: Andean agreement with Colombia, Ecuador and Peru (signed in December 2005); a Southern Africa agreement with Botswana, Lesotho, Namibia, South Africa and Swaziland; and bilateral agreements with Oman, Panama, Thailand and the United Arab Emirates.

Endnote ***c***: The EU has signed agreements with South Africa (1999), Tunisia (1998) and the Palestinian Authority (1997), among others, which require the signatories to ensure adequate and effective protection of intellectual property rights "in conformity with the highest international standards". EFTA is composed of Iceland, Liechtenstein, Norway and Switzerland. FTAs have been negotiated with Chile, Egypt, Jordan, Lebanon, Mexico, Morocco, the Palestinian Authority, South Africa and Tunisia. A requirement in these agreements is generally the obligation to provide "effective patent protection for inventions in all fields of technology on a level similar to that prevailing in the European Patent Convention".