

Struggling to Balance Free Trade with Access to Medicines in the post-TRIPS Era throughout the Arab World

ABSTRACT

Access to medicines in the Arab world will in the future depend on how these countries can deal with the challenges of world trade, and in particular the issue of how to protect intellectual property (IP) without compromising public health needs, especially in terms of access to medicines at affordable prices.

Many countries in the region are members of the WTO and are obliged to apply the TRIPS Agreement as from January 1st 2005, with all its constraints concerning IP rights. More stringent measures are being imposed on these countries as a direct result of the increase of bilateral and regional agreements, especially by the European Union and the United States.

It is widely accepted today that strengthening IP protection has an impact on the price of patented medicines, and subsequently on the availability of affordable drugs, especially in developing countries¹. Arab countries, some with fragile health systems and populations with limited purchasing power, will soon be confronted with the real problem of access to medicines and the attendant consequences for public health.

It is becoming increasingly urgent to begin reflecting upon this problem in the region so that adequate policies can be put in place in order to protect public health, as stipulated in the Doha Declaration in 2001.

The purpose of this paper is to consider some of the options available to these countries so that they can fully benefit from the flexibilities afforded to them by the TRIPS Agreement and thereby secure fairer access to medicines. These flexibilities have not always been taken into consideration by countries when implementing the TRIPS Agreement in national patent laws, as seen in the examples of Egypt and Morocco.

This paper focuses on the Free Trade Agreements (FTA) with the United States as the greatest danger to the right to health in the region, as these agreements are the most restrictive of their kind in terms of IP rights. It details in particular the Morocco-US FTA, concluded in 2004, which includes several 'TRIPS+' provisions, and which now serves as a model for future negotiations with other countries.

Finally, a framework is outlined to further open up dialogue on this issue.

¹ Scherer M.F., Watal J. : Post TRIPS Options for Access to Patented Medicines in Developing Countries. WHO, 2001

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I. The TRIPS Agreement

In 1994, the WTO set out minimum standards for the protection of intellectual property in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, including patents for pharmaceuticals concerning both products and processes.

For those countries that did not provide for product patent protection at the time of enforcing the TRIPS agreement, they will now have to do so by 2005. With both product and process patents, reverse engineering will no longer be possible.

Many countries of the region are already members of WTO (Tunisia, Qatar, Oman, Morocco, Mauritania, Kuwait, Jordan, United Arab Emirates, Egypt, and Bahrain) and are required to implement the TRIPS agreement. Others have the status of observer members and had started accession negotiations within five years of becoming observers (Algeria, Saudi Arabia, Libya, Iraq, Iran, Sudan and Yemen)².

Before the TRIPS agreement was signed in 1994, the various treaties that used to oversee IP agreements at an international level authorised multiple protection systems. In particular, it was acceptable that countries marked by weaker levels of economic and technological development could adapt systems that were more conducive to the diffusion of technology rather than encouraging innovation³.

This enabled many countries of the region like Egypt and Morocco to build up a local pharmaceutical industry based on copying molecules that had been developed elsewhere. This made it possible to pharmaceutical products in local markets at much lower costs, a necessary albeit insufficient precondition for providing the poorest members of society with access to health care.

For example, in Morocco the development of healthy competition between generic and branded products resulted in a direct reduction of prices for these medicines in public offers by 47% and a saving of 266 million Dirham in 1999, according to a WHO study⁴.

II. TRIPS Flexibilities

The TRIPS Agreement sets out minimum protection of intellectual property, and patents increasingly present barriers to access to medicines. However, it also offers safeguards to remedy negative effects of patent protection or patent abuse, and the Doha Declaration on TRIPS and Public Health in 2001 gave primacy to public health over private intellectual property, and clarified WTO members' rights to use the TRIPS safeguards and flexibilities.

These main flexibilities are government use, compulsory licences, parallel imports and exceptions to patent rights.

² See www.wto.org

³ Coriat B., Dumoulin J., Flori Y.A., Barnett T. Souteyrand Y., Moatti J.P : *Patents, Generic Drugs and the Markets for Antiretrovirals*. ANRS

⁴ Himmich H.: Danger sur les génériques. www.alcsmaroc.org

Apart from these, the TRIPS Agreement also offers other possibilities to minimize the impact of patents on public health. One of these is the exclusion from patentability of inventions that are not new, discoveries, and second uses for patented drugs.

The TRIPS Agreement does not fix any grounds for compulsory licences, and governments have broad authority to establish liberal grounds (when a product is essential to public health, when price is a barrier to access etc.) rather than limiting them to cases of extreme emergency. At the same time, countries have the flexibility to adopt fast-track, administrative procedures to handle compulsory licences claims, and to rely on royalty guidelines to set compensation to the patent holder⁵.

Concerning the protection of undisclosed data, TRIPS does not require any form of exclusivity protection and requires protections to be provided only to data for New Chemical Entities. Governments are free to establish their own systems of protection⁶ in this respect.

III. Implementation of TRIPS in National Patent Laws

Many countries in the region did not take advantage of the transition period given by WTO when formulating their national laws on IP to be TRIPS compliant, and did not include all the flexibilities permitted by TRIPS.

One of the reasons for this is that these laws had been formulated before the Doha Declaration in a very difficult international context, at a time when rich countries were pushing hard for a strict interpretation of TRIPS (e.g. proceedings against South Africa and threats of economic sanctions against India and Brazil). Furthermore, the WTO Ministerial Decision of August 30th 2003 concerning the export of generic medicines has not been implemented in national laws.

Two examples of new patent laws show how TRIPS has affected legislation in the region:

1. Egyptian Patent Law 82/2002⁷

In 2002, the Egyptian government repealed the 1949 law on Patents and Industrial Drawings and Designs and replaced it with a new law for the protection of intellectual property rights, namely Law no. 82/2002.

While the new law appears more compliant with WTO standards, there are a number of articles designed to allow flexibility. For example, section 17 allows the Minister of Health to block the registration of a patent if it represents a "health value". The ministerial committee will decide if compensation will be granted to the patent holder, and the amount of any award. These licences may be for public health utility purposes (article 23(1)) or in emergencies or "conditions of utmost necessity" (article 23 (1)). In these circumstances the licences may be granted without any negotiations with the patent holder.

Compulsory licences are also possible in a number of circumstances, including where prices of medicines are high or where medicines are needed for "chronic, incurable or endemic diseases". Article 23 also allows compulsory licences for non-use (which is a situation where the patent is

⁵ Love J.: Access to Medicines an Intellectual Property: The Debate and The Key Players in WTO/TRIPS Agreement an Access to Medicines: Appropriate Policy Responses, Report of the Regional Consultation held in Colombo April 2003, TWN.

⁶ Correa C. M.: Protection of data submitted for the registration of pharmaceuticals. South Perspectives. South Center.

⁷ Sacco S.: Egypt's State Responsibility to Protect the Right to Health after the Implementation of the TRIPS. EIPR.

protected but the goods are not manufactured or sold in Egypt) and anti-competitive practices by the patent holder (such as excessive prices, failure to sell the products in Egypt, discontinuing or reducing production or blocking the transfer of technology).

Article 24 (1) requires that compulsory licences should "basically" provide for local needs, thus not taking advantage of the Ministerial Decision of August 30th 2003, which allows for the export of generic drugs to countries without manufacturing capacity. Also, the Act does not make any reference to parallel imports.

2. Moroccan Patent Law 17/97⁸

In 2000 the Moroccan government, which previously allowed patents on process but not products, promulgated a new law (law 17/97) in order to ensure TRIPS compliance.

The law, which entered into force on December 18th 2004, does not include all flexibilities permitted by the agreement. The law makes provisions for some flexibilities, but these are subject to restrictions. Compulsory licences cannot be delivered during the first 3 years after the patent has been granted or 4 years after the patent request. The Bolar provision, permitting early registration of generic drugs, is not mentioned. Parallel imports are not allowed as Morocco opted for a national system of exhaustion of rights.

There is no mention of the Ministerial Declaration of 30th August 2003 and as in Egypt, compulsory licences can be granted only to supply the national market demands. However Morocco, like Egypt, has production capacity that could supply other countries of the region with good quality affordable generics.

IV. The Mail Box

Both Morocco and Egypt, as well other countries in the region who did not previously allow patents for products such as Tunisia, Kuwait and United Arab Emirates, adopted the mailbox system as recommended by the WTO (art 65.4). By January 1st 2005, the content of these mailboxes was supposed to be made public and the first patents delivered. However, at the time of writing this paper, there is still a lack of information about their content.

In Morocco, more than 800 requests were registered between 1995 and 2005, and the first patents were delivered on December 20th 2004 (just two days after law 17/97 came into force). This prompts the questions of whether the patent office (OMPI) took enough time to study the requests, or whether decisions were made on the basis of patents that already existed in European countries. It is very probable that abusive patents have been granted on products that already exist in generic versions on the local market⁹.

In Tunisia, 800 requests are expected for the mail box, and around 3000 in Egypt. There is an urgent need for studies be conducted in these countries in order to assess the impact of the new patents on access to medicines.

V. The Challenge of Free Trade Agreements

One of the most important challenges faced by countries of the region is how to deal with regional and bilateral trade agreements that insist on the protection of intellectual property without compromising access to cheaper generic drugs.

⁸ Mellouk O.: *Propriété Intellectuelle et Accès aux Médicaments au Maroc*. www.alcsmaroc.org

⁹ Krikorian G. : *Etude sur le contenu de la Mail Box au Maroc*. Etude en cours

In several cases, these trade agreements introduce 'TRIPS+' provisions which go way beyond the WTO TRIPS Agreement, and which countries had rejected during negotiations on that agreement. These provisions also contradict the spirit of the 2001 Doha Declaration on TRIPS and Public Health by placing commercial interests before public health.

For example, Mauritania is obliged to provide intellectual property protection stronger than the minimum fixed by WTO in the framework of the Bangui Agreement. Yet as a least developed country it ought to have until 2016 to implement TRIPS-compliant standards. Other countries are in the process of negotiation with the European Union.

The issue of greatest concern in this area is the recent multiplicity of Free Trade Agreements with the United States of America. Jordan, Morocco and Bahrain have already signed such agreements. Oman and United Arab Emirates are negotiating and will probably sign very soon. Egypt, Qatar and Kuwait will start the negotiations shortly. The wider U.S. goal is to have an overarching regional trade agreement by 2013, and each of the individual bilateral agreements is seen as a step toward that goal.

1. Why are US-FTAs of concern for access to medicines?

In regards to access to medicines, FTAs with the US are of concern at different levels. First, the duration of the negotiations is generally very short when compared with the corresponding process with the EU. They attract little public attention, are often highly technical in nature, and are being negotiated in secret, despite repeated requests from civil society to open them to public debate¹⁰.

The pressure exerted on individual countries is so great that most of them accept high IP standards on medicines as a necessary compromise to achieve gains in other areas. Wider political considerations are also taken into account by governments of the region who wish to pursue improved relations with the United States, especially after September 11th 2001.

It is also necessary to consider the lack of democracy and marginalization of civil society in the region. Governments see civil society as an enemy rather than an ally, and instead of drawing on its potential to strengthen the negotiating power of Arab countries, it is ignored. For example, in Morocco a demonstration organised by the national coalition for access to medication on January 28th 2004 was violently dispersed by the police.

FTAs with the US tend to contain several provisions which delay generic competition and guarantee the pharmaceutical multinationals long monopolies¹¹. These provisions are:

- Rules which effectively turn national drug regulatory authorities into "enforcers" of patents on medicines (patent police)
- New obstacles related to pharmaceutical test data, which will delay the registration of generic medicines ("data exclusivity")
- Extensions of the life span of patents, which will further delay generic competition
- Measures which will allow known substances to be repeatedly patented for each "new use"
- Restrictions on countries' abilities to use compulsory licences as legal tools to ensure access to low-cost medicines.

¹⁰ 10 – Abbott. F.: The cycle of action and reaction: Latest developments and trends in IP and health. UNCTAD Dialogue on Ensuring Policy Options for Affordable Access to Essential Medicines Bellagio, 12-16 Oct. 04

¹¹ MSF: What to Watch Out For In Trade Agreements with the United States. Briefing note MSF May 2004

2. TRIPS+ provisions in the Morocco-US FTA

According to many observers, including representatives of the USTR, the Morocco-US FTA contains "high level" provisions on intellectual property rights which US trade negotiators aim to maintain in other bilateral agreements in the region.

The chapter on intellectual property rights includes many TRIPS+ provisions¹²:

1. "Exclusivity" of undisclosed data

i) A monopoly of 5 years

The FTA imposes exclusive rights on data required for the registration of a medicine that will lead to a marketing monopoly for a minimum of 5 years. The purpose of this type of provision is to set up a monopoly for products which are not patented (e.g. products for which patents that have been rejected) and to block the registration of generics: for example, when a government has decided to bypass patents and issue compulsory licences for government use.

Under FTA rules, the regulatory authorities may no longer register a generic using clinical trial data provided by the brand-name company for the 5 years following marketing approval, unless they obtain the consent of the brand-name company (obtaining such consent is highly unlikely). If the generic producer wants to register a generic version before the end of these 5 years, it must carry out the clinical trials once again which will be costly, take time and be unethical.

ii) New monopoly of 3 years renewable for new clinical information

The Morocco-US agreement includes a new clause (in comparison to other FTAs with the US) concerning rights granted on the basis of new clinical information. Article 15.10.2 opens the possibility of unlimited renewal of exclusive rights by allowing an additional data exclusivity period of three years for new uses for already marketed products.

There is a serious danger that the producers of new clinical information thus might try to block the registration of generics beyond the 5 years of data exclusivity by asserting that there is an overlap with recently approved usages of their products, even though these generics are introduced for old usages. In such cases the legal proceedings necessary to dismiss the claim of a brand-name company may be difficult, costly and time-consuming.

2. Compulsory licences

Using data exclusivity once more, Article 15.10.4 forbids the marketing of generic versions of a patented product during the duration of the patent (except if the patent holder grants authorization, which is illusory, except in the case when a patent holder grants a voluntary licence to another company).

In this case it is no longer for 5 years that a generic version under compulsory licence cannot be marketed, but during the whole duration of the patent. Such a provision invalidates the use of compulsory licences, even in cases of emergency. Thus the exception to patent rights under Article 31 of the TRIPS Agreement becomes totally useless.

¹² Krikorian G.: The US-Morocco Free Trade Agreement: Impact of strengthening intellectual property protection on access to healthcare products in Morocco. Collective for Access to Generic Medicines and Healthcare. Available at : www.alecsmaroc.org

Note 15 indicates that Morocco does not allow applications for marketing approval (this concerns Morocco only) except within the framework of the Bolar provision. There is no mention of exceptions in the case of compulsory licences. It thus seems obvious that for generic products which are locally produced or imported under compulsory licences, applying for marketing approvals is not authorized, even when WIPO claims such provisions will not impede the use of compulsory licences.

3. The extension of patentability to second uses and minor alterations of well-known substances

Article 15.9.2 of the FTA extends the criteria for patentability to already well-known products for second uses (for example, new usages). This establishes very low criteria of patentability which will lead to the granting of questionable and unwarranted patents.

Morocco has given up its rights pursuant to Article 27.3(b) of the TRIPS Agreement, which concerns the possible exclusion of plants and animals from patentable subject matter. It has equally given up the TRIPS flexibility which holds that governments can determine if second medical uses for already well known components are patentable.

4. The extension of the period of patent protection

New extensions under the FTA will allow patents to exceed the previous 20 year term. Patent extensions must be granted to compensate possible delays at the time of patent registration (art 15.9.7). Patent extensions must be granted to compensate the registration delays of pharmaceutical products (article 15.10.3). Nothing in the FTA defines what an 'unjustified lengthening' of the effective protection period is, so the FTA can theoretically extend the patent protection period beyond the 20 years the TRIPS Agreement requires.

At the time of the negotiations of the TRIPS Agreement, the Member States had thought that a 20 year period of protection was sufficient, considering that the registration of patents or the obtaining of marketing approvals implied some delay.

5. Improper patent applications

According to Article 15.9.9 "each party shall provide patent applicants with at least one opportunity to make amendments, corrections, and observations in connection with their applications".

This provision creates an incentive for patent holders to file improper patent applications. Article 15.9.9 forces countries to allow companies applying for patents to amend their patent applications: this represents an incentive to file inadequate patent applications and apply for excessively broad patents.

6. Linkage of patent with marketing approval

Article 15.10.4 of the FTA establishes a link between the granting of a marketing approval and patent protection.

Article 15.10.4 thus requires:

- regulatory authorities to prevent third parties from marketing products (refuse them marketing approval) which are patent-protected.
- regulatory authorities to inform patent holders of the identity of third parties applying for marketing approvals during the patent term.

The FTA somehow forces regulatory authorities to be subject to patent laws. They are thus prevented from granting marketing approvals for generic versions of patented products (locally produced or imported under compulsory licences).

It also forces regulatory authorities to inform the patent holder if a third party applies for a marketing approval and obliges authorities regulating intellectual property to compensate the patent holder with an extension of the patent protection period if there were delays in the registration of the product (Article 15.10.3).

7. Parallel imports

Article 15.9.4 of the FTA forces countries to ban parallel imports of patented products. Yet this right is granted by article 6 of the TRIPS Agreement and reasserted in paragraph 5(d) of the Doha Declaration which states that countries are free to establish their own regimes as regards exhaustion of intellectual property rights.

In the United States, parallel imports of pharmaceutical products is commonly called 'reimportation'. The reimportation of pharmaceutical products is not currently allowed in the US, but legislation is pending to legalize it. There is strong popular support for reimportation and the federal states which want to buy cheaper medicines from Canada are increasingly in favour of it.

8. The revocation of patents

The agreement equally prohibits opposition by a third party while the patent application is being examined. Opposition can be expressed only after the granting of the patent (delays, loss of time). The purpose of this measure is to limit the possibilities of revocation of patents. Cases in which there is no local production, no exploitation of the patent, reasons of public health etc are excluded.

9. The 'Letter of Understanding'

Reacting to the mobilization of civil society in Morocco and in the US (US Congressmen in particular) against the IP provisions of the FTA, a 'letter of understanding' was exchanged between the American trade representative, Robert Zoellick, and a representative of the Moroccan government. The letter is supposed to guarantee that the intellectual property provisions of the FTA would not undermine access to medicines in Morocco.

In fact, because it is not included in the text of the agreement, this letter is in fact subordinate to the terms of the FTA. It has no legal value and cannot constitute any guarantee. Neither does it claim to modify the chapter on intellectual property or to create exceptions to the measures that may impede the promotion of access to medicines.

VI. Counter-Responses

There are many approaches that countries of the region can consider in order to face up to the issue of IP and access to affordable medicines.

TRIPS

The first step is to initiate a debate on the issue at both national and regional level by organizing national/regional workshops on IP, TRIPS and public health. These workshops have already taken place in other regions. WHO and UNDP and some NGOs like TWN (Third World Network) provide assistance to countries in organising such meetings. The workshops can bring together different actors: government representatives from the Ministry of Health, Ministry of Industry or Trade Ministers, Patent Offices, Civil society, NGOs, national pharmaceutical industry, and IP and Public Health international experts.

Their purpose is to facilitate a critical analysis of the national patent laws; to investigate their possible revision; and to help to secure the use of the flexibilities available in TRIPS and affirmed by the Doha Declaration. They can also be an opportunity to discuss possible national and sub-regional strategies, policy options and measures available to adopt safeguard measures for production, import, export, procurement and registration of medicines.

The criteria regarding patentability are a crucial issue. The broader these criteria are, the higher the demand for patents becomes, therefore increasing the possibility of abusive patents. National Patent Offices in the region often do not have the capability to closely examine these patent requests themselves. Generally, they opt to refer to decisions made by Patent Offices in western countries or WIPO, who allow wider criteria. The capacity of patent offices must be strengthened at national or regional level to study such requests. Adopting the strict minimum patentability criteria, as described in the TRIPS Agreement, is the best way to limit the impact of patents on access to medicines and to avoid the practice of abusive patents.

No country has yet used its right to grant compulsory licences, yet we are a long way from ensuring access to medicines to the populations that need them the most. Today, there exist many diseases that warrant the use of such compulsory licences. The epidemic of HIV/AIDS, viral hepatitis, diabetes and cancer are examples of real public health problems that make the issue of access to medicines urgent. The granting of compulsory licenses must become common practice, thereby bringing to light the conflict between IP rights and public health. This will act as a catalyst to reopen the debate on an international level on this question.

Assessment of the implementation of the 'mailbox'

Countries concerned by the 'mailbox' system must be careful while implementing the process, and ask for technical assistance. Exchange of information between countries can avoid abuses of patents requests. Up until now, no impact study has been carried out in these countries to assess the impact of the arrival of the new patents. It will be interesting to implement such studies.

Addressing the FTAs

The strategies adopted thus far to challenge the FTAs have not resulted in influencing the process of negotiations. TRIPS+ provisions could not be avoided even in a country like Morocco, which is the only Arab country where the mobilization of the civil society was significant. It is of paramount importance that regional coalitions be created to resist pressures from US trade representatives. These coalitions must join the global campaign for access to medicines and other regional coalitions that challenge the FTAs (Latin America, SACU etc.).

The US and their bilateral partners are members of the WTO which obliges them to respect their commitments regarding the TRIPS Agreement. In case of conflicts, they can refer to the WTO rules, and therefore there should be no need to include specific chapters on IP in bilateral trade agreements. Furthermore, they have all agreed on the Doha declaration and therefore should not undertake any measure that could be to the detriment of public health. This raises the question of whether IP rights should be excluded from FTAs altogether, or at least where they concern health products.

Impact studies can be carried out before the negotiations and used as arguments to refuse provisions that may undermine access to medicines. TRIPS should be the ceiling in terms of protection of IP in such agreements, and not the minimum requirements.

Research studies on the impact of the FTA on public health can be conducted. Jordan was the first country in the region to sign such an agreement. It is used by US representatives as an example of increasing investment in the region, as a direct result of the high protection of IP. However, no data is available on the impact of the FTA on access to medicines.

Mechanisms like FTA-Watch can be set up in countries that have already signed agreements to monitor the implementation of FTAs, especially during the incorporation of the agreements' provisions into the national laws.

Countries are invited to support and implement regional and institutional declarations and resolutions on international trade and health, and take them into consideration when setting their national policies.