

***The Agreement on TRIPS
and its consequences
on access to essential drugs***

By Anne-Lise Lelong

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In the days following World War II and in parallel to the creation of the International Monetary Fund (IMF) and the World Bank of Reconstruction and Development (WBRD), there arose a will in the international community to give an institutional framework to international trade. Negotiations between 23 countries led to the implementation, in October 1947, of a General Agreement on Tariffs and Trade (GATT). The International Trade Organization, also under negotiation in 1947, was finally not brought to fruition.

The key objective of the GATT was to promote the liberalization of (and competition in) international exchanges by reducing barriers to trade in goods, such as tariffs or quotas on imported and exported goods. Accordingly, the initial agreement was gradually completed by additional agreements adopted during 8 «rounds» of negotiations.

The World Trade Organization (WTO) was established during the last round, the «Uruguay Round» (1986-1994) by the signing, on April 15, 1994, of the Final Act in Marrakesh (Morocco) by 128 countries. Entered into force on January 1, 1995, the WTO now counts 147 members (April 23, 2004 data).

The Act signed in 1994 includes the main agreement establishing the WTO but also other agreements in appendices on various topics such as trade in services and goods, intellectual property, dispute resolution or the monitoring of States' respect of their commitments.

Except for the Agreements on Trade in Civil Aircraft and on Government Procurement, all are «multilateral agreements»: all States willing to join the WTO were obliged to accept them (and, thus, agree to include their rules into their national laws) and the same would apply to those States willing to join the organization in the future.

In particular, this applies to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS): A State's adherence to the WTO's charter makes it compulsory to adhere to the TRIPS agreement: it is not possible to be a WTO member and not to adopt, or to adopt only partially, TRIPS provisions. It is «all or nothing»!

Intellectual property rights, trade marks, geographic indications, industrial drawings and models, patents, integrated circuits diagrams, etc. are, amongst others, areas in which States have defined common standards by signing this agreement. Similarly to the GATT and to the agreement establishing the WTO, the TRIPS agreement introduces the Most Favored Nation and the National Treatment clauses. The Most Favoured Nation clause requires that every WTO member State granting a special commercial benefit to another member State should grant the same benefit to all other members.

The National Treatment clause forbids member countries to discriminate foreign products circulating in their territories in favour of their own national products: for example Switzerland is not allowed to decide that the medicines it produces will be protected by longer lasting patents than imported Italian medicines. As will be described later, it is mainly this appended agreement that has consequences on the pharmaceutical sector.

The Agreement on TRIPS and its consequences on access to essential drugs

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1 Introductory questions

1.1 What is the WTO?

1.2 What is the TRIPS Agreement?

2 The new rules of the game : the TRIPS Agreement

2.1 What was the situation prior to the TRIPS Agreement?

Prior to the signing of international agreements on intellectual property, each State was free to organize the protection of intellectual works on its territory, including in the pharmaceutical sector. Hence, certain countries granted patents only to products while others recognized only the protection of processes. In any case patent protection lasted from 5 to 10 years and only very rarely 20 years. Finally other countries, including most developing countries, had excluded the whole pharmaceutical sector from the scope of application of patents. In these countries manufacturing copies of patented drugs, imports... were fully authorized: no exclusive rights, therefore neither protection for inventors of drugs nor forbidden acts for third parties.

This lack of protection made the manufacturing of drugs at a lower cost possible since in the absence of patent protection, no payment was due either in compensation for the patent use.

Most industrialized countries were already protecting pharmaceutical products and processes by 20 year patents before the TRIPS agreement.

Certain principles of the 1947 GATT were influencing intellectual property, in particular imports and exports. However, until the TRIPS agreement, no international trade agreement had explicitly dealt with intellectual property.

A. Harmonization of national legislations

In pursuance of the TRIPS agreement, all WTO member countries must align their (intellectual property) legislations to mutually agreed minimal standards. This is not some type of incentive or recommendation to comply with the rules but a real obligation for the States.

Indeed State «A» is entitled to lodge a complaint to the WTO Dispute Resolution Body if it considers that the legislation of State «B» is not TRIPS-compliant. State «B» will then be obliged to comply with the Body's ruling or otherwise endure commercial sanctions.

B. Transition periods

Given the large disparity in national legislations, alignment could obviously not be achieved immediately nor at the same pace in all countries.

This is the reason why the agreement provides for transition periods: these are time spans during which States should modify their laws but are not yet in infringement if they fail to respect the provisions of the agreement (during that period).

- industrialized countries: 1 year (until January 1, 1996);
- developing countries or countries in transition towards a market economy: 5 years (until January 1, 2000);
- developing countries lacking patent protection in the pharmaceutical area prior to the TRIPS agreement: 10 years (until January 1, 2005);
- least advanced countries: 11 years (until January 1, 2006).

Let us mention that this transition period was extended until January 1, 2016 by the Doha Declaration adopted in 2001.

The system put in place in 1995 establishes minimum levels of protection that all States are obliged to adopt. These compulsory standard rules are:

- Respect of the Most Favoured Nation clause and of the National Treatment clause, in pursuance of which it is forbidden for one State to grant favours and other opportunities to another State in order to obtain and benefit from patent rights.
- Invention patents should be recognized in all technological fields, including in the pharmaceutical sector. Hence, it is compulsory that pharmaceutical products and processes be susceptible to protection and these should not be excluded from patentability as such.
- Patents must be granted for at least 20 years starting from the application date.

Hence, States are not entitled to grant special protection to medicines: medicines are grouped with usual goods, such as dish washers, cars and other consumer goods, without taking into account their essential, therapeutic and often life saving characteristics. Third parties not authorized by the patent holder will not be allowed to:

- for product patents: manufacture, use, offer for sale, sell or import to that effect the product of interest;
- for process patents: use the process or use, offer for sale, sell or import to that effect at least the product directly obtained by this process.

Patents on processes provide far-reaching monopolies as not only the manner in which a product is manufactured but the product itself is protected by them. If «A» holds a patent on the manufacturing process of a drug x, and if «B» invents a new way to manufacture x, «B» will not be able to manufacture product x without asking the permission from «A» (and «B» will have to pay for it). Let us mention that this provision greatly extends the protection normally conferred by patents on processes, which should not prohibit manufacturing a product by a new process. Hence, process patents grant the same level of protection as product patents. Indeed in both cases payment is due to the holder for manufacturing finished products.

However, considerable freedom is left to States as to the implementation of the minimum levels of protection. They can therefore adopt laws which guarantee a balance between international intellectual property rules and public interest. In particular, it is up to them to define in their legislation what an invention is, what innovation means and industrial applications (conditions for patentability). Article 27 of the TRIPS agreement also states that certain inventions may be excluded from patentability, namely those which should not be marketed «to protect public order or morality, including to protect human, animal or plant life or health»: for example, a State could refuse to grant patents for essential or vital medicines or for antiretroviral drugs but, to date, such a legislation has never been adopted.

On the other hand, States are free to establish regulations that are more protective than the standards defined in the TRIPS agreement.

2.2 What are the States' new obligations imposed by the TRIPS Agreement in terms of patent?

2.3 Why is patent recognition necessary?

On one hand, recognition of their creative work and payment gotten out of their commercial monopoly are supposed to encourage the creators of patented inventions and, therefore, stimulate research. Hence, patents promote innovation (by offering a reward to inventiveness) which, in turn, is supposed to have a beneficial impact on the quality of human life (at least for those who have access to this technical or medical progress).

On the other hand, in return for the protection granted to the patent holder, the latter has to «disclose» its invention, that is to say to describe it in an official document (the patent application). This description has to be clear and precise enough for a professional in the field to be able to reproduce the invention based on these indications. Hence, the technical knowledge base is enriched on an ongoing basis with information on every new patented invention. Future inventors will be able to draw inspiration from this knowledge base for their creations. Trade secrets (manufacturing secrets, industrial secrets...) lack this advantage.

Insofar as nothing is revealed on the invention itself, trade secrets hinder technical progress and do not contribute to increase the global level of inventiveness. The Coca-Cola company, for example, did not patent the recipe of its famous drink so as not to have to disclose all the ingredients used. Its recipe is protected by secret and is therefore protected from exact copies: it has not been released into public domain at the end of a 20 year protection period. As Coca Cola was created at the end of the XIXth century, anyone would have been able to market "genuine" Coca Cola for more than a century now!

Finally, Research and Development in the medical area is very expensive: very large numbers of molecules must be tested before a single of them turns out to be really relevant for the therapeutic effect of interest. Then, the road up to the final arrival of the drug on the market is still very long. Hence, pharmaceutical companies take out patents on the medicines they are developing in order to make sure that they get a return on investment thanks to the commercialization licences which they will be able to grant.

The generalization of patents in the pharmaceutical sector, brought about by the signing of the TRIPS agreement, allows a better protection of the laboratories and industries designing them. Before international harmonization, pharmaceutical companies with limited financial resources were nevertheless able to meet the majority of population health needs thanks to copies of original medicines or the development of new processes.

As the TRIPS agreement reduces these opportunities, one has to worry about what happens to the quality of access to medicines and health care, in particular in developing countries.

In spite of the agreement the overall population health status should not suffer from these new provisions and lives should not be sacrificed for the benefit of intellectual property rights. For this reason, and as is acknowledged in the agreement itself, public health objectives can be opposed to patent rights.

3 The enemy of patents: public health

The right to health has long been considered as one of the fundamental human rights. Already in 1946, WHO wrote down in its constitution that: «The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition».

In 1948 the Universal Declaration of Human Rights stated that: «Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other cases of loss of means of subsistence in circumstances beyond his control».

Since then a number of other international treaties and resolutions have reaffirmed this essential right to access to treatments and health care.

Public health covers all actions and recommendations relating to the protection of citizens' health at a regional or country level and relying on the community. Hence State authorities must endeavor to guarantee a good overall community health status through the implementation of preventive and repressive laws. That may include, amongst others, the implementation of screening rules, the determination of prevention and treatment methods, vaccination campaigns or the adoption of such concepts as the one of *essential medicines*.

On this concept WHO has based, since 1975, its pharmaceutical strategy: essential medicines are, according to the then Director General, «those which are of prime, fundamental importance and which are indispensable to satisfy the population health needs». Because of the pressing needs of these populations, emphasis should be put on the supply and distribution of these medicines. Each State should select the medicines which it deems most important and urgent in view of priority health problems affecting particularly its inhabitants: most States thus establish a national list of essential medicines and refer to clinical instructions to define their health policy.

Essential medicines are selected according to some principles and criteria:

- Identification of the major diseases affecting the country (epidemiological overview based on population monitoring and surveys);
- definition of all the medicines used against these diseases;
- Based on this preliminary list, selection of essential medicines: Several criteria are reviewed for a qualification as such:
 - a) Public authorities are certain of the effectiveness and harmlessness of the medicine;
 - b) the medicine demonstrates a good «total cost/effective treatment» ratio;
 - c) it is available in a form, the quality and stability of which may

3.1 What is public health?

3.2 What is an essential medicine?

3.3 How are essential medicines selected?

3.4 What is the use of the lists of essential medicines?

4 Economic consequences of the TRIPS Agreement

4.1 Obstacle to free competition

be guaranteed (in particular in view of expected storage and usage conditions).

The final lists must be regularly updated by the States in order to take into account therapeutic progress, changes in the epidemiological status, cost of medicines... Since 1997 WHO has been publishing every two years a model list of essential medicines.

They constitute a basis for governments on which to orientate their health policy towards a better access to essential medicines. In setting priorities they allow aid to be focused on a broader availability of these medicines at all times and for all inhabitants, which include, in particular, regular supplies and appropriate information. The procurement and distribution of medicines in the public sector, the selection of health insurance reimbursements, the management of donations and of international aid as well as the organization of local production capacities are thus facilitated by the existence of such a guide.

These lists are also widely disseminated in the country health care facilities as well as to all physicians and pharmacists of the public and private sectors. The objective is improved information of all, both professionals and users. Finally they serve as a basis for teaching public health and the rational use of medicines to students and professionals in continuing education.

This agreement requires that States grant patents on medicines and their manufacturing processes. The existence of a patent provides its holder with an operating monopoly on the drug in question. The «owner» is then the only one to decide who is entitled to produce its drug, commercialize it, import it, ... and under which conditions, in particular pricing policies.

There is a concern that the holder is then (legally) entitled to keep for himself all the market shares he desires or even the whole market:

- either by requesting excessively high financial compensations for licences, so that no partner would be in a position to afford one;
- or by deliberately not granting any licence.

As the unique supply source, the holder will not suffer from any competition and nothing will prevent him from setting the sales price that suits him for his drug. Patents therefore constitute a real danger for the access to medicines: even if manufacturers have no interest in setting too high prices if they want to reach as many customers as possible, most prices will remain largely unaffordable to the populations of developing countries.

A. What is the difference between patented drugs and generic drugs?

Original drugs are patented and sold under brand names by pharmaceutical companies. The term «generic» is used in opposition to this term «patented». Indeed, generic drugs are manufactured from molecules released into public domain at the end of the legal duration of the patent that protected them. A generic drug is the exact replica (copy) of a drug initially patented, which may be freely manufactured by anyone given that the monopoly has expired. For example, Brazil has been granting patent protection to pharmaceutical products only since 1996. Prior to this date, molecules patented in other countries could not be patented in Brazil (because the country did not grant protection to drug inventors). This means that in the past Brazil was free to produce generic medicines from these unpatented molecules. Similarly, aspirin, which has not been under patent for a long time, may be produced by all the industries that wish to do so. However the term «generic» is often used erroneously. For example, in the context of the parallel imports authorized by the TRIPS agreement, imported drugs do not have to be generics: this may be the case if the drug is no longer patented in the exporting country (import is therefore of interest because prices will be lower), but they may very well be original drugs sold at a lesser price in this country. Similarly the use of the term «generic» in the context of compulsory licences is not appropriate: the confusion is easy to make because these drugs are copies of original drugs (manufactured under compulsory licences) but they are not generics because, by definition, the patent has not yet expired.

B. Why are generic drugs manufactured?

When a patent has expired, the former holder is not allowed anymore to prevent certain actions of third parties: molecules and basic active principles are free of rights:

- anyone can arbitrarily decide to manufacture and/or market them;
- the former holder is not entitled anymore to obtain a financial compensation for the exploitation of his molecule.

Hence, in essence, a copy is less expensive than the copied material, which constitutes a significant advantage for developing countries. This is actually the reason why most of these countries had not implemented the patentability of pharmaceutical products and processes before the implementation of the TRIPS agreement.

In addition manufacturing generic drugs requires preliminary research to determine the composition, dosage... of the patented drug: this is what is called reverse engineering. This practice, often used in developing countries, enabled them to maintain a research capacity and, hence, to contribute to the ongoing development of their researchers' knowledge as well as to the maintenance of research laboratories and local production units.

C. What does the ban imposed by the TRIPS agreement consist of?

As we have seen, many developing countries used to grant only patents on processes, which allowed them to produce copies of drugs legally, something

4.2 Ban on the production of copies of drugs

4.3 Production cluster in industrialized countries

that is not possible with patents on products. Copies will no longer be authorized in any WTO member country from the moment the agreement is in force, because they would be violating the monopoly of recent patent holders. The only available medicines will be the ones manufactured and marketed by the latter or by third parties to whom licences have been granted. However, generic production will be legal again once a patent has expired, after 20 years. Nevertheless and considering the recent progress in terms of HIV/AIDS treatment, this global ban is highly deplorable: new therapies, protected by patents, will not be available as generics before many years. Until then millions of infected individuals will have died because they were not able to afford patented medicines.

The pharmaceutical sector of developing countries consists mostly of small, local production units of generic medicines and of underdeveloped Research and Development capacities by lack of financial resources. As the production of copies of patented drugs will be banned once the TRIPS agreement has come into force, developing countries will have to give up this already weak production capital.

On the other hand it is unlikely that they will be in a position to purchase licences from pharmaceutical companies. Since infrastructures are often inappropriate for large scale drug production and manpower is poorly qualified, the upgrading of pre-existing industries seems to be unachievable considering, once more, available resources in these countries. The use of new technologies in recent manufacturing processes will only increase the gap.

As a consequence developing countries will be increasingly dependent on industrialized countries: their drug production down to nothing, they will have to obtain all their supplies from exporting countries, at the prices that these will be willing to consent.

5 TRIPS flexibilities: possible exceptions from patents

The TRIPS agreement provides that exceptions from the monopoly conferred by a patent may be included in national legislations. These exceptions should, of course, remain limited, be explained and justified and they should not unreasonably prejudice the legitimate interests of the patent holder (article 30). States are free to adopt them or not.

A. The granting of compulsory licences

1) What is a compulsory licence?

A licence is a contract by which the patent holder authorizes a third party to carry out one or several actions which are normally forbidden because they violate his monopoly.

If company «A» holds a patent on drug x, it is entitled to grant a licence

to company «B» authorizing it, for example, to market drug x. The (licence) contract between «A» and «B» defines the conditions under which «B» is authorized to market x. Without this contract, «B» would be making an act of counterfeiting if it decided to sell drug x.

A *compulsory licence* is the authorization granted by public authorities to a third party to use or market a patented invention without the holder's agreement. It is indeed a licence as it is aimed at the (total or partial) licensing of an operating right, however, it is compulsory given that it has not been consented by the patent holder who is compelled to grant it. Even so, the owner receives a financial compensation.

2) What are the circumstances in which such licences may be granted?

States are free to define the reasons justifying the use of these exemptions. The agreement states a certain number of them but the list is not limitative:

- The refusal to negotiate (or to attempt to obtain a voluntary licence): when the holder is not willing to grant a licence with reasonable commercial conditions and that, for example, this makes the procurement of a drug impossible;
- a national emergency situation or other extremely urgent circumstances or a non commercial public utilisation of a drug: when there is an imminent threat to public health, following a natural disaster, a war or an epidemic, for example;
- government use (or authorized third parties): for example in order to secure a fair access to health care and medicines to those most in need;
- anti-competitive practices: in particular, artificial price increases or other abuses of dominant position by the holder;
- the lack or insufficient use of an invention.

B. Exhaustion of rights mechanism

1) What is the exhaustion of rights?

In principle, as for any other commercial practice, the import of a patented product requires prior authorization from the patent holder. This act is part of his monopoly.

However, the law may partially exhaust this right by the so called «exhaustion of rights» mechanism. When recognized by States, this legal theory which has as a consequence that the holder is not entitled anymore to control the movement of his product after it has first been put into the market, be it made either by himself or agreed by him. He is neither entitled to oppose its import in other countries, nor to obtain payment for such use.

Let us assume that a drug x is patented in both country «A» and «B» (both of them recognizing the exhaustion of rights). Company «C1» located

5.2 Exceptional use of products

in country «A» holds a patent on drug x and decides to market it in State «A». Thanks to the exhaustion of rights, company «C2» located in country «B» is free to import drug x from «A» and to resell it in State «B», without the authorization of «C1». This constitutes a parallel import.

This mechanism is justified by the fact that since the patent holder has already been rewarded once for putting his product into the market, he is not entitled anymore to control what happens to his product.

2) Consequences of parallel imports

The advantage arising from this exception is that it hinders patent holders' discriminatory practices in terms of pricing: as the product may be available on all national markets, buyers will get their supplies from the market offering the product at the best price worldwide. This decrease in price has favorable consequences, in particular in terms of health care: drug imports from countries providing the lowest prices lead to an improved access to these medicines for the patients of importing countries.

However, since pharmaceutical companies generally grant lower prices to developing countries, one may fear that they will stop these preferential practices to avoid seeing a significant drop in their revenues from importing countries. A standardization of prices agreed with all partners would follow, which would be very much against their interests.

In principle and as has been seen before, a patented medicine cannot be commercialized without the holder's authorization: a third party is not free to use the product, for any purpose whatsoever.

However, States can implement exceptions as long they are not unreasonable in view of the holder's exclusive rights: for example, the exception of acts accomplished in private and for non-commercial uses or in cases of unit drug preparations by a pharmacist and on prescription by a physician.

One of the most interesting exception is the so called «Bolar» clause.

A. The «Bolar» exception

By way of this exception the law authorizes generic drug manufacturers to carry out clinical trials on a patented drug without the holder's authorization and that prior to the 20 year protection expiry.

This anticipated use allows them to create the generic drug corresponding to the patented drug and, hence, to organize its manufacturing and marketing as soon as the patented product is released into the public domain.

The fast market entry of generic versions, once patents have expired, leads to a competition between different products: drug prices decrease which improves patients' access to these treatments.

The Agreement on TRIPS allows the countries to bypass the intellectual property rights if the health situation of a country demands it.

This is what Thailand tried to do in 1998: because of the large number of deaths due to an AIDS related sickness, it organized the production of a generic drug capable of treating it. But the United States, influenced by Pfizer (the pharmaceutical firm holding the copyright on the original drug) forbade the commercialisation of this drug, by threatening to tax the Thai most important exports (wood, jewels, microprocessors...) if they did not abandon the production of this generic drug.

South Africa too suffered from the pressure of pharmaceutical firms. In 1997, for instance, it tried to fight the AIDS epidemics hurting its population by passing a law that made use of the flexibility of the Agreement on TRIPS, that could have allowed for the import of generic drugs. But the implementation of that law was blocked (February 1998) by a judiciary action, undertaken by 39 world pharmaceutical firms (among which Boehringer Ingelheim, Bristol-Myers Squibb, Glaxo Wellcome, Merck and Roche). They denounced, as a matter of fact, South Africa for the alleged violation of its international commitments on intellectual property rights; the Pretoria High Court started the hearings on March the 21st, 2001. However, the international pressure forced the 39 firms, on April the 19th, to abandon their charges. Nowadays, generic versions of antiretrovirals are imported from Brazil, but the South Africa situation is far from being solved.

Confronted with the numerous difficulties created by pharmaceutical firms, the international community found it necessary to clarify which were the countries' rights with respect to intellectual property rights.

In November 2001 the WTO member countries adopted a Declaration in Doha (Qatar) on the Agreement on TRIPS and public health. This declaration was meant to answer the preoccupations that had been expressed, on how that accord could have made the access to certain drugs more difficult for patients from poor countries. It constituted a real victory for the developing countries that had expressed those preoccupations, as it strongly advocated an efficient use of the flexibility of the Agreement on TRIPS for what regards the bypassing the intellectual property rights on drugs.

As a matter of fact the international community recognized that, while the obligations defined by the Agreement on TRIPS had surely to be implemented into the ensemble of national laws, they should never compel countries to work against the objectives and priorities that they have defined on public health and drug access. Therefore, a country could authorize the violation of some intellectual property rights in special circumstances, defined autonomously and related to public health (for instance, in case of national emergencies or other situations of extreme need).

The Doha Declaration therefore affirms that public health has precedence over intellectual property rights, and besides encourages the different countries to make use of this disposition.

6 Prospects

6.1 Remainder: the difficult implementation of the Agreement on TRIPS

6.2 What is the position of the international community with respect to drug access?

6.3 The after-Doha: can a country import drugs, when it is unable to produce them under a compulsory licence?

In November 2001 the WTO member countries had agreed, in their Declaration on the Agreement on TRIPS and public health, that the problems of public health and drug access should have precedence over intellectual property rights. However a subsidiary question was left open. The principle of compulsory licences was certainly confirmed: this principle allows countries in need to organize the production of drugs needed, in particular in case of health emergencies. But the agreement limits this right to the needs of the national market: drugs produced under a compulsory licence should not be exported to another country. Hence the following difficulty crops up: how could countries unable to produce their own generic copies satisfy their needs if they cannot import the drugs? As a matter of fact those countries are just the very countries which need cheap drugs the most.

The problem is two-fold: there will be countries that have a strong need for drugs, but cannot produce them for lack of materials, suitable industrial compounds and financial funds; and there will be other countries which, on the contrary, possess those instruments but cannot produce the drugs for lack of a large enough internal market. Supply and demand cannot match in such national markets, but calls for the two national markets to join, so that people in need could have access to some essential drugs.

This question should have been solved before the end of 2002 by the WTO member countries. A compromise draft agreement (called «de Motta») was prepared under the control of rich countries – the United States and the European Community – and accepted by developing countries under strong pressure. But it was a text largely against their own interests, as it contained a reinforcement of administrative procedures, limitation of the compulsory licences to certain listed diseases, exclusion of all vaccines and other sanitary hardware other than drugs from the licences. Anyway the United States refusal to abandon the establishment of a 'diseases' list' led later on to the abandonment of the text; finally no international agreement was reached.

An agreement was indeed reached on August the 30th, 2003. It recognized the right of member countries to import compulsory licensed drugs, should they be unable to produce them; but at the same time it was inadequate to the needs of developing countries. It even reduced the rights acquired under the Doha Conference agreement, by establishing, for instance, the need of simultaneous licensing of the exporting and the importing countries, by introducing constraining procedures, by allowing for possible opposition from other countries when a compulsory licence was implemented, and so on.

The Cancun Summit that followed the above mentioned agreement (September 10th to 14th), during which problems other than drug access were also discussed, did not produce any new agreement either; it should have constituted a mid-term assessment of the Doha Agenda, but in the end the commercial negotiations were interrupted.

Therefore, at present we can really doubt the efficiency of negotiations at the international level, in particular for the developing countries which, when unable to resist the pressure from the rich countries, are forced to accept agreements that go against their own interests.

Now a new tendency can be noticed. Since 2002, the United States and the European Community have preferred the signing of bilateral conventions with developing countries. These free-trade agreements allow rich countries to obtain, from developing countries, concessions that they would be unable to obtain through WTO negotiations. They can offer more enticing promises, and thus obtain that developing countries abandon their rights on the limitation of intellectual property rights.

A free-trade zone is an area composed of several countries, inside which quotas and other custom duties are eliminated. Trade among those countries is therefore totally free, with no obstacle to the free circulation of goods, services, capital and persons.

These agreements provide some new opportunities to developing countries, but, however, are an instrument for rich countries which can ask poor countries to adopt complementary measures that are favourable to the former, in particular for what regards intellectual property rights. As a matter of fact these agreements cover many various fields, but always contain a section on property rights. Against the promise of trade opportunities rich countries obtain from poor ones changes in their laws that make intellectual property rights even more constraining than those implied in the Agreement on TRIPS: protection periods extended to more than 20 years, protection of data relative to the experimental phases... (this last point cancelling the possibility of asking for a compulsory licence, as the local production units will be unable to copy a drug as they cannot be informed on the production techniques of the original one).

At present the United States are negotiating with several countries (from Central and South America: Chile, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua; from the South of Africa: Botswana, Lesotho, Namibia, South Africa, Swaziland; from the South of Asia: Singapore, Thailand; and others); several bilateral agreements have already been signed.

As an example the free-trade agreements between the United States and Morocco, signed March 2nd, 2004, after more than a year of negotiations; this agreement largely restraints the possibilities for Morocco to ask for compulsory licences. Morocco was thinking of organizing a compulsory health insurance in order to optimise drug access and health care. Now it has to lower its objectives, and its national pharmaceutical industry, which at present second among the African countries, is expected to decline rapidly.

6.4 After Cancun: bilateral agreements