DEVELOPMENT AND HEALTH IN POOR COUNTRIES :

ROLE OF INTERNATIONAL ORGANIZATIONS AND OF SWITZERLAND

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And also by:
CETIM, Geneva (Julie Duchatel and Florian Rochat)
The Swiss Federal Institute for Intellectual Property – IPI, Bern
(Benny Müller, Claudia Mund, Mathias Schaeli, Simon Schmid)
The Swiss Mission attached to the United Nations, Geneva (Jacques Derron, Sabrina Musumeci)
The WIPO Secretariat, Geneva.

As well as by:
The United Nations Library, Geneva, and the WHO Library which enabled us to use regularly their facilities.

This publication was supported by the Fédération Genevoise de Coopération (FGC), which we wish to thank here.

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Published with the support of :
the City of Geneva,
through the Fédération Genevoise de Coopération (FGC)

FOREWORD

In 1994 the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) [1] was signed within the framework of the World Trade Organization (WTO) and forced its member States to re-examine their laws about granting patents and to reinforce their control measures over the respect of intellectual property (IP) rights.

Subsequently applying the Agreement would have very negative effects on the possibilities for poor countries [2] to have access to the most recent essential medicines. Indeed the Agreement has expanded the patent system to the field of pharmaceutical products; the use and production of many recent medicines have been submitted to the authorization of related patent holders and to the payment of corresponding royalties; the few derogations granted to poor countries have been of a difficult access and often only temporary.

The Centrale sanitaire suisse romande (CSSR) has been concerned with the consequences that the Agreement, imposed on poor countries, might have on public health, in particular on the least favoured populations which depend upon the subsidies for the distribution of essential medicines by their health system. In a recent publication [3] we explored the Agreement's impact and the main parties involved and tried to make more understandable some of its derogations and flexibilities; thus our wish was to provide health workers and non governmental organizations (NGOs) of poor countries with a tool for action.

1. The TRIPS Agreement (1994) is quoted as the Agreement in the present publication.

2. In the text we shall use the rather vague and not binding expression of Developing Countries (DCs) for all non–industrialised countries. We are aware of the ambiguities of this concept which puts into the same basket countries such as India and Brazil, for example, as well as Uganda and other countries which are not considered as emerging; in reality the expression « poor countries » describes better the real situation but it is not commonly used by the international community.

3. CSSR (2006).

This present work aims at broadening the first study in view of better understanding three fields which seem to us essential with respect to the problem of a facilitated access to medicines:

1. the ambiguous position of intellectual property (IP) rights in the more general framework of human rights;
2. the mechanism which enabled the progressive shift of global agreements negotiated at WTO to bilateral or multilateral agreements negotiated outside WTO;
3. the role of the main parties involved in the protection of IP, in particular WTO, the World Intellectual Property Organization (WIPO), the International Union for the Protection of New Varieties of Plants (UPOV) and the World Health Organization (WHO), as well as the actions of NGOs active in the field of human rights.

The relations between these three fields will have to be looked into and subsequently the role of Switzerland will have to be made explicit by examining the positions of its representatives in the international organizations concerned.

This work is divided into two parts:

The first part is composed of six chapters which deal separately with:

- the positions and actions of the international organizations which are the subject of this study (WTO, WIPO and its twin UPOV, WHO) and their internal tensions (Chapters 1 to 4);
- the problems related to the free trade treaties signed (or under discussion) between Switzerland and/or EFTA[4] or DCs (Chapter 5);
- the positions and initiatives taken by a certain number of NGOs active in the field of human rights

4. The European Free Trade Association (EFTA) regroups Iceland, Liechtenstein, Norway and Switzerland.

in a globalized world more and more submitted to the defence of IP rights (Chapter 6).

The second part is centred on the positions and decisions taken by the Swiss delegates during the ongoing debates in the international organizations when discussing problems related to the Agreement's respect, to the development in the least favoured countries and to the negotiations of free trade treaties.

In appendix there is a text of Germán Velásquez [5] the title of which is « Access to medicines : between WTO's trade rules and WHO's public health recommendations ».

5. German Velásquez is the former Director in charge of public health, innovation and intellectual property at WHO.

SUMMARY

FIRST PART

PARTIES INVOLVED

INTRODUCTION

INTELLECTUAL PROPERTY RIGHTS AND HUMAN RIGHTS

The generalised patents system foreseen by the TRIPS Agreement and the intense monitoring of the respect of intellectual property rights (IP) [1] are genrally coherent with a narrow economic and commercial vision. But even if these IP rights are not generally contested by poor countries they frequently come into conflict with other rights, which concern billions of human beings and should weigh more heavily in the strategic choices for social development.

Any analysis of intellectual property rights [2] must take place in the larger context of human rights. The tendency to give IP rights the same status as that of human rights bases its justification on Article 17 of the Universal Declaration of Human Rights:

« 1. Everyone has the right to own property alone as well as in association with others. 2. No one shall be arbitrarily deprived of his property [3] ».

However this justification seems specious to us and including intellectual property rights in the concept of *right to own property* mentioned in Article 17 somewhat arbitrary.

In the recent literature at least three rights are recognized as human rights:

1. This supervision is entrusted to WTO (see Chapter 1), to WIPO and to UPOV (see Chapters 2 and 3).

2. A reflection on this link, not always transparent and without mental reservation, between IP and human rights can be found in Yu (2007); this work analyses in particular the relevant resolutions of the United Nations: Intellectual property rights and human rights, Subcommission on human rights: Res. 200/7, U.N. Doc. E/CN.4/Sub.2/RES/2000/7; Committee on Economic, Social and Cultural Rights (CESCR): Statement on intellectual property and human rights, November 2001.

3. DUDH (1948), art. 17; a philosophy of intellectual property is presented in Drahos (1996); the hegemony of knowledge that intellectual property generates is discussed in detail in Drahos et al. (2004).

– the right to health;
– the right to education and information;
– the right to development.

Putting IP rights among human rights has been contested since they come into conflict with the above-mentioned rights. Indeed human rights are universal and inalienable rights whereas IP rights are only granted to some individuals, institutions or economic entities [4]. Putting human rights and IP rights at the same level means wanting to ignore what Drahos and Braithwaite define as the hegemony of knowledge [5].

The right to health comes inevitably in conflict with the patents on pharmaceutical products which block the transition of a new medicine to the status of generic medicine. Indeed a generic can be produced and commercialised cheaply because it is not submitted to the payment of royalties and can thus be distributed on a large scale via the the public health systems of poor countries [6]. But treat medicines and health like any other goods is the epitome of the capitalist market; demanding the respect of IP rights in this field will inevitably increase the final cost of medicines and health.

As remarked by Yu « the increased protection of intellectual property does not only make the access to information, to knowledge and to basic medicine in the world more difficult, but it has also made economic difficulties and culture worse in indigenous communities. According to those who criticize this tendency and try to oppose it it would be undesirable to raise the status of all forms and characteristics of IP rights to the status of that of human rights » [7]. Knowledge which is often presented as a progress for mankind becomes in fact a source of power control.

The right to education and information can come into conflict with patents on paedagogic, literary and

4. See in particular, 3D (2005a), (2005c), (2006a), (2008a), 2008b), (2009); CIEL (2007).

5. Drahos (1996); Drahos et al. (2003).

6. See CSSR (2006), p. 46 ss.

7. Yu (2007), p. 4.

scientific production and on the means of knowledge reproduction and distribution.

The right to development is perhaps more difficult to outline. Indeed this is where the most frequent tensions arise inside the international organizations between industrialised countries and those which are often euphemistically referred to as developing countries (DCs)[8]. But the sources of contradiction are not only found between rich and poor countries: indeed inside DCs antagonistic class interests can create splits among the global integration wishes of their ruling classes and the claims of the least favoured classes; and often the ruling classes in poor countries base their growth strategy on an accelerated integration to the global economic order. So inside a DC different development models can fight each other because of antagonistic social categories.

BILATERAL AND MULTILATERAL AGREEMENTS

From the agreement application difficulties to arrive at a general and homogeneous understanding on trade and services for all Member States (Doha[9] round) have spawned a motley of bilateral and multilateral agreements (we shall come back to that in Chapter 5) between industrialised countries and DCs; these agreements often stipulate more restrictive dispositions than those of the Agreement.

This shift of wishing to control globally the commercial and financial system towards ad hoc bilateral relations governed by free trade agreements presents several dangers, in particular when one of the parties exerts a dominant strategic role enabling it to impose restrictive clauses to the weaker party (in exchange for possible minor and often political concessions which benefit the ruling classes of poor countries). Certain dispositions, commonly referred to as TRIPS-plus, imposed in these bilateral free trade agreements – in particular

8. For simplicity's sake from now on all the developing countries (DCs) and the least advanced countries (LECs) in the official statistics as well will be referred to as DCs.

9. See Chapter 1.

when one of the parties is an industrial country (like Switzerland) and the other one a poor country – , call for a reinforcement of IP rights and can thus have deleterious effects on a facilitated access to medicines and the production of generics (Chapter 5).

ROLE OF THE MAIN PARTIES INVOLVED

These parties (WTO, WIPO, UPOV, WHO)[10] in the arena where initiatives develop and which have an incidence on access to medicines in poor countries cannot be considered separately; a certain effort must be put into understanding and presenting the relations (often conflicting even if diplomatically obfuscated for non-experts) which they cultivate and which often determine their decisions.

In this first part we wish to underline the internal contradictions of the different international organizations involved in the discussions and decisions on IP, and the tensions among them and the relative weight carried by pressure groups as well.

International organizations (IO's) can be *vipers' nests* even if accounts are settled more or less discreetly in the arcanes of diplomatic language. Thus these tensions crop up in internal discussions inside IO's and in discussions among several of them as well. In the civil society of many countries these discussions triggered a variety of positions and actions.

In this work mainly orientated to access to medicines we shall also examine some aspects which, apparently without a direct relation with this problem, still play an indirect and important role. An attempt will be made to define and present them in a critical way:

– the progressive drift in the definition of *patentability of living species* from an *essentially biological* criterion, and thus not patentable, to a criterion *resorting*

10. Recently a new actor came out into the open, the World Customs Organization (WCO), which started or at least participated in the incredible serial of arbitrary seizures of generic medicines in several harbours of Europe (see DB (2009c) and Chapter 1).

to biotechnologies, and thus patentable. Such a drift presents not only a severe potential danger for agricultural practice[11] but has also a parallel effect on biological piracy and thus on the control of many traditional medicines (Chapter 3);

- the ambiguities of WHO in the fight against counterfeit medicines: on one hand a positive aspect which is the defence of the quality and efficacy of medicines which are distributed in poor countries, through uncontrollable dealers; on the other hand a negative aspect which is the collusion with WIPO and the IMPACT *global coalition*, which amalgamates the problem of counterfeiting with the harsh defence of IP rights (Chapter 4);
- the progressive weakening of WHO, facing the increasing power of other UN bodies (devoted to particular diseases) and private institutions (distributing medicines and providing medical care on the basis of profitability and marketing); if one remembers that WHO is the only international organization which defines and updates the (regional) lists of essential medicines one perceives the danger of this weakening which seems to be programmed (Chapter 4).

11. « Ten corporations, among which Monsanto (USA), DuPont/Pioneer (USA), Syngenta (Switzerland) and Group Limagrain (France) control half the world trade of seeds. » Deere (2009), p. 28.

CHAPTER 1

WORLD TRADE ORGANIZATION [1] (WTO)

ITS PARAMOUNT ROLE IN THE ESTABLISHMENT OF A UNIVERSAL LEGAL SYSTEM OF INTELLECTUAL PROPERTY

On the 1st January 1955 the WTO was established in Geneva to succeed the former GATT (General Agreement on Trade and Tariffs). The WTO has the mandate to regulate the trade liberalization the world over.

The WTO is not a specialised UN agency, contrary to various other international organizations such as the World Intellectual Property Organization (WIPO) or the United Nations Conference on Trade and Development (UNCTAD).

The WTO looks after 29 agreements and is based on the following principles [2; 3]

Liberalization/suppression of obstacles to trade. A distinction is made between the tariff obstacles (customs duty) and the non-tariff ones (quotas, import and export licences, subsidies and safety prescriptions, protection of the environment and consumers health). Before the WTO was created negotiations related primarily to customs duty whereas afterwards they concentrated on non-tariff obstacles.

1. Contact details and further information: p. 205.

2. *www.seco.admin.ch/themen/00513/00514/index.html?lang=en.*

3. *www.wto.org./english/thewto_e/whatis_e/tif_e/fact2_e.htm.*

Reciprocity. The concessions granted on a mutual basis must be equivalent and balanced. In this respect the developing countries benefit from a more or less long delay for adaptation, a greater flexibility and particular privileges. Every WTO member state commits itself to abide by the general conditions deriving from the multilateral trade negotiations, as for example to apply a customs duty expressed in percentage to imported goods. These liberalizations agreed within WTO cannot be revoked.

The **non-discrimination** consists of two points:

1. the clause of the most favoured nation (MFN): On the basis of the WTO Agreements the countries cannot in principle introduce a discrimination between their trade partners. If you grant a special favour to someone (e.g. lowering the customs duty levied on one of his products) you have to do it for all the other WTO members (at present numbering 153).
2. the national treatment: an item, a service or an intellectual property right must be treated in the same way as their national equivalent.

Foresee ability and transparency of access to markets. Commercial practices must be foreseeable and cannot be arbitrary: investment societies and foreign governments should be assured that obstacles to trade (customs duty and non-tariff obstacles) will not be applied arbitrarily. The only regulatory commercial measures accepted are customs duty. In principle import quotas are forbidden. At WTO it is thought that tariff measures are more transparent than those applied to the quantities of goods. Tariff reductions decided during the round of negotiations are inscribed in the lists of commitments.

A will of transparency calls for trade regulations of countries to be as clear and publicly accessible as possible. A large number of WTO Agreements demand that governments publish in their country or notify the WTO the practical measures adopted.

Mutual examination of trade policies at regular intervals promotes transparency.

WTO gave itself a Dispute Settlement Body (DSB) which administers the disagreements when one or several member countries are accused of not abiding by the WTO rules.

As is underlined in a report by Global Health Watch, several WTO agreements have an important impact on the couple globalization-public health [4]. The TRIPS Agreement [5], which was the central theme of our last publication [6], is the first international treaty making compulsory the privatization of biodiversity, and consequently establishes an international trade principle. It states that all WTO members must guarantee and apply the intellectual property rights on living matter (see Chap. 2). Patents have a minimal life time of 20 years. This situation causes a net disadvantage to developing countries which hold fewer patents than industrialised countries. Rich countries put the Agreement into force as from 2000; extensions until 2016 were obtained by the poorest countries for putting this Agreement into practice.

Why is the TRIPS Agreement administered by WTO and not by the World Intellectual Property Organization (WIPO)? Before this Agreement a large number of countries had no or very little protection of intellectual property and the IP rights were dealt with internationally by the Paris Convention and administered by WIPO (this will be discussed in detail in Chapter 2). In the course of negotiations which led to the creation of WTO a small number of countries under the guidance of the USA, the European Union and Japan managed to let include the protection of IP rights in the system of policy and trade negotiations. This is equivalent to a transfer of competence from WIPO to WTO and was initiated by these developed countries in view of protecting their industries from the

4. GHW (2005), pp. 31 ss and table p. 32.

5. ADPIC (1994).

6. CSSR (2006).

competition of developing countries, at least some of them like those of South-East Asia. In calling for trade sanctions these developed countries gave themselves the means to exert some pressure on potentially competitive developing countries, in case these did not respect intellectual property.

This TRIPS Agreement has a direct effect on the right to health for all. Indeed introducing the obligation for all its members to produce a patent for new medicines imposes minimum standards of IP protection to all member states. In fact patent holders (in general industries of rich countries) can keep the prices of new medicines artificially high and thus make them inaccessible to the patients of little developed or developing countries[7]. According to the World Bank only 9.5 % of pharmaceutical expenses take place in developing countries which however account for 75 % of the world population[8].

Although different parameters intervene in the access to medicines for the populations of developing countries (local health services adequately staffed, well equipped, managed, financed and geared to local needs, efficient distribution systems and exemption from customs duty and taxes on medicines), the price of medicines remains a heavy burden as for accessing them in developing countries. According to a report of the World Health Organization (WHO) « nevertheless, it was noted that the world's » poor spend a large part of the income devoted to health care on buying drugs privately. The private sector (which includes NGOs and « quality health centres » as well as « quacks ») provides from 50 per cent to 90 per cent of drugs by value, paid out of the patient's » pocket. As a result, spending on drugs dominates household spending for health in developing countries »[9].

With an individual income estimated at less than 2 dollars per day the vast majority of populations in the

7. See, for example, Elangi (2007), on the impact of pharmaceutical patents on the right to health in the context of HIV/AIDS in Africa.

8. Etwareea (2007).

9. OMC/OMS (2001).

developing countries cannot buy with their own means the quantity and type of medicines which they need even at the lowest fixed price.

Following serious opposition to the application of the TRIPS Agreement from a part of the civil society and from developing countries (DCs), and because of the magnitude of the HIV epidemics in the DCs a certain number of flexibilities was introduced in the Doha Declaration on the TRIPS Agreement and Public Health [11], which was adopted in 2001 by the WTO member states at the WTO ministerial conference in Doha. These flexibilities make it possible to bypass the patents rights via compulsory licences and parallel imports [12], whereby enabling theoretically an easier access to essential medicines. In practice these Agreement flexibilities are difficult to apply for developing countries, on one hand because of administrative red tape and on the other hand because of economic

SOME EXAMPLES OF INEQUALITY IN TERMS OF ACCESS TO MEDICINES [10]

« A complete treatment with antibiotics to cure a simple pneumonia in a low income country can cost a monthly minimum salary against only a minimum salary for two to three hours work in a high income country.

To pay for a treatment against tuberculosis in the private sector a Tanzanian should work 500 hours ; in comparison a Swiss should only work 1,4 hours.

In 2000 the Lamivudine used in the treatment against HIV/AIDS was on average 20 % more expensive in Africa than in ten industrialised advanced countries ».

10. OMS (2003).

11. Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the « Declaration ») and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement and to report to the General Council before the end of 2002 » In August 2003 the General Council of WTO adopted a decision relative to the implementation of this paragraph 6. In this decision it is mentioned that the TRIPS Council will have to reexamine every year how the system works so as to make sure it is applied effectively ; *docsonline.wto.org/DDFdocuments*, (OMC (2001)).

12. CSSR (2006).

and political pressure exerted by the industries and governments of rich countries [13;14;15].

Today it appears clearly that this pressure is exerted especially during trade negotiations which take place between individual countries outside WTO (bilateral, regional and subregional negotiations, see Chapter 5). These negotiations, steadily increasing after the failure of the negotiations inside WTO, include rules which go beyond the TRIPS Agreement and cancel some protections that these offer to the developing countries. These new standards, referred to as « TRIPS-plus », compel the developing countries to go well beyond their obligations as foreseen by the WTO multilateral trade system [16]. The « TRIPS-plus » rules aim at limiting the power of governments to grant compulsory licences and to embark into parallel imports, to slow down the access to generic medicines by giving the pharmaceutical companies a protection of clinical data and by extending the patents duration. For example the European Union seeks to introduce dispositions on pharmaceutical patents in a certain number of free trade agreements which could imperil access to medicines in developing countries [17]. According to Global Health Watch « the use of trade agreements to undermine public health and its rules by governments is of a particular concern in view of the actions of « the Big Pharma » which constantly put profit margins above the patients protection. These actions exert a more and more corrupting influence on public health and on the academic and clinical practice as well [18].

Protection against counterfeit drugs can be another means of pressure which seems to be used in order to raise the standards of intellectual property protection. Indeed, on several occasions medicines in transit were seized on ground of fraud against European rules [19] governing intellectual property rights. As an example [20]: the seizure by the Dutch customs of a cargo of generic medicine against arterial hypertension

13. GHW (2005), p. 106.

14. Deere (2009), chap 5.

15. Coordination (2003).

16. GRAIN (2001), The « TRIPS-plus » advance under a mask », GRAIN, July 2001, *www.grain.org/briefings/?id=53*.

17. IPW (2009).

18. GWH (2005), pp. 108-109.

19. Regulation N° 1383/2003 of the European Union regarding the possibility of seizing goods suspected of violating IP rights: *www.ecta.org/private/*REGULATIONS/*17.*

20. IPW (2009b).

(500 kg of Losartan on the 4th December 2008) arriving from India and destined to Brazil. Although Losartan is an authorized generic medicine, the seizure took place after an anonymous firm (according to some sources, the American pharmaceutical corporation Merck) claimed to hold a patent for this medicine in the Netherlands. Moreover, on the 4th of March 2009 the same customs authorities seized a package of 49 kg of Abacavir sulfate, a second line [21] medicine for the treatment of AIDS, also coming from India and destined to Nigeria. Naturally the EU defends the Netherlands, being of the opinion that these measures were taken in compliance with the international trade rules and under the responsibility of the Dutch government to protect populations against bad quality medicines. However according to the representatives of the Indian and Brazilian governments the extraterritorial application of the patents rights is not in conformity with the dispositions of the Doha Declaration on TRIPS and public health. Several NGOs active in development aid reacted strongly to these facts and wrote two separate letters to the directors of WTO [22] and WHO [23] urging them to intervene at the EU so that its rules about counterfeit drugs be reexamined and modified as soon as possible. On the 20th February 2009 a letter was also sent by G. Perry, director-general of EGEA (European Generic medicines Association) stating the preoccupation of the association he heads as far as these seizures of generic medicines [24]. According to IP Watch [25], the reply of P. Lamy, director-general of WTO, to the NGOs letters underlined that the matter was discussed between the two WTO member states concerned, i.e. Brazil and India, but that there should be no reason to involve the dispute settlement body of WTO, but that he remained at their disposal should the problem persist [26]. Despite all this seizures continue ! Indeed on the 5 May 2009, 3 million pills of the antibiotic amoxicillin, sent by India to the Republic of Vanuatu in the Pacific ocean (one of the poorest countries in the world) was delayed at Frankfurt airport on the basis

21. The present anti-HIV medicines having lost their effectiveness after the virus developed its resistance second line, even third line, medicines are called in.

22. Letter of 18.02.09 to Pascal Lamy, director of WTO. *www.keionline.org/misc-docs/seizures/WTO_seizures_18feb.pdf.*

23. Letter of 18.02.09 to Margaret Chan, director of WHO. *www.keionline.org/misc-docs/seizures/WHO_seizures_18feb.pdf.*

24. Letter of 20.02.09 from G. Perry, director-general of EGA to L. Kovacs, director. *www.ip-watch.org/weblog/wp-content/uploads/2009/03/rotterdam-seizure-letter-to-customs-commissioner-09.pdf.*

25. IPW (2009a).

26. Answer of Pascal Lamy of 4.09.2009 to the letter sent by NGOs about the seizure of medicines: *www.keionline.org/misc-docs/seizures/dglamyresponse.pdf.*

of a violation of registered trade mark [27]. This last seizure caused an escalation of calls for a change in the EU [28] regulation. According to IP Watch [29] « a meeting of the general policy Commission of the WCO (World Customs Organization) will deal with the replacement of a controverted group (group SECURE) combating counterfeiting and piracy by a less rigid structure which will limit itself to a dialog. And the commission will decide whether it is relevant or not to include« public health » and« safety » in the mandate of the WCO combating fraud Commission ».

The Doha round of negotiations, which was initiated at Doha in 2001 and has not yet succeeded, was called 'development round'. The right to development is indeed often mentioned in the debates and reports (as well as other institutions such as the World Bank and the International Monetary Fund). It is accepted that the major problems in matter of development such as the bad health of the populations, the education deficiencies, the non-access to world markets can only be solved by establishing a better collaboration between rich and poor countries and by recognising the autonomy of developing countries. However this is often only rhetorics of western political elites. During the debates on development the weight of intellectual property protection for poor countries is seldom taken into account. So as is underlined by Drahos and Braithwaite : « Here we have a group of fuzzy values that include cooperating with the poor, recognising their autonomy and helping to empower them. How do these values square with the detailed technical rule-making that goes on with respect to intellectual property rights in trade fora ? » [30].

The WTO facilitating role of international trade via multilateral negotiations is now blocked. What future then for WTO ? Should it be forgotten, should it be limited to removing obstacles to transactions or should its philosophy be reinterpreted in asking « (…) WTO to go

27. IPW (2009d).
28. IPW (2009e).
29. IPW (200f).
30. Drahos et al. (2003).

beyond its strict basic business and seek the best possible balance between individual freedom and states responsibility for the years to come ? » [31] According to Hoekman and Mavroidis : « (…) WTO will have to concentrate on market access rather than promote a development agenda or extend its field of application to rules or other domestic policies. » [32]

From the failure of the Ministerial Conference at Seattle in 1999 interactions between governments and civil society have played an important role regarding the commercial stakes. Public opinion was mobilised by alterglobalist groups and various NGOs against the positions of rich countries towards poor countries. Although the WTO Secretariat has a liaison office with NGOs which organises public events where NGOs are invited, WTO is the only international organization which does not have a formal relation with NGOs [33]. Public access to WTO documents is still incomplete and generally speaking WTO should be more open to various groups of the civil society.

In agreement with Global Health Watch we think that the protection of IP rights with respect to the accessibility of essential medicines and health related technologies should not be administered by WTO but by public health institutions and that later on it should revert to a separate status within (possibly outside) TRIPS [34].

31. Messerlin (2002).
32. Hoekman et al. (2007).
33. 3D (2005b).
34. GHW(2005), p. 112.

CHAPTER 2

WORLD INTELLECTUAL PROPERTY ORGANIZATION [1] (WIPO)

2.1 *THE MANAGEMENT OF PATENTS, ESPECIALLY IN THE FIELD OF HEALTH*

The TRIPS Agreement [2], which constituted the main theme of our 2006 [3] publication and which we analysed briefly in Chapter 1, foresees the possibility of obtaining patents for an « invention » but not for a « discovery » [4;5]. These two terms are defined as follows : « A discovery is rather related to fundamental research and consists in finding or observing something – a result, a concept, a process – for the first time. A discovery is always new, but as a pure mental activity, cannot be patented.

It is not sufficient for an invention to be new, it must not be obvious even for scientists and professionals who would refer to previous knowledge and state of art.

An invention has more to do with applied research. It consists in proposing solutions or technical answers to technical or fundamental problems.

An invention is often the application of a discovery of a practical solution to a technical question. Even if the idea at the base of an invention constitutes a discovery, it does not mean that this invention is a discovery. » [6]

1. Contact details and further information : p. 205

2. ADPIC (1994).

3. CSSR (2006).

4. In section 5 of Part II, Patents, Article 27 : patentable item the Agreement foresees « Pending the dispositions of paragraphs 2 and 3, a patent can be obtained for any invention of product or process and all technological fields provided it is new, that it involves a creative activity and is likely to lead to an industrial application. ».

5. But we shall see in Chapter 4 how this distinction becomes more and more blurred and makes the number of patents applications soar in very different fields. Armstrong &al. (2005) suggest about the « three stages test » which governs the exceptions to the author's right – but the validity of which is far more general – : « Some could say that ▷

The Agreement also foresees limitations to this right of patenting:

« 2. The Members [of the TRIPS Council] can exclude from patentability the inventions for which it is necessary to prevent a commercial exploitation on their territory so as to protect public order or morality and to protect as well the health and the life of persons and animals or protect plant species or avoid severe harm to the environment (…).

3. The Members can also exclude from patentability:
a) diagnostic, therapeutic and surgical methods for treating persons or animals;
b) plant species and animals other than micro-organisms, and essentially biological processes for obtaining plant species or animals other than non biological and microbiological processes (…). »

The dialogue between the main parties involved which have to see to it that the Agreement is respected by the Member States[7] takes place in a subtle game of « patentability » and « non-patentability ».

« Patentability » and consequently the necessity to manage and monitor the respect of patents define the role and power of the World Intellectual Property Organization (WIPO)[8] and of the Union for the Protection of New Varieties of Plants (UPOV), which will be analysed in detail in Chapter 5[9]. Together with the WTO these two international organizations constitute the core of central actors of the Agreement. Indeed the Convention establishing the WIPO in 1967[10] states:

Art.4 « The Organization (…) shall promote the development of measures designed to facilitate the efficient protection of intellectual property throughout the world and to harmonize national legislation in this field (…). »

▷
this test is so vague as to be of little use or so vague as to be extremely useful. It is certain that it does not offer any certainty, i.e. that the capability of a person to obtain a protection for his behaviour (copy) with such a test would probably depend on the quality of his lawyer, which is often proportionate to his means. Rules and intellectual property lawyers have benefitted for several decades from this symbiotic relation and is even clearly formulated by the lawyers themselves ».

6. Guédon (2005).

7. Among the actors the World Customs Organization recently came out of its relative obscurity to interpret arbitrarily and erratically some dispositions of the Agreement; see Chapter 2 WTO and IPW (2009a), (2009b), (2009d), (2009f), (2009g).

8. May (2007), ch.2: The WIPO's antecedents and history; ch.3: How the WIPO works. Armstrong et al (2005), Sahai (2005), 3D (2006) and Remiche (2006) give a critical description of its aims and decision-making structure. CIEL (2007) and May (2007) present thoroughly its role and the challenges which WIPO has to meet at the present time. Deere explores the position of WIPO in its relations with DCs. May (2007), pp. 5-14, also presents clearly the definitions and concepts which are essential to follow the debate on « intellectual property ».

9. The Director-General of WIPO is the Secretary-General of UPOV.

10. OMPI (1967/1979).

The 1975 Agreement[11] between the UN and WIPO[12] broadens further the task to:
« (…) take the responsibility to (…) encourage creative intellectual activity and facilitate the transfer to developing countries of technology related to intellectual property in view of accelerating economic, social and cultural development ».

In collaboration with WTO, WIPO seems to have perfectly satisfied the first request to « improve IP protection »[13]. As an example one can look at the changes in the legislation of DCs between 1998 and 2007: out of the 18 « least developed countries » considered, 11 did exclude the patentability of medicines in 1988 and in 2007 only 3; in 1998 out of 37 « developing countries » 17 and none in 2007[14].

If WIPO did also satisfy the second request to « promote creative intellectual activity and (…) accelerate economic, social and cultural development » opinions differ widely on this topic.

Indeed defining the development of a country consists first in defining its freedom and opportunity of choice with respect to its necessities – or really in function of its ruling class – . And very often this freedom translates into legislating on the patentability or non-patentability of a certain class of goods. Under the pressure of several DCs WIPO has undertaken slow steps towards considering more thoroughly the DCs development demands with respect to the strict obligations of abiding by the IP[15] rights.

The Agreement foresees the possibility of « excluding from patentability » certain goods but discussions on this theme must necessarily come out of the field of IP. Disputes run around the primacy of commercial and economic interests for some of the actors (WTO, WIPO, UPOV) and development and public health interests for others (some DCs, WHO, NGOs). As Christopher May

11. WIPO(1975).

12. defined as « UN special institution ».

13. The new WIPO Director-General, Francis Gurry, thinks that WIPO is going to play a more and more important role in the future: « At present we are in a transitional economic period where one can see the generation source of riches pass from physical capital to intellectual capital. Because of this shift from real to virtual requests for the intellectual property right develops exponentially in the world. » Interview with C.Jourdan (Jourdan (2008)). The considerations of Ch. May on the dangers of « reification of intellectual property rights » still remain (May (2005), (2006)).

14. Deere (2009), Appendix 4, pp. 333-334.

15. We'll closely look upon this fundamental aspect of WIPO's upcoming reform in Chapter 2.4.

remarks: « WIPO succeeded in giving and maintaining an image of its role as a purely technical agency, what kept it out of any criticism (…) [but], like other actors of the present global economic system [it] is highly politicised and must be [re]inserted into any analysis of the global economic management » [16].

An increasing number of international organizations (governmental, private, non-governmental) participates in the debates about IP [17]. The impact of NGOs as a pressure group in continuous re-definition of aims, powers and perspectives of WIPO and UPOV becomes more and more important [18]; it is going to be treated in greater depth in Chapter 6, but it might already be useful to bear in mind the considerations of CIEL – Centre For International Environmental Law – on the importance of the « civil society » action in the power game inside the international institutions. In 2000 when the Traditional Knowledge Committee was established at WIPO the majority of the civil society organizations did start participating. This committee deals with very important topics such as biopiracy, rights of indigenous communities and innovation in regional traditional knowledge. The civil society has also been involved in other working groups of WIPO, in particular in the debates about the Development Agenda. In all these cases the debates were enriched and balanced thanks to the participation of the civil society. Nevertheless this participation must be improved, the major obstacle being the lack of information provided by WIPO as to its nature, its objectives its modus operandi [19].

Below [20] we shall describe the tensions arising from the contradictions between IP and development and between IP and human rights [21], when other important sources of tension are also due to regional preoccupations [22], where requests for economic growth, employment and human rights sometimes lead to conflicting and even explosive situations.

16. May (2007), p. 3.

17. This point is analysed in detail by C. Deere. Deere (2009), pp. 133 ss.

18. See in particular « NGOs, civil society and Think Thanks » in Deere (2009), pp. 134 ss.

19. CIEL (2007), pp. 5 ss.

20. See Chapter 2.4.

21. This antagonistic report was treated briefly in Introduction and in Chapter 1 about WTO and in particular the TRIPS Agreement. The positions of several NGOs will be referred to in Chapter 6.

22. See, for example, OMPI (2007b), OMPI (2007c) and Vialibre (2007).

In this present study the most important aspect, in our opinion, of the WIPO and UPOV activities remains the role played by these organizations every time the problems of « patentability » had a direct impact on public health, in particular on the access to essential medicines for poor countries. Indeed the Agreement enabled putting into force the respect of IP protection to public health and medicines, making innovation patentable in the pharmaceutical field, what made more difficult the generalised access to generic medicines. Following their entering WTO countries like India which did not previously grant patents on medicines and had become at the same time important producers of generic medicines were forced to do it [23].

WIPO and UPOV thus became important together with WTO among the actors responsible for constant tension between the interests of pharmaceutical corporations and those of sick populations. The weight carried by these two organizations has not stopped increasing.

In this context we shall present and analyse in the second part of this book the positions taken by Switzerland in the decision making bodies of WIPO and UPOV when it comes down to cast a vote in favour of a commercial or economic priority or on the contrary in favour of public health and development [24].

23. See: India, in CSSR (2006), case study, p. 72.

24. Of course the fields covered by IP are much larger than that of medicines and of other important components of public health; the Agreement's impact and implementation, under the pressure of WTO, WIPO and UPOV, was strong in many areas; see Deere (2009) for an exhaustive analysis of this question.

2.2 *CLOSE COLLABORATION BETWEEN WIPO AND WTO*

« We are often told that we have entered a new era, a new society: the « information society ». This statement caused an increased interest and a certain concern regarding the « rights of intellectual property ». Indeed intellectual property is the form through which many

essential resources of this « new » society are converted into a commodity » [25] .

The institutions, laws, national and international agreements governing IP and guaranteeing its respect by individuals, firms and States constitute a political and economic field which covers much more than the acceptance and control of patents and trade marks, which at the beginning were the field of activity of WIPO. However after the TRIPS Agreement [26] was ratified the protection of IP has been regarded more as related to commercial preoccupations and growth, specific realms of WTO [27].

Analysing the difficulties faced by WIPO consecutive to the signing of the Agreement Christopher May notes : « One of the important reasons, which serves to explain why the developed countries (stimulated by the negotiators of the United States and the European Community) wished to shift the global IP question towards WTO, can be identified as their wish to reinforce the international control over IP » [28]. Indeed WIPO seemed to lack the structure and necessary power to check the respect and obligations related to IP by all the member states of WTO and their nationals.

The Convention creating WIPO [29] foresaw already the necessity of collaborating with other international organizations :

Art. 3.i : « to promote the protection of intellectual property throughout the world through cooperation among States and, where appropriate, in collaboration with any other international organization ».

The collaboration with WTO [30], depositary of the TRIPS Agreement, was thus indispensable. However the relations between WTO and WIPO (which is a member of the TRIPS Council) and the definition of the respective fields of competence needed a period of adjustment :

25. May (2005).

26. ADPIC (1994).

27. See chapter 1.

28. May (2007), p. 32.

29. OMPI (1967-1979).

30. Let us remember that WTO is not a part of the United Nations system.

« The agreement [between WTO and WIPO] (…) divided the global management of IP in two distinct parts. On one hand the political controversies would have been dealt with by WTO and its TRIPS Council. (…) On the other hand WTO did recognize the reason for using the important resources of WIPO regarding help to training and development in the DCs. » [31]

After an informal phase of collaboration [32] the signing of a formal agreement was arrived at on the 1st January 2006 [33] between the two organizations. In its article 4.2 this agreement stipulates :

« The International Bureau [of WIPO] and the WTO Secretariat shall enhance cooperation in their legal-technical assistance and technical cooperation activities relating to the TRIPS Agreement for developing countries, so as to maximize the usefulness of those activities and ensure their mutually supportive nature. »

In OMC/OMPI (1998) a fairly detailed presentation of the different help modalities is given which the two organizations offer to member states, in particular : « planning and coordination of technical cooperation activities », « modernisation of the intellectual property systems and the means of enforcing the rights » and « a cooperation in technical-legal assistance. »

The nature of help supplied by WTO and WIPO to developing countries was thus defined : « To help these countries it is essential to pass from integration to participation, and to give them the means look after the protection of intellectual property at their national level. » [34]

Later on this cooperation was used, in particular, to help (if this term is correct ; « push » would be more adequate) the developing countries to respect what was defined as « deadline of the year 2000 » [35] and, then more harshly, as an « expiration date » [36]. Indeed

31. May (2007), p. 34.

32. C. Deere is of the opinion that « the Agreement asked the developed countries and the WTO Secretariat to assist the DCs in implementing the Agreement. Recognizing the daunting task the Secretariats of WTO and WIPO agreed in 1996 to work together on the technical assistance relative to the Agreement. Deere (2009), p. 181.

33. OMC/OMPI (1996).

34. OMC/OMPI (2001) ; in a thorough analysis of the relations between WTO and WIPO A. A. Latif thinks however that – « considering the complex dynamics of the governance of international IP » – there are still some misunderstandings in the perception by the DCs of the specific responsibilities and tasks of the two organizations ; and thus they are frequently led to discuss their problems separately in the two forums (Latif (2005), II.3.

35. OMC/OMPI (1998).

36. OMC/OMPI (2008) : « For the least advanced countries a similar programme [was] launched in 2001 in order to help these countries in respecting there target date of the 1st January 2006. ».

the countries referred to as « the least advanced ones » were given until the 1st January 2006 to enforce the dispositions of the TRIPS Agreement, adapting their legislation for author's rights, patents, trade marks and other fields of intellectual property. They were also to adopt efficient means of fighting in particular against piracy and counterfeits [37].

In official documents the harshness of these demands made to DCs was somewhat attenuated. The economic, commercial and legal conditions imposed by the Agreement appear to be swamped in a larger context in which an interest for social questions is displayed. Abiding by intellectual property is presented as a contribution to the economic progress and wealth of the DCs, sometimes even including a « cultural » element. For example « The task which consists of complying with the TRIPS Agreement is considered as a challenge for the DCs (…). But it also offers the possibility of using intellectual property to speed up the economic, social and cultural development » [38].

A new WTO-WIPO initiative which aims at helping the least advanced countries to profit from the protection of intellectual property was launched on the 14th June 2001. It is interesting to read the comments on the talk given by Kamil Idriss, then Director-General of WIPO during the ceremony marking this event : « He [Kamil Idriss] also underlined that intellectual property was an instrument for technological progress, economic growth and creation of wealth for all nations, in particular for the least advanced countries ». The intervention of Mike Moore (then Director-General of WTO) goes along the same line : « Enforcing these obligations also represents an opportunity for the poorest countries to profit from intellectual property so as to speed up their economic, social and cultural development » [39].

Putting the Agreement into force implies abiding by all the IP rights and all the patents held by firms of the

37. OMC/OMPI (2001).

38. OMC/OMPI (1998).

39. OMC/OMPI (2001) ; see also OMPI (2007b).

industrialised countries, including those which are relative to essential medicines and not yet in the public domain. However the mechanisms which should generate « wealth » and « culture » in the poor countries which abide by the demands of the Agreement have never been made clearly explicit [40]. « Development » as is considered by WTO and WIPO, i.e. solely in terms of « technical progress » – with a possible fast reference to « culture » – does not always coincide with the definition of « development » worked out by DCs, at least by some of them.

The necessity to abide by « progress », « growth » and « culture » was expressed in a large number of documents under the form of purely economic and commercial arguments but has remained a lofty principle. These last years a debate could not be avoided on the interpretation of these terms and how they must translate into concrete actions. Moreover a coherent strategy from WIPO is necessary and called for.

This debate is going on within WIPO on the Development Agenda and on the Geneva Declaration ; this topic is important which will be treated in Chapter 2.4. But first in Chapter 2.3 the present situation of « patents on living matter » will be presented ; these patents are of utmost importance in the management of public health.

40. It is particularly difficult to imagine how respecting the patents on medicines imposed by the Agreement and by the pharmaceutical corporations of the industrialised countries could generate « progress » in the field of public health in the poor countries. See, for example, Elangi (2007) on the impact of pharmaceutical patents on the right to health in the context of HIV/AIDS in Africa.

41. Global Appeal : « Prevent the granting of patents on conventional seeds and animals ». *www.no-patents-on-seeds.org.*

2.3 *PATENTS ON ANIMALS AND « TRADITIONAL » PLANTS (I.E. NON GENETICALLY MODIFIED)*

Recently an umbrella organization for the defence of non industrial agriculture and consumers' interests launched a Global Appeal [41] to alert the public opinion on the « drift » of the European Patent Office

(EPO). Indeed the EPO [42] has started accepting patents requests for plant and animal varieties « living species » obtained through biological methods ; to the eyes of lay people these appear quite « conventional », i.e. without using microbiological means. In the Appeal it is stated that accepting this new family of patents contradicts the European Patent Convention (EPC) and introduces severe interferences in traditional agricultural practice [43].

This extension of the « patentable » field unfortunately derives from the ambiguities contained in the patents laws ; such ambiguities are not fortuitous and neutral but enable the actors in the game to argue over interpretations where the stronger often wins.

Indeed let us start by recalling Article 27.3 b of the TRIPS Agreement [44], quoted above, which stipulates that :

« Members may also exclude from patentability : (…) b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. »

In the article the expression « essentially biological processes » can lead to technical legal quibble – It is indeed sufficiently vague for its interpretation to be left at the mercy of the institutional actors of this power play. It also causes difficulties of interpretation in the field when confronted with the conditions and application modalities of the law.

The same undefined expression is also found in the EPC [45] :

« Art. 53 : European patents are not granted for : (…) b) plant or animal varieties or essentially biological processes for the production of plants or animals (…) », which seems to define a field of « patentability

42. The European Patents Office or EPO is an organization which grants patents at the European level. Its head-office is in Munich in Germany. It has also a department in the Hague and offices in Berlin, Vienna and Brussels. It was created by the European Patent Convention (1973), which came into force on the 7th October 1977. It is the executive organism of the European Patent Organization which is an intergovernmental organization created on the basis of the European patent Convention EPO. The EPO was modified on the 13th December 2007 (EPO, 2007).

43. No-patents (2006) ; see also for Switzerland *www.horizons-et-debats.ch*, Hoffmann (2006).

44. ADPIC (1994).

45. See European Patent Office (EPO), *www.epo.org* ; CBE (2007).

exclusion », the importance of which is then reduced or weakened by Art. 23 quater of the EPC Implementing Regulations [46] (which in turn introduces other ambiguities : « technical process », « technical feasibility ») :

« Biotechnological inventions are also patentable when they apply to :

a) a biological matter isolated from its environment or produced through a technical process, even if it preexisted naturally ;
b) plants or animals if the technical feasibility of the invention is not limited to a plant variety or a determined animal race (…) » [47].

In Switzerland [48] Art. 2 of the Federal Law on Invention Patents [49] also seems to be ambiguous :

Art. 2 B « Exclusion from patentability (…) »
2. Cannot be patented either : (…)
b) plant varieties and animal races and biological processes for producing plants or animals as well ; however pending al. 1 microbiological processes or other technical processes, the products thus obtained and inventions on plants or animals are patentable if the technical feasibility is not limited to a plant variety or animal race. »

In this well cultivated deliberate vagueness, requests, oppositions, judgments and final acceptance of patents by EPO [50] were formulated ; all this led to the above mentioned Global Appeal.

In the list [51] of the most important applications for patents granted by EPO (which go well beyond the limits by EPC and the directive 98/44/EC of the European Union as to the patentability of living organisms) the broccoli [52] example is found ; « in 2002 the European Patent Office (EPO) granted a patent to Plant Bioscience, a society of the United Kingdom, for a method enabling the development of a specific component of the Brassica species, i.e. the

46. Idem.

47. It will be seen that this « clause b » is going to play a determining role in the modifications accepted by the producers after some opposition, in view of having their patents requests accepted by EPO.

48. It must be borne in mind that Switzerland is an integral part of the European Patent Office ; consequently it is bound to abide by the patents accepted by EPO, unless a contradiction between the Swiss laws and the EPO decision is brought to light.

49. Federal law on patents (Loi sur les brevets, LBI)1 of the 25th June 1954 (Status on the 1st of July 2009) *www.admin.ch/ch/f/rs/2/232.14.fr.pdf*.

50. Among the opponents one finds frequently Syngenta, a powerful Swiss chemical corporation.

51. List on *www.no-patents-on-seeds.org*.

52. EPO (1999) ; see the Broccoli file, on *www.no-patents-onseeds.org* ; and also the clause b) quoted in note 47 which enabled the producers to obtain a patent just going from a particular variety of the « brassica » type to the proper plant.

broccoli, through traditional selection processes (marker assisted). The patent includes the selection processes and the broccoli seeds and edible broccoli plants as well obtained from these selection processes ». Another case can be quoted : the process enabling the production of a lettuce presenting a sustainable resistance to a pathogen (aphid) ; this resistance does not consist in a genetic modification but in 2004 a patent was still granted to the agrobusiness Dutch firm Rijk Zwaan [53]. In this list there is also a process aiming at increasing yields in the food production industry [54].

These are not isolated cases. As the number of patent applications for genetically modified plants presented to EPO fell from about 500 in 2002 to 300 in 2006 applications for non genetically modified plants soared from 6 in 2002 to 45 in 2006 [55].

The present drift continues towards patents on gene sequences and some proteins : the legal artifice consists in applying for a patent not for a « gene sequence » or « a protein » (it would show that it is a « discovery » and not an « invention »), but for the presumed metabolic activity, in particular contexts, of this sequence or this protein [56].

It is thus important to interpellate the offices responsible for granting patents and the national officials who represent the different States in these offices, on the interpretation of the most obscure and ambiguous terms in the different international conventions.

However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement. At the same time it will requested that expressions and concepts likely to lead to possible drifts be defined in the least ambiguous and clearest way.

53. EPO (1997) ; see The lettuce case, on *www.no-patents-on-seeds.org* ; and also the clause b) quoted in note 47 which enabled the producers to obtain a patent just going from a particular variety of the « Compositae » family to the proper family itself.

54. EPO (2003) ; see Patents on breeding of animals, on *www.nopatents-on-seeds.org*.

55. « Statistics on patents on plants and animals through genetic engineering and traditional methods as well ». No-patents (2007).

56. see, for example, DB (2006b).

Patents obtained for « traditional » methods imply that the animal races or plant varieties considered have not been submitted to genetic modifications. NGOs and researchers have expressed their concern as to the possible consequences of such patents on the autonomy and rights of farmers. In this respect Hoffmann thinks that « farmers are being deprived of their age-old right of producing seeds freely and passing them on. They are being deprived of using biodiversity in view of raising cattle and cultivating resistant plants and supplying consumers with healthy food » [57].

Nevertheless it seems difficult for us to share this concern as these patents call for extremely sophisticated concepts and methods. No farmer interested in selecting a new animal race or plant variety would be able to use the laboratory hybridization methods described in the above-mentioned patents. In the Global Appeal as well it is written that « in any country what remains of the farmers rights will disappear and the producers will no longer benefit from a free access to plant varieties and animal races for selection and reproduction purposes. These patents will annihilate the rights of farmers and privileges of breeders which are indispensable to their survival, to food sovereignty and biodiversity preservation in agriculture. In the developing countries the vast majority of farmers are small farmers who depend entirely on preserving and exchanging their seeds » [58]. These statements seem to us difficult to acknowledge. It is indeed clear that the crossing, hybridizing and selecting methods used in the large laboratories of multinational agrobusiness firms are very remote from the possibilities of small farmers in the developing countries. In this context the appeals to « biodiversity preservation » and « food sovereignty » can appear rhetorical.

But this process is nonetheless dangerous : the gradual transition, which is difficult to monitor or may only be monitored by powerful actors, starting from strict definitions of what is patentable and what is not and

57. Hoffmann (2006).

58. No-Patents (2006).

arriving eventually in a vague space where everything can become patentable through scientific or legal quibble – especially for strong and influential parties supported by ultramodern laboratories. In this matter we see the reasons for caveats and actions of public awareness of *no-patents-on-seeds*: the « non-patentability » space is being progressively eroded by multinational firms and the test of strength always seems to turn in their favour.

However it must be borne in mind that States have the right to set the limits of patentability. For example the International Convention for the Protection of New Varieties of Plants [59], which will be discussed in Chapter 3, foresees that:

« Each member State of the Union may limit the application of this Convention within a genus or species to varieties with a particular manner of reproduction or multiplication, or a certain end-use. »

Despite the power of some parties involved it is probably still possible, through a mobilisation at the national and international level, to slow down the drift of EPO and WIPO and to restrict the granting of patents on animal races and plant varieties only to the cases where the procedures used differ non-equivocally from the selection methods used or reasonably usable by small producers.

There is a new element in this battle between the producers of new animal and plant varieties and the forces fighting for a greater autonomy of farmers and breeders with respect to the powerful multinational firms which dominate over the market and patents on living species. It is an essential concern within WIPO in favour of reflecting over relations between IP, genetic resources, traditional knowledge and folklore.

For some years an intergovernmental committee has met and convocated periodic meetings on these

59. UPOV (1978).

topics [60]. The stakes are enormous considering the multiple important consequences, among others :

- Who is the owner of the genetic resources elaborated and eventually selected by rural indigenous communities ?
- How to differentiate the knowledge acquired in a laboratory from public knowledge (traditional, local, regional of a whole population) ?
- How to separate traditional behaviour (for example the empiric use of some parts of plants for a presumed therapeutic purpose), often without any experimental support, from a scientific knowledge based on controlled experiments ?

Medical tradition is supposed to contain or at least suggest a controllable and useful use of, in therapeutic terms, some plants or animal or even mineral parts. It can thus be seen that the stakes between the « patentability of laboratory discoveries » versus the « non-patentability of public knowledge » becomes a major concern for the local populations who want to avoid that their traditional medicines are pirated by pharmaceutical corporations and that consequently their use is blocked by patents.

In Chapter 3 on UPOV these considerations will be presented within the larger framework of patents applications or patents already granted for plant species.

2.4 NEW CHALLENGES : THE DEVELOPMENT AGENDA AND THE GENEVA DECLARATION

On its web page WIPO defines its mandate in this way : WIPO assists all the states, in particular the developing countries (DCs) and the least advanced countries

60. See the decisions taken during the fourteenth meeting (Geneva 29th June– 3rd July 2009), OMPI (2009), and the provisional report, OMPI (2009a).

(LACs) in their use of the intellectual property (IP) system so as to foster the economic, social and cultural development [61].

As was seen in Chapters 1 and 2.2, when the TRIPS Agreement is put into force and then hardened through a series of bilateral free trade agreements leading to the signing of TRIPS-plus agreements WIPO moves to the front stage at the expense of WTO; it does so in particular by putting its technical support, its economic and political council in the field of intellectual property at the disposal of its Member States, especially the DCs and LACs.

But WIPO is a specialised UN agency [62] and as such its objectives must be compatible with those of the other UN agencies [63]. It should thus contribute to the acknowledgement of human rights and to the putting into practice of development means in the member states which need them most.

Underlining this contradiction between the protection of IP and the development of poor countries several initiatives have been put forward to orientate the WIPO agenda towards development.

THE WIPO DEVELOPMENT AGENDA

After the Doha round [64] in the context of implementing the TRIPS Agreement [65; 66] and under the pressure of rich countries wishing to reinforce national laws on patents (Trips-plus) [67; 68] Brazil and Argentina propose during the WIPO general assembly in 2004 the Development Agenda (DA) with the following guidelines:

- the necessity for WIPO to reintroduce the development perspective in the discussion over IP;
- the obligation for WIPO as a UN agency to take the development objectives into account;

61. *www.wipo.int/ip-development/en/* and *www.wipo.int/about-wipo/fr/core_tasks.html*.

62. OMPI (1975).

63. May (2007).

64. The website of WTO proposes the Doha Programme with its successive talks and programmes on *www.wto.org/english/thewto_e/whatis_e/tif_e/doha1_e.htm*. See also OMC (2001).

65. ADPIC (1994).

66. CSSR (2006).

67. Krikorian (2005).

68. Love, James and Hubbard, Tim. Make the medicines affordable: a « R&D+ » Treaty to replace the « TRIPS + » to read on *http://vecam.org/article1042.html*.

- within the framework of its main activity of standards setting WIPO must include the flexibilities enabling the development of each country;
- to reduce the obstacles to technology transfer and scientific research;
- to put more emphasis on equitable practice and fight against anti-competitive behaviour than on reinforced rights of patent holders and fight against offences;
- to provide a technical aid more adapted to each individual country enabling a better grasp of the cost and benefit of IP protection in each case. This aid shall also enable optimizing the benefits foreseen by the TRIPS flexibilities;
- WIPO must serve all sectors of society and the interests of all its members and make its activities more transparent to the public and in particular to the NGOs[69].

This request of putting development in its proper place in the debate over IP did not just appear in 2004. In 1958 some DCs expressed their doubts over the relevance of reforming the international patents law and in 1961 Brazil did propose to the UN a resolution on the relation between IP and development[70].

For the first time with this Agenda at WIPO the importance of IP development was going to be discussed as the main theme and not as a topic of various measures. At the centre of the Agenda one finds the compatibility of IP promotion and the objectives expected from a UN agency[71].

THE GENEVA DECLARATION ON THE FUTURE OF WIPO

In September 2004 after finding « a world crisis of the governance of knowledge, technology and culture » several public interest NGOs, personalities, scientists, militants and citizens met in Geneva to ask WIPO to reorientate its missions and actions and sign the Geneva Declaration on the future of WIPO. This document calls

69. May (2007).
70. De Beer (2009).
71. May (2007).

on WIPO to reform its « culture of implementing and expanding the privileges of monopolies without considering the consequences » which have caused severe economic and social costs and requests that the WIPO Agenda be reexamined.

The Declaration supports the DA and asks for a fundamental reform of the technical assistance programmes enabling the DCs to implement the TRIPS abiding by the flexibilities foreseen in the Agreement and facilitating the access to health for all. Regarding the legislations on patents and authors rights WIPO is requested to help the DCs in implementing the limitations and exceptions which are essential for justice, development and innovation.

The signatories do not ask that an adequate protection of IP [72] be given up, but that « WIPO works within the wider framework as described in the 1974 agreement with the United nations and in particular that the creative intellectual activity be fostered and that the techniques related to industrial property be transferred to the developing countries in view of accelerating the economic, social and cultural development » [73] and that WIPO takes a more balanced and realistic view of the social limits and benefits of the intellectual property which is only a tool, and not the only one, which supports the creative intellectual activity [74; 75].

The declaration still underlines the limits of the protection of « unique size » IP which proposes adopting the strictest IP protection levels for all and which « leads to unfair and heavy results for the countries struggling to satisfy the most basic needs of their citizens ».

THE FRIENDS OF DEVELOPMENT GROUP (FOD) REINFORCES THE DEVELOPMENT AGENDA

The coming into force of the TRIPS Agreement took place on a background of a fierce debate between

72. At the Federal Institue of Intellectual Property (IPI) one is hardly convinced about it. At a meeting two IPI members let us understand that a part of the tension between IP defenders and DA proponents arises from the blocking attitude of the latter regarding all IP rights.

73. OMPI (1975).

74. *www.cptech.org.*

75. Gross, Robin World Intellectual Property Organisation (WIPO) in GISW (Global Information Society Watch) 2007 Report.

industrialised countries, defending a reinforced IP, and the partisans of the flexibilities made possible by the Agreement. These were designed so as to reduce the discrimination as to access to medicines and health for all between poor and industrialised countries. In this context, twelve countries[76] united under FOD handed over in 2005 a declaration in support of the DA to the permanent mission of Brazil. This declaration calls for a general reform of the WIPO[77] mandate and proposes to the Member States a five-point programme:

1. Include explicitly a development clause in compliance with the WIPO obligations as a UN agency.
2. Envisage a treaty on Access to knowledge and technology.
3. Create an independent WIPO Evaluation and Research Office (WERO).
4. Adopt orientations and guiding principles for the technical assistance programme.
5. Reform the WIPO standards and practice taking into account the different development levels when applying standards on authors rights and patents (as opposed to the « single size (XL) » approach and becoming more transparent to the civil society and providing a larger participation of NGOs in the activities of WIPO[78].

THE IMPLEMENTATION OF THE DEVELOPMENT AGENDA

For the representatives of the developed countries which rejected the Development Agenda for WIPO, the extra cost of development and respect of human rights is not up to WIPO.

Its role of technical expert in IP rights does not necessarily mean that it must be involved in development.

In 2008 after 4 years of time buying based on the contradiction between a strict defence of IP and

76. These 12 countries are Bolivia, Cuba, the Dominican Republic, Ecuador, Egypt, Iran, Kenya, Peru, Sierra Leone, South Africa, Tanzania and Venezuela.

77. See Musungu: *www.iprsonline.org/ictsd/docs/Musungu_Bridges8-9.pdf*.

78. To read on http://ipjustice.org/WIPO/IIM3/NGO.Stmt.IIM3.Dev.Agenda.pdf.

development aid (in particular regarding the recommendations made to WIPO about considering the preservation of public wealth and the elaboration of standards at WIPO) the first session of the new WIPO Committee on development and intellectual property took place. During this session the Committee on development and intellectual property (CDIP) is created; it is composed of member states and open to all accredited intergovernmental and non governmental organizations.

The preparatory document[79] indicates that CDIP is to implement the recommendations contained in the 45 proposals relative to the actions to take and adopted by the WIPO General Assembly.

For the first session (March 2008) the chairmanship and the Secretariat had prepared two initial working documents: a preliminary report on the immediate implementation of 19 of the 45 proposals adopted and a working document on the implementation of the 26 other proposals.

During this first session CDIP discussed in a general way a certain number of recommendations and accepted to put forward the proposed activities to the Secretariat. Informal consultations will take place on the remaining recommendations between the first and the second session in view of identifying the ones which are not contested.

After the April 2009 meeting 19 of the 45 recommendations were adopted by the General assembly in view of an immediate implementation[80; 81]. However the Member States underlined that these 19 proposals did not in any way have priority over the others and that their implementation, or some aspects of it, would not be examined by CDIP in coordination the competent bodies of WIPO.

79. OMPI (2008b).

80. OMPI (2008c).

81. WIPO News, 16th March 2009.

The 45 recommendations [82] are divided into 6 groups:

A. Technical assistance and reinforcement of capacities;
B. Establishing standards, flexibilities, policy of public authorities and public field;
C. Transfer of technology, techniques of information and communication and access to knowledge;
D. Evaluation and studies of incidences;
E. Institutional questions, mandate and governance;
F. Others.

Are included: 19 recommendations for immediate implementation by WIPO and 26 recommendations for which CDIP is asked to elaborate a work programme.

When reading the WIPO official documents in preparation of the sessions the45 recommendations content appears to be the result of a consensus and no abrupt change of the WIPO philosophy is detected. However the implementation discussion in the successive sessions is long and tedious. Among the points causing a debate: the principle of treating all recommendations without any priority – point of view of the DA defenders – against a hierarchical order in the questions which implies a postponement for some of them; the definition of public field does not have the same meaning in DCs/LACs as in the industrialised countries. This question of public field is at the core of the discussion on traditional knowledge and genetic resources (recommendation N° 20) [83], this creates a split between holders of patents with a strong industrial capacity, who are interested in finding formalised information in the open data bases whose content could be at the basis of R&D, and countries with a high traditional biological heritage.

For the latter this knowledge is a negotiable asset and this is what causes a dispute.

82. *www.wipo.int/ip-development/en/agenda/recommendations.html.*

83. OMPI (2009b).

In October 2006 the WIPO General Assembly decided to extend by one year the discussions related to a proposal of an action plan for development [84]. According to Intellectual Property Watch which had access to the confidential report of a meeting held the day before the General Assembly, the developed countries intended to limit the range of the action plan and to use their persuading power to obtain the support of developing countries. (At WIPO the developed countries are grouped inside the B or B+ group and include some other countries represented at the European Patent Office) [85].

Finally there seems to be a fairly large consensus that the IP rights defence is only appropriate when countries have reached a certain development level. If certain aspects of the DA were taken into consideration it can be feared that the terms change with the worsening economic situation. In the concluding remarks of a recent collective work on the implementation of the DA proposals Christopher May asked three questions to bear in mind in the coming years [86]:

– The debate on the IP rights has opposed the countries whose patent holders had benefitted from the IP protection to those for whom these rights have only represented an extra cost. But with the economic recession and a certain shift of the technological centres the balance was modified: some rich countries (United States, Europe, Japan) which have fought for a strict IP protection will perhaps find themselves, in a matter of IP rights, in the present position of the developing countries and the least advanced countries. Indeed the TRIPS Agreement and WIPO have largely defended the interests of the technology leaders. But what is going to happen if these leaders change? So the opinions on the importance of further reinforcing the IP protection might change and the interest for compulsory licences might increase at the expense of the global harmonization of the patents system.

84. IPW Monthly Reporter, Vol. 3, N° 10, October 2006.

85. *www.ip-watch.org.*

86. May (2009).

– Are the firms going to keep more jealously their intellectual property and capital? It is already the case and there are several reasons for it: it is an answer to the deterioration of the economic situation but also because authors rights have been identified by WIPO and the national offices as a weak point in case of crisis, for example in the case where the former employees of a firm take away pieces of sensitive information and pieces protected by IP laws.
– An alternative to IP rights is to go to modes of open access[87] of information transmission. The DA does not call for it explicitly but the call for a greater flexibility in the treatment of knowledge and information implies clearly an interest for an « open access » alternative.

With Christopher May we are tempted to think that the DA implementation is a last chance for WIPO to keep its role of IP manager. Practice has changed as far as IP is concerned. And if the DA enables treating new problems in an original way as was seen, for example, free access to information the answers to the new economic conditions might well be surprising.

87. The open access movement encompasses the set of initiatives undertaken in the prospect of letting research results widely accessible without restriction of access.

CHAPTER 3

INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS [1] (UPOV)

The International Union for the Protection of New Varieties (UPOV) is the international organization [2] which deals with the problems related to the protection of intellectual property (patents and author's rights) in the field of the creation of new varieties of plants [3].

Reflecting on the role, the initiatives and internal tensions at UPOV will bring us close to the major preoccupations of CSSR : the dangers presented by the present system of strict defence of intellectual property rights and in particular their extension to the agricultural field, dangers for the populations of poor countries and in an indirect way for access to medicines in the DCs [4]. This is due in particular to the demands contained in the International Conventions for the protection of new varieties of plants as will be seen below within UPOV. These demands raise numerous questions and cause some perplexity in the practical field (like the protection of agricultural traditions, especially in the DCs) and in the ethical field as well (with respect to the patentability of living species ; the Federal Commission of Ethics for genetic engineering in the non human field dedicated a Contribution to the Discussion in 2001 [5]).

1. Contact details and further information : p. 205.

2. UPOV is an independent intergovernmental organization, the Convention of which was signed in 1961, then revised in 1972, 1978 and 1991. Its mission is thus defined on its internet home page : « To provide and promote an effective system of plant variety protection with the aim of encouraging the development of new varieties of plants for the benefit of society », where of course a so called protection of plant varieties is in fact a protection of the producers of plant varieties. The Director-General of WIPO is the Secretary-General of UPOV, but the International Office of WIPO works totally independently from UPOV and the International Office of UPOV works totally independently from WIPO », UPOV (2002).

3. There does not (yet ?) exist an international organization for the defence of producers of animal (race) varieties but this ▷

Among the most delicate points:

- the fact that patents cause ever stronger restrictions to the right of re-sowing the new plant varieties, once they have been used. This has a definite impact on the life and future of millions of farmers in the DCs and consequently on the populations health of these countries. At present it can be stated that 90 % of the seeds used in the DCs for food-producing crops are farm seeds (seeds put aside by farmers, the remainder consisting generally of hybrid seeds which cannot be resowed because they degenerate)[6]. This statement on the primordial importance of the resowing practice is arguable. Firstly, the origin of this figure of 90 % is unknown. Then intensive agricultural farms are strongly increasing in numbers in industrialised countries but also in many DCs and hybrid seeds carry an ever larger weight in the agricultural practice. However resowing is still a very important practice in the poorest countries and regions, in particular in the family farms of subsistence level;
- in the biological and agricultural fields the insidious drift from the patentability of an invention to that of a discovery or of a production of a plant variety encourages the piracy of traditional knowledge (for example regarding unregistered plants), even if it seems to us that some reactions, in particular from India, are not based on a factual analysis[7] but more on the supposed ill intentions of other parties. However the dangers are real and deserve to be looked at with great attention.

The essential problem lies in the argumentation in favour of the possibility or impossibility of patenting living matter, at least in some well defined situations. This dialectics was caused by the ambiguities of the TRIPS Agreement[8] and by the divergent interpretations which can be given on the relevant articles of the Agreement.

▷
defence enters clearly into the more general framework of the tasks of WIPO, as was already discussed in Chapter 2.2; see in particular EPO (2003).

4. For a detailed analysis of the relation between patentability of living species, pharmaceutical products and access to essential medicines see Scherrer (2006); for a more general analysis of the effects of introducing the IP concept into the agricultural field see Sahai (2005) and Tansey et al. (2008) (in particular the contributions of Roffe, Roffe (2008) and Rajotte (2008) to this latter book).

5. CFE (2005).

6. Desjardin et al. (2006).

7. See, for example, Ramesh (2009) where multinational firms are accused of wanting to patent, among other things, the traditional yoga positions; but the Traditional Knowledge Digital Library quoted in this article and whose Director is Dr Kumar Gupta will probably be able to help fighting bio-piracy.

8. ADPIC (1994); see Chapter 2.

Here we are trying to synthesize briefly the basic elements of the problem. However it is clear to us that the interpretation of a law is never a purely semantic problem but is dependent on a power struggle between the least advanced populations and the big industrial and agricultural corporations (of the private or public sector)[9]. We shall seek to identify the positions and decisions taken by industrialised countries, and in particular by Switzerland[10] (see part II), in this hard defence of IP rights in the very close fields of food production and public health.

Let us recall that within the rules managed by WTO, WIPO and the TRIPS Council Article 27.3 b) states that:

« Members may also exclude from patentability:

b. plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement »[11].

It would seem that only the varieties obtained through essentially biological processes can be excluded from patentability (the new varieties of plants), but not the processes defined as non essentially biological (like, among others, the genetic manipulations). But all still depends upon the meaning of the expression essentially biological which is generally interpreted as « production process … which usually consists of natural phenomena such as cross-breeding or selection »[12]. It is the result of a constant jurisprudence of the European Patents Office that the difference between an essentially biological (not patentable) process and a process which is not (and thus likely to be patented) is a level difference »[13;14].

9. « Ten societies, among which Monsanto (USA), Dupont/Pioneer (USA), Syngenta (Switzerland) and Group Limagrain (France) control half the commercial sale of seeds in the world », Deere (2009), p. 28.

10. For a first approach of the Swiss agricultural policy see OFAG (2008).

11. This reexamination of article 27.3 started in 1998 as was demanded by the Agreement and is still going on; see OMC/UPOV (2005); for a more thorough analysis of the Agreement stakes see especially Helfer (2005), Sahai (2005), Rajotte (2008), Roffe (2008) and Deere (2009). All the contributions in Tansey et al. Deal more generally with the problem of « future food control ».

12. In No-Patents (2006) and (2007) there are statistics and analyses on the report between patents granted and to plant varieties produced by genetic manipulations or without any manipulation of this type (essentially biological) between 1980 and 2006 for the first ones and between 2000 and 2006 for the second ones.

13. Ost (2006).

▷

UPOV is active in this great ambiguity of official texts for what concerns the agricultural field; in principle all these problems should be solved by UPOV. Indeed this organization was created in 1961 well before WTO. It derived from the International Convention for the protection of new varieties of plants – revised in 1978 [15] and the last time in 1991 – which settled the remuneration of producers of new plant varieties [16] – as will be seen this last version of the convention has caused problems and very heated debates [17].

In UPOV (1978) some *forms of protection* are defined in Article 2:

«1. Each member State of the Union may recognise the right of the breeder provided for in this Convention by the grant either of a special title of protection or of a patent. (…)
2. Each member State of the Union may limit the application of this Convention within a genus or species to varieties with a particular manner of reproduction or multiplication, or a certain end-use.»

But in UPOV (1991) a much larger *Scope of the Breeder's Right* is defined in Article 14 and for the first time the term *reproduction* is introduced:

«1. a. (…) shall require the authorization of the breeder: (i) production or reproduction (multiplication), (ii) conditioning for the purpose of propagation, (iii) offering for sale, (iv) selling or other marketing, (v) exporting, (vi) importing,…»,

with admittedly *compulsory exceptions* in Article 15:

«1. The breeder's right shall not extend to (i) acts done privately and for non-commercial purposes, (ii) acts done for experimental purposes and (iii) acts done for the purpose of breeding other varieties, …»

▷
14. We worded questions on the present interpretation of the expression essentially biological during a meeting and later by mail with civil servants of the Federal Institute of Intellectual Property in Bern. Their answer was: « Your questions are not easy to answer. There are few decisions and few legal documents on the question of how to interpret essentially biological ».(private communication, September 2009). Before the development of modern biotechnology the essential difference between patentable and not patentable in the biological field was to be reproducible by an experienced person, and consequently industrially applicable, and to be not reproducible. This evaluation criterion seems to be harder and harder to apply.

15. Quoted further as UPOV (1978).

16. Quoted further as UPOV (1991).

17. Deere (2009) , §3.3.4; « plant variety protection » gives a detailed and critical analysis of the two conventions; Helfer (2005) is also useful for comparing the two conventions.

and an *optional exception*:

«2. [Optional exception] … each Contracting Party may, within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, restrict the breeder's right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety … »

But how and within which limits has the possibility of ruling over this *Optional exception* been and will be exercised in the future by the governments of the Member States? The present situation appears highly ambiguous.

In 2003 during a WIPO-UPOV colloquium on The intellectual property rights in the field of plants biotechnology, Francis Gurry, then Director-General of WIPO, declared: « For WIPO plant biotechnology refers above all to the patents system [18] ». But he added: « Plants can be excluded from patent protection but innovation must be encouraged in the field of plant varieties » [19]. What choice will then be left to the different governments in the industrialised countries with an intensive, powerful and mechanised agriculture or in the DCs often dependent on their monoculture to encourage innovation?

Each country can also have specific laws and application rules. The new Swiss law is still in the consultation phase [20]. For France let us quote for example B. Müller:

« According to the French law (act 145) accompanying the UPOV ratification in 1991 and in particular Article 16 (L623-24-1) farmers can obtain a derogation to the exclusive right of producers to reproduce seeds on the species mentioned in a decree of the State Council.

18. Gurry (2003); see also UPOV (2003).

19. In other terms this is equivalent to « defining sui generis rules » in the WIPO/UPOV jargon!

On the site *www.iprsonline.org/resources/docs/Solagral_fiche5* « sui generis systems (or literally « of its own kind ») in the context of the TRIPS Agreement are constituted by default as an alternative to patents. They lie at the crossroads of remuneration for innovations (TRIPS objectives) and access to genetic resources and protection of traditional knowledge (aims of the Biodiversity convention) ».

20. See « Agricultural Policy 2011: Second series of decrees, 22nd January 2008 », OFAG (2008); for a critical analysis see also USP (2009).

This means that farmers will depend on the good will of the State Council in order to be able to resow the crop of certain varieties, determined by decree, and thus without any democratic debate. What has been a right up to now would become an exception to the rule. Moreover a farmer who would resow his crop under derogation would owe « an indeminty » to the producer » [21].

It is worth noting that France has not yet passed a law implementing the ratification of the 1991 UPOV Convention.

There must have been several reasons why most States have shown themselves very lukewarm towards signing and then ratifying the 1991 UPOV Convention, but the main problem seems to lie in the farmers' right to resow seeds which are already under a patent.

As a summary here is the situation on the 12 December 1978 :

- 36 countries ratified UPOV 1991 ;
- 43 countries ratified UPOV 1991 ; among which Germany, Japan, Russia and the USA among the industrialised countries and the European Union as such ; and Turkey among the DCs ; however there were some countries which hesitated before ratifying UPOV 1991, among which Spain (signed in 1991, ratified in 2007), the USA (signed in 1991, ratified in 1999), the Netherlands (signed in 1991, ratified in 1996), and among the most recent ones Switzerland (signed in 1991, ratified on the 1st August 2008 !) ;
- at present there remain 6 countries which signed but have not ratified UPOV 1991 : Belgium (signed in 1991), Canada (1992), Ireland (1992), Italy (1991), Denmark (1991), France (1991) ;
- others have neither ratified nor signed UPOV 1991, among which Norway and New Zealand as industrialised countries and Brazil, China and India as DCs [22].

21. Müller (2006) ; see also Desjardin et al. (2006).

22. Data supplied by the UPOV Secretariat, which we thank.

There is no apparent logic in this variety of situations regarding the ratification of UPOV 1991; commercial problems and internal pressure may have delayed or even prevented the ratification process from starting. But there is a preoccupying element: it was often claimed that the European Union was putting pressure to bear on DCs so that they adopt the most severe rules in the field of seeds [23] IP, and that « DCs are (…) encouraged to ratify the 1991 Act [Convention] so that they can benefit from bilateral or regional agreements relative to trade and investments » [24]. We shall be coming back to these blackmail actions to DCs from some industrialised countries in Chapter 5 devoted to free trade bilateral treaties.

23. GRAIN (2003).

24. « Resistance to the 1991 Act »; Helfer (2005), p. 33.

CHAPTER 4

WORLD HEALTH ORGANIZATION [1] (WHO)

4.1 IS THE REFERENCE IN MATTER OF HEALTH LOSING ITS INFLUENCE ?

In 1948 the World Health Organization was created as a specialized United Nations agency. The preamble of its constitution states that :

« Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.

- 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.
- The health of all people is fundamental to the attainment of peace and security and is dependent upon the fullest co-operation of individuals and States.
- The achievement of any State in the promotion and protection of health is of value to all (…) »

Its constitution defines its essential functions :

« Ch.2, Art.2 : In order to achieve its objective, the functions of the Organization shall be : a) to act as a directing and coordinating authority on international health work (…). » [2]

A daunting task still broadened by the 1978 Alma Ata Declaration :

1. Contact details and further information : p. 205.

2. WHO Constitution (ratified on the 7 April 1948, present text of the 15 September 2005), OMS (1948/2005) ; see OMS (2007), Green (2008), Lee (2008) and OMS (2008).

« The Conference strongly reaffirms that health, which is a state of complete physical, mental and social well being, and not merely the absence of disease or infirmity, is a fundamental human right and that the attainment of the highest possible level of health is a most important world-wide social goal whose realization requires the action of many other social and economic sectors in addition to the health sector. » [3]

Global Health Watch (GHW, 2005) [4] presents a fairly complete panorama of the complex task given by the United Nations to international organizations active, at different levels and with different responsibilities, in the field of public health ; the first of them is WHO.

While recognizing the importance, the relevance and the efficiency of WHO's action in different sectors the global judgment of GHW is far from reassuring : health in the world could be jeopardized by initiatives and positions taken which include « the practice of multinational corporations, the false promises of a genetic revolution, the scandal of hunger in a world of abundance, the failure of United Nations bodies, such as WHO, to abide by their original mission of promoting the health of poor populations ». [5]

The initiatives, the activity, the disputes and the publications of WHO [6] are the source of our interest – as Centrale sanitaire suisse romande – regarding the access to medicines in poor countries [7]. From these positive elements and analysing the present activities, difficulties and possible shortcomings of WHO we focus our attention on the access to essential medicines, stopping only briefly on other parallel problems which are particularly relevant in this field :

- essential medicines ;
- collaborations of WHO with WTO and other international organizations ;
- the particular case of the agreement between WHO

3. OMS/UNICEF (1978).

4. GHW (2005) ; in this book the complexity of the task already appears when reading the headers of chapters devoted to the global analysis of the fields interfering in public health policy : « Global health problems : Medicines, Sexual and reproductive health, Gene technology ; Health of vulnerable groups : Indigenous peoples, Disabled people ; The wider health context : Climate change, Water, Food, Education, War. »

5. GHW (2005), p. ii.

6. See OMS (1999), WHO (2003), (2006) and the preface of German Velásquez to CSSR (2006), pp. 7-9 and pp. 76-78, and the numerous publications of C. M. Correa, G. Velásquez and colleagues quoted in the references of CSSR (2006).

7. CSSR (2006).

and the International Atomic Energy Authority (IAEA);
- the absence of initiatives in research on *orphan diseases;*
- the ambiguities in the fight against counterfeit medicines;
- the progressive and programmed weakening of WHO in the framework of international organizations (of the UN family, of the public or private sector) devoted to the promotion and defence of public health.

ESSENTIAL MEDICINES

Let us recall here the definition of essential medicine: such medicines satisfy the prime necessities of the population [8]. An adequate access of poor populations to essential medicines is far from reality: « Between 1.3 and 2.1 billion people in the world do not have access to essential medicines; despite the efforts of the last decades the situation has changed little. The proportion of the world population which did have access to essential medicines passed from *ca* 63 % in 1987 to *ca* 70 % in 1999. Close to 80 % of those who do not have access to them live in poor countries and 20 % in low income countries. » [9]

The work and the initiatives of WHO for promoting the access of all to essential medicines seem very positive. WHO fought in particular against the restrictive interpretations of the TRIPS Agreement which tend to make it more and more difficult to produce or import generic medicines corresponding to essential medicines [10]. In particular WHO tried to make the DCs responsible politicians aware of the dangers of too rigid an application of the Agreement for the access to essential medicines: « Considering that in the definition of patentability the terms new and implying an inventive activity are not strictly defined the countries must establish their own criteria in this respect. They have to bear in mind that establishing too large patentability criteria can lead to a phenomenon of eternal patentability (…). So the

8. WHO (2005); the list of essential medicines, periodically updated by WHO, depends on the regional conditions and their evolution.

9. GHW (2005), p. 100.

10. G. Velásquez et al. (1999), OMS (2001), G. Velásquez (2003), WHO (2003), WHO (2006); the Agreement's flexibilities to favour the supply of essential medicines, as decided at Doha in 2001 in the framework of WTO, was discussed before in ch.2.

health ministries must work in collaboration with the other ministries (…) to revise their national legislation in a matter of patents, so as to take into account public health objectives. » [11]

Quite recently WHO took a clear position with respect to the seizure of generic medicines in transit (see Chapter 2), asking in a press release that the trade and transfer of medicines, including generic ones, be neither slowed down nor perturbed [12].

It can be noticed that emphasis always seems to have been put on access to essential medicines. However it seems that parallel programmes [13], destined to a more rational use of essential medicines – programmes intensely discussed up to about ten years ago – have been largely abandoned [14].

COLLABORATIONS OF WHO WITH WTO AND OTHER INTERNATIONAL ORGANIZATIONS

WHO's Constitution assigns it the role of collaborating with all the international institutions and those of the public and private sectors which are active in the field of health and of coordinating their action :

« Ch.2, Art.2 : In order to achieve its objective, the functions of the Organization shall be :(…) :b) to establish and maintain effective collaboration with the United Nations, specialized agencies, governmental health administrations, professional groups and such other organizations as may deemed appropriate. » [15]

Consequently it is hardly surprising to notice the very dense network of agreements and collaborations signed by WHO. Here we would like to recall briefly WHO's role in some of its multifarious activities and commitments, emphasising the dangers of dispersion and loss of privileged position that some of these collaborations can cause.

11. OMS (2001), p. 2.

12. See *www.who.int/mediacen tre/news/statements/2009/access-medicines-20090313/en/.*

13. Programmes including the fight against over prescribing these medicines, which causes an increase in costs and the apparition of bacterial resistance ; fight against inadequate prescriptions which cause the use of more powerful and expensive medicines when lighter and cheap medicines would have done.

14. GHW (2005), p. 116 ; Global Heath Watch interprets this abandonment as the consequence « of reforms in the field of health policy, liberal deregulation and commercialization of the public health system ».

15. OMS (1948/2005).

The complete list of agreements can be found in OMS (2007); their range goes from UN to UNESCO, from ILO to IAEA. In many cases they are just formal cooperation agreements which do not go beyond their mutual recognition and their respective fields of action. However it will be seen later on that the agreement with IAEA has often cast doubts on the real independence of WHO with respect to other United Nations structures.

We consider that works carried out by WHO in the cooperation framework of WTO are significant: already in 2001 a *Report of the workshop on the differential price setting and financing of essential medicines, elaborated with WTO*, clearly posed the problem of price adaptation imposed by the seller on the buying power of governments and households in various countries and also of the role of intellectual property rights in the setting of prices [16].

In 2002 a joint study of WHO and of WTO's Secretariat on The WTO agreements and public health enabled to clarify the role which the dispositions relative to public health protection could have on access to essential medicines and their price [17]. Later on this study became an important instrument to establish the primacy of compulsory licences and parallel imports over IP rights.

The discussions over the Doha Declaration and its aspects in favour of taking into account public health requests within the framework of IP rights have been reexamined several times inside WTO without reaching a binding conclusion (see Chapter 2). In this formally indeterminate framework WTO issued on the 2nd October 2008 a communication to the TRIPS Council in which it stresses its role in defending interests related to public health: « (…) WHO helps its Member States to take measures for protecting public health and for facilitating access to medicines while respecting the dispositions of the TRIPS Agreement and of

16. OMC/OMS (2001).

17. OMC/OMS (2002).

the Doha Declaration. »[18] In this document WHO describes its efforts at assisting Member States by making more accessible the flexibilities foreseen by the TRIPS Agreement. Doing so WHO underlines that it finalises a series of documents containing technical information. Moreover WHO mentions the publication of a guidebook « relative to the application and granting of compulsory licences and of authorizations of use by the public sector of pharmaceutical patents ». In parallel the support given by WHO materialized as training workshops for national decision-makers and direct help to certain countries.

Let us recall here that WHO is a member of the TRIPS Council[19] and as such has the right and the possibility to intervene in discussions over the difficulties of the Agreement interpretation and as well over the changes and adaptations decided periodically. This responsibility establishes naturally relations of exchange and collaboration with WTO and with WIPO as well. The Director-General of WIPO, Francis Gurry, proposed recently that a WHO highly qualified staff member becomes Deputy Director-General of WIPO[20]. This might generate the risk that WHO accepts more and more tasks of defending IP rights (for example in the case of essential medicines) and of fighting against counterfeit medical products (see below) loosing sight of the aspects strictly related to its mission of public health defence.

THE PARTICULAR CASE OF THE AGREEMENT OF WHO WITH IAEA

The agreement between the International Atomic Energy Agency and the World Health Organization (1959) foresees in its Art.I – Cooperation and consultation :

« 1. The International Atomic Energy Agency and the World Health Organization agree that, with a view to facilitating the effective attainment of the

18. OMC/OMS (2008).

19. However for reasons unknown to us WHO only has an ad hoc observer status at the Council whereas the World Bank, IMF, OECD, UN, FAO, the World Customs Organization, WIPO, UPOV and other international organizations enjoy the regular observer status (see *docsonline.wto.org*).

20. IPW (2009b).

objectives set forth in their respective constitutional instruments, within the general framework established by the Charter of the United Nations, they will act in close co-operation with each other and will consult each other regularly in regard to matters of common interest.

2. In particular, and in accordance with the Constitution of the World Health Organization and the Statute of the International Atomic Energy Agency and its agreement with the United Nations together with the exchange of letters related thereto, and taking into account the respective co-ordinating responsibilities of both organizations, it is recognized by the World Health Organization that the International Atomic Energy Agency has the primary responsibility for encouraging, assisting and co-ordinating research on, and development and practical application of, atomic energy for peaceful uses throughout the world without prejudice to the right of the World Health Organization to concern itself with promoting, developing, assisting, and co-ordinating international health work, including research, in all its aspects.

3. Whenever either organization proposes to initiate a programme or activity on a subject in which the other organization has or may have a substantial interest, the first party shall consult the other with a view to adjusting the matter by mutual agreement. » [21]

After numerous disputes over the lacunae and weaknesses of WHO's interventions in the radioactive disasters caused by Chernobyl and the use by the United States (in Irak) and NATO (im Serbia and Bosnia) of depleted Uranium shells [22], Gregory Hartl, spokesman of the World Health Organization, wrote in 2004:

« The 1959 Agreement with the International Atomic Energy Agency (IAEA) is a classical agreement between

21. OMS (2007), pp. 62-66.

22. Among the last disputes that of Philippe Bovet (*Le Monde Diplomatique*, September 2006), who interprets the text of the agreement in a rather tendentious way: « At the core of this indifference there is the World health organization. Through a 1959 agreement WHO must get an authorization from the International Atomic Energy Authority (IAEA) to start working on these topics ! »

United Nations organisms and has no influence on the impartial and independent exercise of WHO's responsibilities inscribed in its Constitution (promote, develop, help and coordinate the international health action), and does not subordinate WHO to IAEA. »[23]

This is a poor statement because the reasons for these lacunae and weaknesses have never been explained satisfactorily by the persons in charge of this sector (danger of radiations to health) at WHO.

DEFICIENCY OF INITIATIVES IN RESEARCH ON ORPHAN DISEASES

Despite the progress in pharmaceutical investigation techniques the field of *orphan diseases* (i.e. diseases which have been neglected for a long time because of the very high costs of research and the low return on investment for the big pharmaceutical corporations) continue being little investigated. However these diseases are neither benign nor very rare nor difficult to treat. On the contrary they are serious diseases which affect millions of individuals and which could be treated if adequate medicines were studied and put onto the market at prices accessible to poor countries. Clearly it is a fundamental public health sector for the well-being of citizens in particular in DCs but constitute a market where the possibilities of profit are minimal.

It has been estimated that only 16 new molecules out of the 193 patented ones in Europe and in the United States between 1975 and 1999 were specifically developed for tropical diseases which are frequent in DCs[24]. And among this small number of new compounds some had to be withdrawn from the market during this period either because of their dangerous side-effects or because of their high cost or because they were not profitable. For example the leishmaniosis, a disease due to a parasite and which affects about

23. Letter to the *Monde Diplomatique*, April 2004.

24. MSF (2001), Trouiller et al. (2002).

12 million people in tropical countries, is essentially treated by pentavalent antimony. This compound was discovered about 100 years ago and has very serious side-effects and demands a long treatment. Moreover it is losing its effectiveness due to new resistances in the parasite. The example of eflornitine (Ornidyl®) is also interesting: it was proved effective for treating the sleeping sickness. This molecule had been developed by Merell Dow laboratory as an anticancerous medicine but did not find any outlet for this indication; it was thus abandoned by lack of patients with a sufficient buying power! [25, 26]

In 1975 a group of international organizations took the initiative of creating the *Special Programme for Research and Training in Tropical Diseases* (TDR), defined as a *Global and independent programme of scientific collaboration* in view of supporting research on infectious diseases affecting in particular the poor and marginalized populations.

But we had to wait until 2003 for institutions active in the field of health and research [28] to join DNDi (Drugs for Neglected Diseases initiative). In 2003 DNDi thought of investing 250 million dollars over 12 years to develop 6 to 7 medicines for fighting the sleeping sickness, the leishmaniosis and Chagas' disease, three lethal diseases which threaten 350 million persons every year.

From its creation this public/private partnership with no lucrative purpose and committed in R&D on neglected diseases has already obtained concrete results. Two therapeutic associations against malaria have been developed. These two treatments are not protected by any patent and can thus be produced by several manufacturers at competitive prices [29].

The special research and training programme on tropical diseases of WHO (WHO/TRD) participates as an observer to the works of the Scientific Council of DNDi

25. GHW (2005), p. 102.

26. Zio (2005).

27. UNICEF, United Nations Development Programme (UNDP), Worl Bank (WB) and WHO; see Hunt (2006).

28. The Indian Council for Medical Research, the Oswaldo Cruz Foundation (Brazil), the Pasteur Institute (France), the Medical Research Institute of Kenya and the Health Ministry of Malaysia, 7 March 2003.

29. *www.dndi.org*; see DNDI (2009) and MSF/DNDI (2009), (2009a).

to bring its scientific and technical expertise. This is a fairly marginal position in a field where WHO should play a pioneer role. However now there is a Department at WHO which monitors neglected [30] tropical diseases and develops its activities according to a World plan of fight against neglected tropical diseases, 2008-2015.

THE AMBIGUITIES IN THE FIGHT AGAINST COUNTERFEIT MEDICINES

Contrary to the field of orphan diseases that of counterfeit medicines and medical products, certainly dangerous and very active, has noticed the initiative and active intervention of WHO. Confronted to the increasing activities of production, distribution and sale of counterfeit medicines, especially in DCs [31], WHO took the initiative in 2006 to convoke all the parties involved to a meeting in Rome. It was decided to set up a global coalition called IMPACT (International Medical Products Anti-Conterfeiting Taskforce) and to launch the Rome Declaration on this topic [32].

Unfortunately the field of counterfeit medicines is rather slippery and WHO does not seem to have estimated correctly the risks to be led, beyond the real dangers presented by clearly counterfeited medicines, towards a fight against non-authorized products (possibly generic ones) badly labelled and less elegantly manufactured than original medicines. The demands and pressures coming from organizations defending IP rights ended up creating a climate of suspicion towards IMPACT.

For WHO a counterfeit medicine is a product « which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient

30. *www.who.int/neglected_diseases.*

31. See « Selling medicines at the back of a bus », GHW (2005), p. 105 ; « Informal supply ; lack of regulation of pharmaceutical markets is a key problem for many poor countries », GHW (2005), p. 113.

32. WHO (2006a) ; see also the Guidelines on counterfeit medical products, published by WHO, WHO (1999).

(inadequate quantities of) active ingredient(s) or with fake packaging »[33].

However it was noted that so far there is no universal definition of a counterfeit medicine. In particular there is no clear indication that medical products which are not authorized in a given country but are elsewhere cannot be considered as counterfeit products.

A recent and critical analysis made by an Indian NGO – Third World Network (TWN) – describes in detail the dangers of the IMPACT approach towards counterfeiting of medical products and the mistrust of DCs civil societies towards this organization[34]. In particular this text states an objection against IMPACT's programmes which – in order to check whether a pharmaceutical product is counterfeited – would tend to put on the same level extremely different situations:

- erroneous, incomplete, badly worded or possibly absent labels;
- products with a composition different from that indicated and products the dosage of which is less than that indicated;
- bad production or storage conditions which degrade the medicine quality (e.g. excessive exposure to heat and/or humidity), and often very simple conditioning of generics.

This Indian NGOs analysis is seen as a threat by organizations participating in IMPACT which are more interested in defending IP rights than the public health against counterfeit products. Although several general assemblies of WHO examined this problem so far no clear decision has been taken.

The uneasy situation caused by the possible contradictions between preoccupations for public health and IP rights is reflected significantly in the saga of changes in the

33. *www.who.int/medicines/services/counterfeit/faqs.*

34. TWN (2008).

Agenda of the last general assembly of WHO (WHA 62, May 2009) [35]. Some of the documents which had been prepared by the secretariat can still (May 2010) be downloaded from WHO's website and tell about the difficulties met :

« A62/13 (…) :

In the South-East Asia Region combating counterfeit medicines/medical products was discussed by the Regional Committee in 2008. The Committee re-emphasized the importance of the public health focus in combating counterfeit medicines and separating them from intellectual property rights issues. »

« A62/14 (…) :

There is clear consensus among the Taskforce's partners that « counterfeit » medicines should not be confused with issues relating to medicines that are not authorized for marketing in a given country, nor with trademarks or related intellectual property rights issues. Health-related aspects of counterfeit medical products fall within WHO's remit, and the other aspects come under the mandates of other bodies or international organizations. »

It is clearly a field where the vigilance and critical interventions of NGOs active in access to essential medicines can play an important role to avoid that WHO slips on the dangerous slope of IP rights under the guise of public health.

WHO'S PROGRESSIVE AND PROGRAMMED WEAKENING IN THE FRAMEWOK OF INTERNATIONAL ORGANIZATIONS DEVOTED TO PROMOTING AND DEFENDING PUBLIC HEALTH

According to its rules WHO should have a first role and a pioneer function in the field of public health at a global level ; but other powers (transnational institutions

35. The Provisional Agenda EB124/27 if the 6 January for WHO's 62nd General Assembly (18-22 May 2009) contained a point 12.10 : counterfeit medical products, with two attached documents : A62/13 (counterfeit medical products, report of the Secretariat, 30 April2009) and A62/14 (counterfeit medical products ; Special International Group of fight against counterfeiting of medical products (IMPACT), Report of the Secretariat, 30 April 2009) ; see apps.who.int/gb/ebwha/pdf_files/A61/A62_13-fr.pdf (consulted on the 1st May 2010) ; all this has vanished from the final agenda (30 April 2009), where there is no trace of counterfeiting. Certain cuts in WHA62's agenda were subsequently justified by the necessity to shorten the assembly because of the A flu.

like for example the World Bank and the International Monetary Fund) have increased their working space among the decision-makers. In this space they often carry more weight than WHO.

« The growing influence of neo-liberal economy and the attacks against multilateralism driven by the United States have created a difficult context for WHO's work. This organization, deprived of resources and sometimes badly guided is not capable of finding an efficient response. [36] » The influence of private foundations (e.g. Gates, see box p. 64) and of certain projects of public-private collaboration (e.g. GFATM, GAVI [37]) continues increasing and the question of WHO's position in this new situation is not yet solved [38].

With the same questions and preoccupations as these experts UNAIDS (the common programme of the United Nations on HIV/AIDS), UNITAID [39] and the Global Fund to Fight AIDS, Tuberculosis and Malaria can be quoted [40]. The latter is a public-private collaboration structure between governments, NGOs, private firms and communities affected by these diseases ; this structure is presented as a new approach to the international financing of health.

Another particularly interesting example is that of the Global forum : « The mission of the Global forum for health research is to focus research efforts on the poors health (…). This is an international independent Geneva based foundation, funded by the Rockefeller Foundation, the World Bank, WHO and the governments of Canada, Ireland, Mexico, Norway and Switzerland. » [41] Among the topics discussed during the Forum 10 (Cairo, 2006) one finds : research on neglected diseases ; during the Forum 11 (Beijing, 2007) : the impact of poverty and gender on health, the role of innovation. All these topics seem to be part of the core mission of WHO.

36. GHW((2005), p. 269.

37. GFATM : The Global Fund to fight AIDS, Tuberculosis and Malaria : World Alliance for vaccines and immunization.

38. GHW (2005), p. 275.

39. UNITAID was created in September 2006 to support the efforts made at present to fight HIV/AIDS, malaria and tuberculosis. « UNITAID's mission is to contribute facilitating the access of populations of developing countries to treatments against HIV/AIDS, malaria and tuberculosis by reducing the price of medicines and quality diagnostic means, which are today too expensive for most of the developing countries and to make this as rapidly as possible. » *www.unitaid.eu*.

40. *www.theglobalfund.org* ; in its international council one finds WHO, UNAIDS and the World Bank.

41. Global Forum (2006), (2008).

WHAT HAS THE GATES FOUNDATION DONE FOR GLOBAL HEALTH ?

« The massive boost to global health funding that the Bill & Melinda Gates Foundation has given since its inception in 1994 is astonishing. The Foundation's current expenditure of around US$3 billion annually has challenged the world to think big and to be more ambitious about what can be done to save lives in low-income settings. The Gates Foundation has added renewed dynamism, credibility, and attractiveness to global health. In particular, the Foundation inaugurated an important new era of scientific commitment to global health predicaments. For example, other more well-established funding organisations—such as the US National Institutes of Health—now take their international health responsibilities far more seriously thanks to the Foundation's energetic advocacy. Perhaps even more important is the fresh and deep political commitment to health that the Foundation has fostered.

(…) The concern expressed to us by many scientists who have long worked in low-income settings is that important health programmes are being distorted by large grants from the Gates Foundation. For example, a focus on malaria in areas where other diseases cause more human harm creates damaging perverse incentives for politicians, policy makers, and health workers. In some countries, the valuable resources of the Foundation are being wasted and diverted from more urgent needs. (…) The first guiding principle of the Foundation is that it is « driven by the interests and passions of the Gates family ». » [42]

Extract from an editorial recently published in The Lancet

42. *The Lancet*, 9 Mai 2009, Editorial : « What has the Gates Foundation done for global health ? »

Other example : with all its financial might the Carter Center entered the integrated monitoring of neglected tropical diseases [43] (integrated, global, are now keywords in titles of public health projects). According to the Center it is « a neglected opportunity which can now be seized ». And numerous initiatives from private foundations can be seen proliferating to save public health on our planet in lieu and place of WHO.

On the basis of official documents it is difficult to appreciate what is the current reaction of WHO's direction towards this proliferation of organisms devoted to public health and to the definition of some aspects of health policy. Undoubtedly additional funds were brought by this proliferation to fight some of the severest and widespread diseases. It has given birth to new initiatives like that of the Patent pool for medicines [44]. However at the same time it took away from WHO its central role in the definition and implementation of a coherent, integrated and global public health policy.

Below we shall examine the developments of new projects, stimulated by WHO, in the fields of innovation, intellectual property and public health.

4.2 *FROM THE INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH (CIPIH) TO THE INTERGOVERNMENTAL WORKING GROUP ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY (PHI)*

In May 2003 during the World Heath Assembly (WHA56) WHO voted the creation of an ad hoc commission, CIPIH, whose objective is to present a global analysis of the effects of the IP regime on access to essential medicines in DCs and of the potential role

43. The Carter Center, Atlanta, Georgia, USA ; WHO/Carter (2008).

44. « The idea supported by the patent pool is that patent holders – firms, researchers or universities. put voluntarily to the disposal of the community their patents, against payment of royalties. This mechanism is not new, what is new is its use for innovation in the medicines field. » UNITAID got the green light to create a patent pool on the 3 July 2008. See *www.unitaid.eu*.

See also : *www.msf.fr/2008/08/05/884/la-communaute-de-brevets-une-solution-pour-resoudre-le-probleme-de-laces-aux-medicaments.*

www.avocats-publishing.com/348-LES-PATENT-POOLS.

www.wipo.int/patent-law/fr/developments/standards.html.

of innovation in the development of new medicines for DCs specific diseases.

CIPIH

This resolution asked WHO to « establish the terms of reference of an appropriate organ of limited duration » which should have « submitted a status report to the 2004 Assembly (WHA57) and a final report with concrete proposals to the Executive Council at its hundred and sixteenth session of May 2005 … » In its analysis the Commission shall envisage how IP rights can be applied so as to stimulate a research and innovation which take public health into account. It shall also analyse how financing and other forms of encouragement, in particular the participation of institutions, can orientate research and innovation in this sense [45]. It is interesting to notice that the Commission was created for a limited duration and that its terms of reference would expire as soon as concrete proposals would have been presented to WHO's Executive Council. Nevertheless and, as it will be discussed below, the structure and the terms of reference of PHI which succeeded CIPIH in 2006 are quite different.

CIPIH was born in 2004 « to collect data and proposals from the different actors involved and produce an analysis of intellectual property rights, innovation, and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries [46] ».

At the first meeting of the Commission (April 2004) Lee Jong-Wook, WHO's Director-General at the time, stated : « Bold and innovative thinking is required – not only to find technical solutions but to find economic, social and political ones as well » and Ruth Dreifuss, chairperson of the Commission, insisted : « (…) medical science tends to focus disproportionately on diseases and ailments of the developed world » [47].

45. *www.who.int/intellectualproperty/fr.*

46. Abstract from the CIPIH Secretariat, *www.who.int/intellectualproperty/fr.*

47. WHO/CIPIH (2004).

An intense activity of organization and initiatives followed the first Commission meeting; it was to define the role and the limits of IP rights and innovation in the access to medicines and, in a more general way, in the improvement of public health. CIPIH produced a large number of reports, thematic studies, documents by a wide range of decision-makers; it also organized many meetings to discuss them [48]. An intermediate report followed in 2005 [49], and a final report was published in 2006 [50]; then the Commission was dissolved.

The final Report defines the terms of reference which WHO had given to CIPIH:

« [The Commission]

- Summarize the existing evidence on the prevalence of diseases of public health importance with an emphasis on those that particularly affect poor people and their social and economic impact;
- Review the volume and distribution of existing research, development and innovation efforts directed at these diseases;
- Consider the importance and effectiveness of intellectual property regimes and other incentive and funding mechanisms in stimulating research and the creation of new medicines and other products against these diseases;
- Analyse proposals for improvements to the current incentive and funding regimes, including intellectual property rights, designed to stimulate the creation of new medicines and other products, and facilitate access to them. »

In the Report in the specific field of access to essential medicines the recommendations that the Commission presented to International Organizations (including WIPO as far as the protection of intellectual property rights is concerned), to member States and to the pharmaceutical industry are coherent with the terms of

48. The site *www.who.int/intellectualproperty/topics* still contains most of these documents (consulted in June 2009); see also WHO/CIPIH (2007) for frequently asked questions on CIPIH.

49. OMS/CIPIH (2005).

50. OMS/CIPIH (2006)(quoted in what follows as « the Report »);see also WHO/CIPIH(2006). The report is found online at: *www.who.int/intellectualproperty/documents/thereport/FRPublicHealthReport.pdf*. The WHO Bulletin then published a thematic issue devoted to the final report and to the necessary broadening of the themes treated so as to cover ethical problems, human rights and patents on living species, WHO (2006).

reference received but often cover a field much larger than the only problem of neglected diseases :

« 4.6 All companies should adopt transparent and consistent pricing policies, and should work towards reducing prices on a more consistent basis for low and lower middle income developing countries. Products, whether originator's or generic, should be priced equitably, not just in sub-Saharan Africa and least developed countries, but also in low and lower middle income countries where there are a vast number of poor patients. » [51]

« 4.12 Governments should remove any tariffs and taxes on health care products, where appropriate, in the context of policies to enhance access to medicines. They should also monitor carefully the supply and distribution chain to minimize costs that could adversely influence the prices of medicines. » [52]

The Report also recalls the relevant aspects of the TRIPS Agreement and the Doha Declaration and criticises the inertia of the DCs governments :

« 4.13 The Doha Declaration clarifies the right of governments to use compulsory licensing as a means of resolving tensions that may arise between public health and intellectual property, and to determine the grounds for using it. Developing countries should provide in their legislation for the use of compulsory licensing provisions, consistent with the TRIPS agreement, as one means to facilitate access to cheaper medicines through import or local production.

4.14 Developed countries, and other countries, with manufacturing and export capacity should take the necessary legislative steps to allow compulsory licensing for export consistent with the TRIPS agreement.

4.15 The WTO decision agreed on 30 August 2003, for countries with inadequate manufacturing capacity,

51. OMS/CIPIH (2006), p. 180.
52. *Op. cit.*, p. 180.

has not yet been used by any importing country. Its effectiveness needs to be kept under review and appropriate changes considered to achieve a workable solution, if necessary. » [53]

In Appendix to the Report there are personal contributions by Commission members ; some deplore that the Commission did not go far enough in the criticism of the IP regime [54] ; on the contrary some others deplored the fact that the IP regime was considered necessarily negative for the access to medicines [55].

It can be deplored that CIPIH had such a brief existence and could not make full use of the vast material assembled between 2004 and 2006. As can be seen below the permanent international structure which succeeded it fits well into the framework of a bureaucratic system dominated by governments and their interests. So WHO's role has weakened even if the resolution approved by the World Health Assembly in 2008 states that « the public health, innovation and intellectual property strategy is designed to promote new approaches to pharmaceutical research and development ».

PHI (INTERGOVERNMENTAL WORKING GROUP ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY)

The CIPIH report, which presented many concrete proposals to WHO's Executive Council, was followed by the creation of an intergovernmental working group on public health, innovation and intellectual property (IGWG) [56]. This group composed of Member States of WHO [57] held its first session from the 4th to the 8th December 2006 in Geneva.

This new structure testifies the compromise achieved to come out of the deadlock in which CIPIH was stuck. In this sense in a conference held in Geneva

53. *Op. cit.*, p. 145.

54. « The report deals with the deep distortions, without going deep into them, observed at present in the functioning of the patent system which enables the proliferation of pharmaceutical patents on small ameliorations hindering the competition of generic products. (…) We deplore that the Commission was not able to develop further the proposals aiming at mobilizing financial resources and scientific capabilities, notably those which are available in developing countries and necessary to fight against disease affecting mainly the poor. » Carlo Correa and Patkee Pothisiri, *op. cit.*, p. 235.

55. « There is a confusion in the report between what is called evergreening and incremental innovation which is the very basis of medical progress and which requires a good protection of intellectual property rights to stimulate more innovation. », Trevor Jones, *op. cit.*, p. 236 ; see also Fabio Pamolli, p. 237 and Hiroko Yamane, p. 238.

56. Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, voir Chan (2007), WHO/ PHI (2007), (2008), (2008a).

57. Switzerland participates in it : the Swiss representative is M.G. Silbershmidt, from OFSP ; see OMS/PHI (2006).

on the 22th January 2007 Sisule F. Musungu (then programme coordinator affiliated to South Center) asked himself on the context of its creation : « The reason of IGWG is simple but nevertheless important to recall. The necessity of IGWG appeared because CIPIH, for different reasons, could not achieve its mission (…). » [58]

To support the work of IGWG, WHO set up in September 2006 a secretariat for public health, innovation and intellectual property (PHI) :

« The Secretariat on Public Health, Innovation and Intellectual Property (PHI) was initially established by WHO to facilitate implementation of Resolution WHA 59.24.

That resolution requested the Director-General to convene an Intergovernmental Working Group (IGWG) to draw up a global strategy and plan of action aimed at, inter alia, securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries. The IGWG completed its work in May 2008, when the Sixty-first World Health Assembly adopted Resolution WHA 61.21 : Global strategy and plan of action on public health, innovation and intellectual property. » [59]

PHI's first session took place in Geneva from the 4th to the 8th December 2006 and established a first Report [60] which was presented to the World Health assembly in May 2008 [61]. Between the context, the aim, the principles, the elements … one navigates again among a high number of statements on necessary actions and often trivial remarks. This report sounds rather bureaucratic in the *international organization* style and the hope that all the work initiated by CIPIH will bear fruits seems to fade away.

58. Musungu (2007).

59. *www.who.int/phi/about/fr* (consulted on the 8 May 2010).

60. This Report also gives the list of the member states of PHI and the participants, OMS/PHI (2006).

61. WHO/PHI (2008b), only in English.

A global analysis of the momentum which led from the creation of CIPIH to that of PHI, with its increased weight of state structures and private interests goes well beyond this document. A first attempt of analysis will be found in a work ordered by the human rights Council for a meeting of the Working Group on the right to development (April 2009)[62]. In particular it will be noticed how when passing from the CIPIH report to that of PHI the sentences which pilloried the articles of the TRIPS-plus type in the free trade treaties were watered down and transformed into recommendations[63]

62. Forman (2009); it can be read online at: www2.ohchr.org/english/issues/development/right/docs/A-HRC-12-WG2-TF-CRP5-Rev1.pdf).

63. *Op. cit.*, p. 15.

CHAPTER 5

MULTILATERAL AND BILATERAL RELATIONS

THE REINFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS BEYOND THE STANDARDS FORESEEN BY THE TRIPS AGREEMENT

In Chapter 1 devoted to WTO we saw in detail the role played by this organization in the right of international trade and the multilateral agreements inscribed in the framework of the TRIPS Agreement. We also evoked the implementation and the evolution of the TRIPS standards, the difficult balance between intellectual property and development, and especially, as far as public health is concerned, the new obstacles to the access to medicines and medical care for the economically weakest populations.

In a 2003 article, J.F. Morin, who described particularly the case of the United States, depicts the situation in this way : « The controversial Agreement on the trade-related aspects of intellectual property rights (TRIPS) is being progressively overtaken by a series of bilateral agreements. At the time of the creation of the World Trade Organization (WTO) in 1995 the TRIPS Agreement was considered as the « new frontier » of international patents right (…) the strong dispute inside WTO on the patentability of essential medicines, partially resolved in 2003 by the Doha Declaration on public health, might have led us to believe that the TRIPS Agreement was still

the driving force of the international patents rights. Although the media attention is focused on multilateral organizations like WTO and on big international summit meetings like that of Doha, the limits of the international patents right is being pushed further by the decree but no less efficient approach of bilateral agreements. » [1]

As far as medicines are concerned one of TRIPS Agreement's missions was to put into place the patent system in the framework of intellectual property. But a new series of free trade agreements (FTA's), negotiated outside WTO, impose even higher levels of protection of IP rights. The measures foreseen include the extension beyond twenty years of the patents duration, the interdiction of using the results of clinical research on the effectiveness and harmlessness of protected medicines, the commercialisation of generic products during a certain period of time and, in some cases, the limitations to grounds for justifying the granting of compulsory licences [2; 3].

However for Morin « The multilateral approach presents several advantages in international negotiations on patents. First it enables replacing a series of bilateral negotiations which monopolise time and precious resources. Then it promotes harmonization of the different national legislations, which translates into a simplification of procedures and a cost reduction in transactions for national patent offices and for patent applicants. So from the XIXth century with the Paris Convention for the Protection of Industrial Property, the international patent regime has progressed via a multilateral approach [4]. With the adoption of the TRIPS Agreement the driving force of the international patent system passed from the World Intellectual Property Organization (WIPO) to WTO but remained at the multilateral level. » [5]

1. Morin (2003).

2. Compulsory licences are referred to when the public authorities authorize a third party to manufacture a patented product or to use a patented process without the holder's consent. This is one of the flexibilities foreseen by the WTO TRIPS Agreement. See the WTO Internet site : *www.wto.org/french/tratop_f/trips_f/public_health_faq_f.htm*.

3. Correa (2006a).

4. Paris Convention on the protection of industrial property of the 28 March 1883.

5. Morin (2003).

BILATERAL TREATIES

Bilateral treaties are direct and individual agreements between two or more countries. The European Union for example has specific partnership agreements with ACP countries (Africa, Carribean countries, Pacific countries). At the time of the agreement adoption (Lomé Convention) EU is a supranational entity representing 15 nations when the ACP group numbers 78 member states from Africa, Carribean and Pacific countries. This partnership defines mutual relations in terms of trade, aid and migration inter alia. Though it concerns 93 countries, this treaty is considered as bilateral in the sense that it was negotiated between two collective blocks. Identical synergies can be seen with the African Growth and Opportunity Act, AGOA and the Andean Trade Preference Act, ATPA which define the trade privileges of the United States with 34 subsaharan African countries for the former and 5 Andean countries for the latter.

A single policy applied to all countries and which was allegedly accepted by both parties determines which are the advantages and eligibility conditions[6]. Such agreements make the term bilateral extremely vague and necessitate to take great precautions. Basically the importance is for countries to get together either in a couple or in a group to negotiate special economic relations based on rules which only apply to them[7].

These agreements can deal with various topics such as trade, investments, scientific research, cooperation or development aid or intellectual property. The most important agreements as far as economic relations are concerned are trade and investments. However these five types of bilateral treaties have one thing in common : they often contain obligations to respect by signatories, i.e. agreements on intellectual property rights on living species. These measures often go well beyond the TRIPS Agreements.

6. AGOA is governed by the national law of the United States. It was not negotiated between the United States and Africa. However the United States claim that the criteria on which it is based are accepted by the beneficiary governments. *www.agoa.gov/Contact_us_FAQ/FAQ/faq.htm*.

7. Grain (2001).

TRIPS-PLUS MEASURES

The TRIPS Agreements only represent a minimum standard, largely insufficient for industrial countries and transnational corporations involved. One after the other developed countries negotiate special closed arrangements with governments of the South in view of reinforcing intellectual property rights on biological resources. These TRIPS-plus standards are put into force through a series of bilateral, regional or sub-regional agreements. The governments of developing countries are forced to go well beyond their obligations foreseen by the multilateral trade system of WTO. So far that even the TRIPS Agreements will soon become obsolete.

For Carolyn Deere bilateral agreements constitute the most powerful form of economic pressure used by developed countries to enforce the TRIPS-plus reforms of IP. They prepare a world environment ready to accept the plus-standards. She describes some examples of these TRIPS-plus dispositions in bilateral agreements showing the dangers which they present[8]:

- **Shorter transition periods:** some countries can be forced to give up certain privileges related to transition periods of the WTO regime. Certain agreements for example stipulate the application of patent rights within shorter delays than those requested by the TRIPS Agreement.
- **New obligations:** certain countries can be forced to extend patents to new items, to give up certain exceptions, to increase the demands requested for copyright, to adopt the 1991 UPOV[9] style in the protection of plant varieties, to supply patents for biotechnological inventions, to adopt restrictions as to the grounds enabling the granting of compulsory licences[10], to adopt restrictions on parallel[11] imports among other limitations.
- **More binding international standards:** many EU states request the respect – in the DCs –

8. Deere (2009) p. 152.
9. See Chapter 4.
10. CSSR (2006) p. 95.
11. *Op. cit.* p. 96.

of IP criteria complying with international standards. Since these « international standards » are being continuously modified it is hard to understand this expression.

– **Restrictive interpretations of TRIPS dispositions:** DCs often have to adopt the interpretation of TRIPS dispositions from the counterpart with which they negotiate the bilateral agreement, i.e. adapt to the standards of the EU or of the United States [12].

In 2001 the organization GRAIN studied bilateral agreements signed between developed and developing countries. This study showed how DCs are incited to accept TRIPS-plus standards in matter of biodiversity [13]. Five types of treaties were investigated which relate to trade, investment, international aid, science and technology and intellectual property rights.

According to the object of the agreement, TRIPS-plus characteristics can be distinguished [14]:

1. For animals and plants:

Extension of protection standards such as:

– **reference to UPOV**
UPOV is not a reference in the TRIPS Agreement. There is no explicit yardstick for an « efficient sui generis system » and developing countries think they have options other than UPOV;

– **No exception to the obligation of patenting living species**
Countries are authorized by the TRIPS Agreement to exclude patents on plants and animals;

– **Reference to « the strictest international standards »**
The « strictest international standards » is a vague concept and without any precise reference to the

12. Deere (2009) p. 152 ss.

13. Considering the number of these treaties easily reaches one thousand GRAIN only studied those concerning the United States and Europe (systematically), and Japan, Australia and Switzerland as well (very partially) between March and June 2001.

14. GRAIN (2001).

TRIPS Agreement. Though this is not automatically characteristic of the TRIPS-plus Agreement it is highly suspicious especially when the clause of the most favoured nation in the framework of bilateral investment treaties comes into play.

2. For micro-organisms:

– **Obligation to adhere to the treaty of Budapest** [15; 16]
There is no reference to the treaty of Budapest in the TRIPS Agreement. This treaty compels the parties to recognize the physical deposition of micro-organisms instead of the complete description of the invention under the aegis of an international deposition authority.

3. For biotechnology:

Obligation to protect biotechnological inventions.

– There is no reference to biotechnology in the TRIPS Agreement. A new category of intellectual property protection is introduced here. When it is not stated it also implies the possibility of patent protection on plants and animals.

Another sensitive point is the question of the use of a known product. As mentioned above the TRIPS Agreement remains ambiguous: is this new use patentable? the question has remained open. The United States' law considered that:

« [WTO] Members can also exclude from patentability: diagnostic, therapeutic and surgical methods for the treatment of persons or animals. [17] » [18]

So a member state of WTO can refuse to patent a new use of a product known for treating cancer but recognized later efficient in the treatment of AIDS.

15. WIPO data base on legislative texts of intellectual property. Budapest treaty on the international recognition of micro-organisms registration in view of obtaining a patent, made in Budapest on the 28 April 1977, and modified on the 26 September 1980.

16. Swiss Confederation, RS0232.145.1 Budapest treaty on the international recognition of micro-organisms registration in view of obtaining a patent. Signed in Budapest on the 28 April 1977. Approved by the Federal Assembly on the 10 March 1981. Ratified by Switzerland on the 189 May 1981. Came into force for Switzerland on the 19 August 1981 (State on the 27 January 2009), *www.admin.ch/ch/f/rs/0.232.145.fr.pdf*.

17. TRIPS Agreement, section 5 of Part II, Patents, article 27, § 3a.

18. Kantor (2005).

The treaties signed by the United States with Australia, Marocco and Bahrain do not authorize this flexibility. The agreement signed with Australia stipulates that « each new use or new method of use of a known product necessitates access to a patent ».

The agreements with Marocco and Bahrain go further still. They mention precisely that the patentability of new uses of known products includes the ones which « are used for he treatment of men or animals » [19]. Generally if a rule is adopted in one treaty it is kept in the next ones ; one can well imagine that the United States will use the agreements with Australia, Marocco and Bahrain to convince the Andean countries to change their laws so as to permit the patentability of a second therapeutic use of medicines already known. If one refers to the DR-CAFTA treaty which commits some Central American countries and the European Union, what will be seen below in detail, Guatemala did modify its legislation in this sense after the agreement's implementation [20].

With Morin one can think that if free trade agreements are legally compatible with the Doha Declaration on public health they contravene its spirit. The Doha Declaration was clearly adopted to safeguard the flexibilities for developing countries so as to maintain a minimum protection [21]. If a member of WTO wants to increase its standards on patents the decision should come from an internal process and not be imposed by a foreign party, be it a transnational corporation through a private contract, an international organization through a technical programme or a foreign country through a bilateral treaty.

Among the means of economic pressure used to let TRIPS-plus reforms be accepted the rich countries resort to bilateral commercial agreements [22;23]. These are generally negotiated in the strictest confidentiality : the texts are kept secret up to the moment they are

19. Morin (2006).

20. Cerón et al. (2009).

21. Abbott,on *www.geneva.quno.info/pdf/OP14Abbottfinal.pdf.*

22. Deere (2009).

23. IPW (2008).

accepted. Parliaments and senates are not consulted, public opinion is kept out. In general only trade, finance and foreign affairs ministers are invited to participate in their elaboration » [24].

BIG TYPES OF TRADE AGREEMENTS PROPOSED BY RICH COUNTRIES

From the coming into force of the TRIPS Agreement the United States have signed a large number of free trade agreements (FTA) containing TRIPS-plus dispositions (Bahrain, Central America and Dominican Republic, Chile, Colombia, Jordan, Marocco, Oman, Panama, Peru, Singapore, South Korea).

In 2006 the democratic party obtained the majority at the United States Congress and as a consequence a new round of negotiations of agreements with Colombia and Peru which had not yet been ratified. In both cases some TRIPS-plus dispositions were watered down.

The United States had also signed another type of framework agreements [25] with DCs and regional groups of states which contained neither TRIPS-plus chapter nor explicit commitments but an article underlining the signatories commitment to promote the protection of intellectual property, and even more: in certain cases to consider more binding IP standards in the future [26].

DR-CAFTA AGREEMENT, AN EXAMPLE OF FTA

To evaluate the dynamics of national and international laws and their effect on public health Cerón and Snodgrass Godoy examined the free trade agreement passed between Central America, the United States and the Dominican Republic (DR-CAFTA). They present this agreement as an example of the application of IP legislation and distinguish three types of situations [27]:

24. *Op. cit.*

25. Trade and Investment Framework Agreement (TIFA).

26. Deere (2009) p. 151 ss.

27. Cerón et al. (2009).

- the countries which implemented IP standards more binding than those requested by trade agreements;
- the countries which had adopted this type of IP protection measures even before signing these agreements
- the countries where the agreement ratification generated a public debate on questions of IP, what consequently increased the weight of public health in the IP legislation.

This last case comes near that of South Africa where the apparently inexorable evolution towards a stronger and stronger IP protection was thwarted by a large mobilisation and a defence of flexibilities proposed by the TRIPS Agreement, notably as far as compulsory licences are concerned [28].

The DR-CAFTA agreement served as a basis for trade agreements with Colombia, peru and other latin American countries.

All CAFTA countries are WTO members. To comply with the TRIPS Agreement Salvador undertook its first IP legislation in 1993-1994, the other countries of this region undertook it in 1999-2000. Previously in the area, like in the rest of the world, IP protection was not really applied to pharmaceutical products. Though the same pressure was applied on all central American countries to adopt the new IP legislation, its content and the political will as well have varied considerably from one country to another and even within a country with time.

The DR-CAFTA Agreement was ratified by a small majority of the United States Congress in August 2005 after being ratified by the Dominican Republic, Salvador, Guatemala, Honduras and Nicaragua a little earlier this year. Costa Rica approved it by referendum at the end of 2007. On certain key points the Agreement imposes a more binding standard than

28. See: Hamel (2001).

that of the TRIPS one under the form of TRIPS-plus; in particular this was the case with Guatemala where a restrictive IP legislation was adopted before ratification but political disputes related to the ratification process led to the refusal of such a legislation in favour of alternative solutions more receptive to public health. In other cases the laws were not passed before 2007.

The TRIPS Agreement set standards which were subsequently replaced by DR-CAFTA that many central American countries chose to interpret so that the IP hurdle was placed still higher. The TRIPS Agreement set for the first time the patent duration to 20 years. The DR-CAFT Agreement set this limit beyond 20 years.

Although in the area concerned by the CAFTA Agreement all the countries are subject to the same international laws particular legal dispositions in each country, political will and available resources to apply these laws cause radically different consequences between these countries. So health and in particular access to medicines is very dependent on the trade system of the country. Multiple factors influence the national praxis in a particular field: wish to join the regional trade agreement, currying favour with the United States, national political tensions.

In the Dominican Republic and in Guatemala the United States continued putting pressure to bear for higher IP standards, even after the agreement was ratified.

The fact that some countries adopted higher standards of intellectual property after ratification can reflect a lack of foresight in the elaboration of national legislation but can also be due to the pressure exerted by powerful economic partners.

In each country the ratification process allows a certain democratic participation and political mobilisation over the right to health.

In central America the ratification of the DR-CAFTA Agreement generated more disputes than that of the TRIPS Agreement which had preceded and had not caused great debates. The best example of democratic participation is that of Guatemala where the commitment of the civil society to the ratification process led to the abrogation of a more restrictive IP legislation in favour of alternate solutions more sensitive to public health. In these countries where the mobilisation over these topics is stronger (than in our rich countries) it can be feared that the exclusive insistence on the ratification process can obscure the multiple facets of intellectual property policy. Nevertheless this process is an important moment of debate for public health defenders.

The discussions on the ratification process of the agreement kept the spirits awake over the impact on public health, but after the agreement was ratified the attention of the public relaxed and the field was wide open to the new IP dispositions. The defence of public health must not only be limited to the text of the agreement.

In central America many generic medicines are being imported from countries outside the area, notably from Colombia and India. In answer to the increasing demands of the free trade American agreements in matter of IP (in the case of Colombia) the direct challenges of American pharmaceutical corporations (like in India) and the political pressure of the American and other governments these countries reinforce their national IP legislation what has inevitably a direct impact on the medicines they export. In central America and in other regions without large capacities for medicines production, the availability of generic medicines is not only influenced by local legislation but also by decisions taken in remote tribunals. So the arrival of affordable medicines can be blocked at the source.

In seeking to understand and fight the effects of IP on the access to affordable medicines the different protagonists of the civil society must be receptive to national particulars and to changes at the international level as well.

CHAPTER 6

NON GOVERNMENTAL ORGANIZATIONS (NGOs)

An NGO is commonly defined as a non governmental association with no lucrative purpose. Usually NGOs have an official structure and are in most cases registered towards national authorities. They are more and more involved in international negotiations of which they can sometimes influence the agenda and the running. Here we shall examine especially those which are active in the field of IP and public health.

NGOs ACTION AND TRIPS AGREEMENT

In its 2002 report the Commission on intellectual property[1] rights states « we were struck by the magnitude and influence of the NGOs recent activities in matter of IP. We think that NGOs make and can continue to make in the future a positive contribution to promoting the interests of developing countries. The NGOs campaigns aiming at making public opinion well receptive in the fields of development and health have been important elements which bolstered the cause of developing countries during the negotiations of Doha ministerial Declaration. »

The participation of NGOs in the international debates relative to the TRIPS Agreement started as from the last phases of the Uruguay Round. Between 1993 and 1995 NGOs like Third World Network (TWN), Health Watch International (HWI) and GRAIN published articles

1. CIPR (2002); British Commission of Intellectual Property Rights. The British Government had created this commission to respect the commitment made in its second White Paper on international development entitled « Eliminating World Poverty: Making Globalization Work for the Poor » (December 2000). This commission is composed of experts from different horizons and various countries and chaired by John Barton, law professor at Stanford University. It handed over its report entitled « Integrate intellectual property rights and development policy » to the British Government in 2002.

putting in evidence the impact of this Agreement on development, public health and agriculture [2; 3; 4]. Between 1999 and 2002 NGOs working in the fields of public education and human rights started participating in debates on IP protection; campaigns were launched , notably on access to medicines or seeds (for example the MSF campaign entitled « Access to Medicines Campaign » was launched in 1999 [5]). During the WTO Ministerial Conference in Seattle in 1999 MSF and OXFAM called for the setting up of a working group on access to medicines; TWN established a dialogue with a group of delegates from African countries at WTO and encouraged them to undertake coordinated actions with Brazil and India on the problem of intellectual property and access to medicines.

In 2000 MSF called on the countries of French-speaking Africa not to sign the Revised Bangui Treaty [6]. These countries numbering 16 [7] are regrouped inside the African Organization of intellectual property (AOIP), which delivers the medicines patents to them. This Bangui Agreement which governs IP protection at the regional level was signed a first time in 1997 and then submitted to a revision in 1999 by AOIP in view of making it compliant with the TRIPS Agreement; in so doing the standard conditions of IP protection were reinforced significantly. This revision excluded practically AOIP countries from the two margins of manoeuvre allowed by the Doha Declaration: the revised Bangui foresees that compulsory licences can only be granted to AOIP regional operators what makes their use highly improbable, if one considers the weak industrial potential of this region; parallel imports are limited to the AOIP region as well, what reduces considerably their effect.

For example one of the damageable consequences of the ratification of such a treaty for French-speaking African countries will be the impossibility to import low cost generic medicines such as antiviral products

2. Das (1998).

3. Hathaway (1993).

4. Drahos (1995).

5. MSF (1999).

6. MSF (2000).

7. The African countries inside AIPO are: Bénin, Burkina Faso, Cameroon, Congo, Ivory Coast, Gabon, Equatorial Guinea, Mali Mauritania, Niger, Centrafrican Republic, Senegal, Chad and Togo. Equatorial Guinea is not a member of WTO and has no obligation to apply the TRIPS Agreement.

from Brazil or India. Despite the invitations by MSF and other associations committed in the campaign for access to medicines for refusing to sign this treaty it came into force in 2002. One of the consequences of this ratification was that the poorest of the French-speaking African countries saw the obligatory limit date for applying the TRIPS Agreement[8] advancing by about 10 years.

In February 2001 OXFAM International launched a Cut the Cost campaign the aim of which was to obtain a revision of the TRIPS Agreement in favour of public health. As was seen in Chapter 2.4, in 2004 coordinated actions among various developing countries and various NGOs were launched asking for a development agenda at WIPO[9] and for a new treaty for access to knowledge as well (*Access to Knowledge*, A2K).

In the Spring of 2001 at Pretoria a trial started against the South-African Government by 39 pharmaceutical firms. The latter is accused of violating the intellectual property rights by adopting in 1997 a law favouring the use of generic medicines. Following violent critiques from a large number of NGOs, from the public opinion and from the press everywhere in the world the 39 laboratories withdrew their complaint without the South African Government modifying its law. « This trial was a model for two reasons. On one hand (…) private interests were opposing general interests. On the other hand the unfolding of the trial revealed a new power play : claims of South African patients were taken into account by the justice system ; the associations of South African patients which were previously opposed to their government sided with it ; the international public opinion was mobilised so that the patients of poor countries be given a extended access to medicines ; the Western press contributed largely to tarnish the image of pharmaceutical laboratories – including the financial press which cut off its solidarity with private industry ; the political powers of rich

8. Deere (2009) ; see Chapter 4 : « NGOs, civil society, and Think Tanks ».

9. *www.twnside.org.sg/title2/twninfo163.htm* ; see also Déclaration de Genève (2005).

countries which originally supported the pharmaceutical industry when it lodged its complaint withdrew progressively their support » [10].

In 2007 Novartis launched two complaints against the Indian state : an appeal against the rejection by an Indian court of its application for a patent on Glivec, medicine against a form of leukaemia (chronic myeloid leukaemia) and a complaint against the Indian law on the ground of noncompliance with WTO rules. The Bern Declaration – a Swiss NGO, supported by other organizations like MSF – and Swiss political personalities among whom the former health minister, Mrs Ruth Dreifuss, sent a letter to Daniel Vasella, chairman of Novartis. They let their indignation known as to these new attempts to restrict the flexibility available to DCs for adapting the TRIPS Agreement to their public health needs [11] (Novartis was one of the 39 pharmaceutical industries which sued the South African Government, see above).

In August 2007 before the High Court in Chennai, India, Novartis lost its two cases. Hence Novartis applied again twice for a patent on Glivec. According to the Bern Declaration « When thousands of human lives are at stake in India and elsewhere Novartis refused to accept the passed court decisions and lodged once more a new appeal. However world sales of Glivec neared 4 billion Swiss francs in 2008. This medicine does not need a supplementary patent in India to yield a good financial return » [12].

After the Doha Declaration other NGOs were created such as Trade-Human Rights-Equitable Economy (3Dthree) which made explicit the relation between IP protection, human rights and access to medicines [13]. In 2005 a series of NGOs called for a moratorium at WTO on regional and bilateral agreements containing TRIPS-plus standards which undermine the access to health in developing countries [14].

10. Hamel (2001).

11. DB (2006).

12. DB (2009a).

13. 3D (2005a,b) ; (2006) ; (2006a,b).

14. Working Agenda (2005).

In 2006 CSSR established in Geneva published a booklet which analysed the impact of the TRIPS Agreement on access to medicines[15]. In 2008 at the start of the negotiations in view of signing a free trade bilateral agreement between EFTA and India several Indian NGOs made known their preoccupations by the claims of Switzerland (EFTA member) in favour of reinforcing IP in India; this would have had as a consequence a restriction of access to seeds and vital medicines; two NGOs established in Switzerland, the Berne Declaration and Alliance Sud, organized a meeting between representatives of the Swiss federal Administration to discuss Switzerland's objectives in this agreement (the problems caused by bilateral agreements were discussed in Chapter 5).

ACTION STRATEGIES OF NGOs[16]

The action strategies of NGOs are variable. They go from organizing conferences to campaigns with a well defined profile or to calls on the national and international media. In Geneva, international NGOs such as CPTech (Consumer project on technology), CIEL (Center For International Environmental Law), International Center for Trade and Sustainable Development (ICTSD), Médecins Sans Frontières (MSF), OXFAM International, The Quaker United Nations Office (QUNO) et TWN established collaborations with DCs governments in order to fight with them for obtaining a reform of the IP protection system. Other NGOs established in Geneva worked in the same direction with international organizations also based in the city such as South Center, UNCTAD or even WHO. So little by little a group of professional aware of the relation between IP protection and development was formed in Geneva. In various developing countries ICTSD, TWN and OXFAM organised debates on the impact of IP protection between experts, NGOs and local politicians. NGOs of certain developing countries such as African Trade Network, Treatment Action Campaign (TAC,

15. CSSR (2006).

16. Deere (2009), see Chapter 7: « TRIPS implementation in francophone Africa ».

South Africa) and others were active in these debates. Certain NGOs worked as lobbyists towards political decision makers in their own country: in Europe for example NGOs like Consumers International, ACTUP or MSF committed themselves in action of lobbying towards members of Parliament and political parties to put pressure to bear on them in view of stopping the TRIPS-plus pressure on developing countries. Unfortunately these actions yielded few results; according to a critical analysis of the status carried out by GRAIN [17] « the TRIPS-plus dispositions are gaining ground in an increasing number of countries and few people monitor this change and act; this process only promotes the efficacy of the bilateral approach », used as a means of imposing these new standards.

NGOs FUNDING AND INDEPENDENCE

According to K.D. Reimann [18], « for NGOs (…) the years 1980-1990 were « blessed » years in terms of material resources coming from external donors of the international community. Whereas financing was rather moderate in the years 1960-70 it trebled during the 1980's and still doubled in the 1990's. It is estimated that NGOs received between 6 and 7 billion dollars between the middle and the end of the decade 1990 (…). Among the critiques addressed to NGOs, the most serious are those which question their performance and efficiency with respect to sometimes astronomical sums they received ». At present NGOs are financed by public and private sources but the erosion of State powers due to globalization leads to a primacy of private financing.

Certain NGOs like MSF, OXFAM and Action Aid financed their work on the TRIPS Agreement through their own funds coming from subscriptions of their members and through fund raising campaigns. A certain number of private foundations with a philanthropic aim have brought a financial support to some NGOs to help them promoting the debate on IP

17. *www.grain.org/rights_files/trips-plus-where-2003-en.pdf.*

18. Reimann (2005).

protection for public interest and development. For example the Ford Foundation is an important source of income for American and international NGOs [19]. In other cases various NGOs are financed by development agencies of several rich countries; for example the Swedish International Development Agency has supported ICTSD (International Center for Trade and Sustainable Development) in different developing countries. Depending on the financial source of certain NGOs the question of their independence of action and opinion from their donors crops up. This problem was thus tackled in a dossier published in May 2005 [20] by the Swiss NGO Alliance Sud, in a paragraph devoted to the expectations of NGOs of the South with respect to those of the North. A certain concern towards NGOs of the North can be noticed; there seems to be two groups among these NGOs « On one side solidarity NGOs which make alliances with social movements and listen to problems of the masses. On the other side NGOs which cooperate more and more with governments – from which they depend for their finances – with the risk of ending up supporting the neoliberal agenda and (…) becoming poverty makers which is their *raison d'être* ».

NGOs IMPACT

An academic study on the impact of NGOs actions in the field of IP was carried out in the United Kingdom and published in 2006 [21]. This study based on interviews of around sixty delegates from different international NGOs, academic experts in the field of IP, delegates from developing countries to various international organizations, shows that NGOs assist delegates from developing countries in negotiations on IP, attempt to make these same delegates from different countries meet and mobilize the press and public opinion. Some remarks from this study: The relations between NGOs and delegates from developing countries are usually perceived positively; however a better coordination of

19. The Ford Foundation is a philanthropic organization with its headquarters in New York. It was created thanks to the donations of Edsel and Henry Ford. It set as its goals the reinforcement of democratic values, the reduction of poverty and injustice, the promotion international cooperation and the accomplishment of human beings. It is an independent non-profit foundation which is completely separated from the Ford Motor Company. See *www.fordfound.org/about*.

20. Egger (2005).

21. Matthews (2006).

their actions is desired and a vision closer to reality as well. Sometimes NGOs do not understand the needs of DCs and the delegates from these countries do not realise what help these NGOs can bring. However NGOs are considered as a counter-power, especially in the context of WIPO. Sometimes NGOs undergo the reproach of not being sufficiently neutral. In this sense they are sometimes considered intrusive and overestimating the role they can play. Differences between various international organizations also make difficult the work of NGOs which try to give a coherent information to the developing countries delegates. According to the opinion of certain developing countries delegates, the NGOs representatives participating in international debates do not always intervene efficiently : sometimes they only make opposition proposals on a general level but lack concrete arguments contrary to industries representatives, for example.

However relations of NGOs with governments of developing countries are more difficult than with their delegates. In certain developing countries there is no communication between what takes place in international negotiations and what is discussed and decided at government level in the capitals. Here NGOs would have an important role to play in facilitating information transfer between delegates and governments.

This study shows too that by lack of means NGOs of the South are relatively absent from international negotiations in Geneva. These groups are more active at the national or regional level. At long term this situation in which most of the time NGOs of the North represent the interests of NGOs of the South is not acceptable and mechanisms should be found so that the latter have their own representatives in international negotiations.

This study also shows that the work of NGOs promoted the awareness of the impact of IP on public health. NGOs put in evidence the fact that intellectual property

rights can stimulate but also impede development if a balance is not struck between promoting innovation and disseminating knowledge for the good of the majority of populations [22].

WHAT LEGITIMACY FOR NGOs ?

From the end of the cold war the number of NGOs has increased and they play an increasing role on the international scene. They are considered by some as representing only themselves and especially not the civil society. As was underlined by P. Niggli [23] and A. Rothenbühler [24] « for many governments, international organizations and multinational corporations associating with their activities is today a must. But the same institutions criticize NGOs more and more and cast doubt on their legitimacy. They would like them to be more conciliatory and at the same time showing a certain spirit of contradiction ». [25]

Doubt is cast more and more often on NGOs legitimacy. « The fact of an NGO to dispose of millions of contributors does not allow it to claim speaking in the name of people and thus enjoy a legitimacy of popular representation equivalent to an election » [26]. Attempts have been made to impose some form of regulation upon NGOs :

1. In 2003 the creation by Kofi Annan, then Secretary-General of the United Nations, of the « Panel of Eminent Persons on Civil Society and UN Relationships ». This group's aim was to reinforce the presence of the civil society in international politics and was to elaborate juridical guidelines – which would still leave a certain freedom of action – to which all NGOs would be obliged to refer to. Thus « regulated » NGOs would be « legitimized » : then they would have the right to represent the civil society. However in its report [27] this « panel » does not mention any juridical guideline but takes as a hypothesis that there are three types

22. Munoz Tellez (2006).

23. Peter Niggli is director of Alliance Sud and in charge of the policy development sector.

24. André Rothenbühler is a collaborator at the Déclaration de Berne and reporter at the press agency Infosud.

25. Niggli et al. (2004).

26. Calame (2004).

27. Niggli et al. (2004).

of international protagonists: governments, civil society and private sector; the task is to regulate the interactions which will determine a future global governance (somehow a corporatist regime, model as proposed by Michael Edwards, director of the Governance and Civil Society of the Ford Foundation [28]).

2. In 2003 the Bush Government launched NGOWatch whose mission was to inform the American Government and multinational corporations about the risks they faced collaborating with NGOs [29]. Apparently this project has not developed.

3. The Foreign Policy Centre [30], think tank of the British Government, suggested rules of conduct for NGOs which would be put under a monitoring authority in charge of seeing to the respect of these rules. With the help of these rules the authorities would try to discriminate between « good » and « bad » NGOs.

According to Pierre Calame, director of the International Foundation Charles Léopold Mayer for man's progress, « since only prerogatives of public power are at the disposal of NGOs they find a powerful lever for their actions in information systems. For example the implication of OXFAM in the Cancun trade negotiations and its contribution in the failure of agricultural negotiations in which rich countries sought to keep for themselves rights of subsidies to their agriculture which they denied to the others showed the efficacy of an information dossier which was superior to all others » [31]. NGOs should take advantage of their partnerships and international information networks in developing them in a more professional and long term way.

Do NGOs have to prove their legitimacy to continue acting? Is this not an incentive to bureaucratization? Does the legitimacy of NGOs not reside first in the

28. Edwards (2000).

29. NGO Watch, *www.NGOwatch.org*.

30. The Foreign Policy Centre is a think tank of the British Foreign Affairs Ministry, which was launched in 1998 under the patronage of the former British Prime Minister Tony Blair in view of elaborating a vision for an equitable and regulated world order. *fpc.org.uk/about*.

31. Calame (2004).

testimony on the precarious conditions of the populations with which they work and in showing the hurdles to overcome for the development of these populations ?

In conclusion thanks to their well founded positions NGOs enabled opposing the abuses of a purely commercial and economic logic. However as an NGO and in agreement with S. Brunel [32], we have to ask ourselves a certain number of questions notably : « Because of their success are NGOs not exposed to the risks they denounce tirelessly : lack of transparency, soaring running costs of their administration, absence of actions evaluation ? Today does humanitarian action really contribute to the development ? This question is of paramount importance : it justifies the NGOs existence and means of action since, let us remark, they originally exist only to contribute to the development (and for the last decade to a so-called sustainable development). In this field which lessons can be drawn from the last thirty years ? ».

32. Brunel (2003).

SECOND PART

ROLE OF SWITZERLAND AND ACTION PERSPECTIVES

INTRODUCTION

In this part the position of Switzerland with respect to the reinforcement of IP rights which was not discussed in our previous work on access to medicines and the TRIPS Agreement will be presented following the analysis framework of the first part. We wish to approach this question without any a priori of denunciation or accusation but with the desire to understand and document the decisions taken by the Swiss Government, the influences of multinational corporations and NGOs operating in Switzerland regarding the IP reinforcement and Switzerland's commitments for an equitable development in poor countries. We shall try to analyse how coherent (and incoherent) are the decisions taken by the Authorities and the Swiss Administration with respect to the objectives assigned and presented in the document entitled : « Swiss external health policy ; Contract document of objectives for the external policy in matter of health [1;2].

This critical discussion should lead us to present the positions taken by Switzerland and its pharmaceutical industry in the past but also to foresee alternative solutions, discussions and disputes on which the NGOs active in the field of health should be particularly vigilant. Our task is to anticipate, suggest, alert – and not just criticise and condemn – the Swiss presence in the international organizations which carry much weight on public health policy and in particular regarding access to medicines. We would also like to contribute making more transparent the

1. CH (2008a) ; the elaboration of this document, quoted in this publication as Contract Document, follows a decision by the Federal Council of the 18th May 2005. « This document is the result of an internal agreement between the competent services of the Swiss Federal Administration. Its main objective is to improve the instruments of internal cooperation and to provide common and clear objectives to the services of the Federal Administration which are active in the field of foreign policy in matter of health », p. 3.

2. It is important to take note, for any future action, that « the main actors inside the Administration are DFI (OFSP), for the international policy in matter of health, and DFAE (SDC for what regards the development policy and the humanitarian policy in the health sector and DP for what regards the questions of general external policy raised in the fora dealing with health questions, host state policy and specific topics such as consular protection abroad). Other federal services play an important role : (…) the Office of integration DFAE/DFE for harmonization with the EU, DFE (SECO for decisions of economic policy relating to health ; (…) DFJP (IPI for rights of intellectual property relating to health) », CH (2008a).

motivations which determine the positions taken by Swiss delegations within WTO, WIPO, WHO and other international organizations concerned.

Then action proposals will have to be worked out so as to incite members of Parliament to question our delegates and support the NGOs concerned with actions of lobbying.

COOPERATION, HEALTH, HUMAN RIGHTS AND INTELLECTUAL PROPERTY

The Contract Document on the Swiss external policy in matter of health, mentioned above (see note 1), should enable an efficient intervention of the Administration in cases where some basic principles of this policy are violated by economic or political Swiss protagonists. In this document nice intentions are found such as :

« As an example the improvement of access to basic medicines for developing countries at an affordable price can be quoted ; this is one of the *Millenium development goals*. Switzerland whose pharmaceutical industry is important and which has a long humanitarian tradition has an interest in protecting adequately intellectual property and in facilitating the access of poor countries to vital medicines (let us remark that the private sector is more and more conscious of its social responsibility at the world level in the health sector what presents new possibilities of cooperation). »

This also underlines the contradiction of putting IP rights and human rights on the same level. Moreover where is the coherence between these nice principles and the inertia of the Swiss government vs. the interminable series of appeals lodged by Novartis against decisions of the Indian justice ? In compliance with the TRIPS Agreement and its national legislation, India refused to grant a patent to an anticancerous medicine

(Glivec) which did not present any significant advantage over its generic equivalent already produced [3]. As far as we know, no official declaration of the Swiss Government criticising Novartis for its die hard insistence has ever been released.

The Contract Document adds: « Guarantee an adequate intellectual property protection so as to incite to research and development of new medicines or vaccines ». According to the conventional way of thinking – and as a political alibi – this presupposes that all biological, medical and pharmaceutical research can only come from the initiative and innovation provided by private capital. [4]

It can not be ignored that much progress in these fields is made in university laboratories and other public research institutions and is then diverted for profit towards multinational corporations and start up ventures financed by private capital: « The public sector does not face its responsibilities and does not compensate for the shortcomings of the private sector; even worse it considers more and more that financing research is an investment which creates economic value and encourages the commercialization of discoveries made in a public environment. » [5]

In the following chapters we shall explore the occasions when Switzerland did not take position during tensions arising between needs of poor populations and requests by Swiss industries (in particular pharmaceutical); and the occasions when Switzerland took position in favour of one or the other opposite views.

3. See DB (2007b), (2009a), Novartisboycott (2009) and Chapter 6.

4. How to resist, for example, the powerful lobbying of the Swiss group of AIPPI (International Association for the protection of intellectual property), dedicated to « the improvement and protection of intellectual property » ? (*www.aippi.ch*). AIPPI, numbering 8000 members representing more than 100 countries, « works on the development, expansion and improvement of international and national treaties and laws relating to IP » (*www.aippi.org*).

5. MSF (2003).

CHAPTER 1

POSITIONS OF SWITZERLAND TOWARDS IP PROTECTION IN THE FRAMEWORK OF WTO

On the 1st of June 1995 Switzerland joined WTO. In so doing it adapted its legislation to satisfy the requirements of the TRIPS Agreement relative to IP protection.

The State Secretariat for Economic Affairs (SECO) is Switzerland's main representative towards multilateral institutions such as WTO. According to SECO: « Switzerland's economic foreign policy is based on WTO. Even our free trade agreements are related to WTO agreements. As a member of WTO Switzerland participates actively in the solution of problems, in the implementation and respect of existing agreements and in the development of the regulation system. » [1]

The Parliament and the cantons are consulted on important decisions like the transmission or modification of negotiation mandates at WTO. Switzerland commits itself to a swift and positive conclusion of the Doha round of negotiations and should it comes to a success « the Parliament and if necessary the electors will cast a vote on the result » [2].

As was seen in Chapter 1 of the first part, the TRIPS Agreement caused many oppositions in developing

1. *www.seco.admin.ch/themen/00513/01122/01124/index.html?lang=fr.*

2. *Op. cit.*

countries. Indeed from its coming into force in January 2000 the price of medicines have soared in the countries which adapted their legislation, what does obviously not facilitate their access for poor populations.

Generally speaking in international debates and in meetings of the TRIPS Council Switzerland frequently takes rigid positions on IP protection well beyond the minima standards foreseen in the Agreement [3]. For the Swiss delegates participating in these debates the TRIPS Agreement favours public health : therefore it must not be considered as an element of the problem but rather as an element to the solution[4]. Switzerland aims at « (…) constantly stimulating the efforts of research, development and innovation in corporations ». So according to our authorities only a solid protection, safeguarded in a rigorous international framework, enables justifying enormous research costs in several sectors dedicated notably to life sciences. « (…) Also at a multilateral level Switzerland intends to continue committing itself to a reinforcement of dispositions governing intellectual property protection. » [5] These positions match perfectly with those which were published by the chemical and pharmaceutical industry in its foreign economic strategy for 2008-2010 : « to be able to commercialise successfully its products in the whole world the chemical and pharmaceutical industry needs a free access to world markets, a recognition of its novel performance under a strong and if possible homogeneous protection of intellectual property , and investments » [6].

But does a strict IP protection really favour research and innovation ? According to a report published in 2008 by the International Expert Group on biotechnology, innovation and intellectual property, it appears « that it is not certain that patents really increase inventiveness and diffusion » [7]. In the same report one can also read that « in 2007 the CEO's and top managers of the pharmaceutical industries declared that their business model erecting

3. CH/OMC (2000).

4. CH/OMPI (2001).

5. CH/OMC (2009).

6. *www.sgci.ch/plugin/template/sgci/*/33589* (no longer available).

7. TIP (2008).

IP high barriers around the most sold medicines died two years ago »[8]. Consequently Switzerland will have to find arguments other than stimulation of research and innovation to justify the increase in IP protection.

On the 5th of July 2006, the Federal Council signed the 6th of December 2005 amendment on the TRIPS Agreement, the goal of which was to make accessible to developing countries the Swiss production capabilities in the field of novel medicines by exceptionally authorizing the export of Swiss products manufactured as if under a compulsory licence. Thus Switzerland revised its patents law accordingly. This revision came into force on the 1st of September 2008. However all along the negotiations which led to this amendment Switzerland insisted on « (…) limiting the solution of the Swiss paragraph to HIV/AIDS, tuberculosis, malaria and epidemics of an analog dimension »[9]. In agreement with the Swiss-WTO Coordination we do think that « this questionable interpretation of the Doha Declaration excludes in fact non-transmissible diseases and implies that the targeted transmissible diseases must have an epidemiological magnitude similar to HIV/AIDS, tuberculosis and malaria pandemics. Switzerland's insistence on the gravity means that it considers that using compulsory licences should be conditioned by emergency situations or exceptional circumstances »[10].

The question of access to medicines in developing countries does not seem to be on the agenda of political debates in Switzerland. For example when consulting the database Curia Vista[11] which takes stock of all the data relative to items treated by the National Council and the States Council we only found, as from 2001 (i.e. since the Doha Declaration), a very small number of members of Parliament's interventions on facilitated access to medicines for developing countries. A few interventions were found like for example the motion[12] presented by the councillor Mrs A.C. Ménétrey-Savary and going along the line of facilitated

8. *Op. cit.*

9. Coordination (2003).

10. *Op. cit.*

11. *www.parlament.ch/f.*

12. Motion 01.3580, introduced on the 04/10/2001.

access; the Federal Council proposed to reject it. In 2004 the national councillor R. Gysin put forward an intervention on the bilateral trade agreement which EFTA is about to sign with different developing countries; R. Gysin deplores a total lack of transparency and inter alia the presence of clauses which undermine the facilitated access to medicines [13]; in 2005 Mrs Amgwerd presented a motion in which she asked for a net reinforcement of Switzerland's financial commitment in favour of the World Fund against HIV/AIDS, tuberculosis and malaria, Switzerland being a founder member; she underlines inter alia that Switzerland which possesses a highly developed pharmaceutical industry can contribute to improving the access to indispensable medicines for developing countries. The Federal Council proposed to reject this motion [14]. In an edition of the weekly paper *Domaine public* published in 2003 B. Joerchel Anhorn deplored Switzerland's democratic deficit: « The Swiss Parliament only has the power to refuse or accept a final result of negotiations, even if they are related to their field of competence ! » [15]. A lack of political interest of Switzerland for the problem of access to medicines was already deplored by MSF in 2003, which then asked our authorities to establish a real policy in this matter [16].

Switzerland played an important role in promoting « Public health, innovation and intellectual property: global strategy and plan of action » (adopted by WHO on the 24th May 2008). It also committed itself in favour of achieving the Millennium Development Goals, which were approved by 189 countries during the summit organized in September 2000 by the United Nations. With its commitment Switzerland, as an industrialised country, has to provide the necessary resources so that developing countries can reach the Millenium Goals, including enabling them to access essential medicines in collaboration with pharmaceutical corporations (goal 8, target 17 [17]). But this commitment is at variance with the restrictive policy of

13. Question 04.3357 introduced on the 17/06/2004.

14. Question 05.3900 introduced on the 16/12/2005.

15. Joerchel Anhorn (2003).

16. *www.tsr.ch/info* 12/06/2003.

17. « In cooperation with the pharmaceutical industry make essential medicines available and affordable in developing countries. » *www.ilo.org/public/french/bureau/exrel/mdg/briefs/mdg8.pdf.*

IP protection which Switzerland, as an EFTA member, applies in free trade agreements. In these negotiations rules often go well beyond the WTO minimum standards as far as the duration validity of patents and exclusive rights on experimental data are concerned. As is underlined by 3D « these rules delay the introduction of cheaper generic medicines and impede the access to medicines for the poorest persons of the trade partner States » [18].

Recently Switzerland was accused by various NGOs not to abide by its international commitments [19]. Indeed in 2008, Thailand granted compulsory licences for medicines patented by Roche and Novartis. Under pressure from its pharmaceutical industry [20] the Swiss Government then asked the Thai Government to modify its policy of granting compulsory licences. It's argument was that compulsory licences in Thailand threaten research and development of new medicines and are likely to turn foreign investors away from the country. With Thai NGOs the Bern Declaration reacted to this position of Switzerland and sent a letter to the Federal Council in which it is invited to « (…) respect the commitments taken when adopting the Doha Declaration on the TRIPS Agreement and public heath in November 2001 as the Federal Council declared before the Parliament and to follow the Commission's recommendations on intellectual property, innovation and public health. In its deeds Switzerland must support the use of the TRIPS Agreement's flexibilities by developing countries » [21].

In negotiations with India in view of a free trade agreement Switzerland is suspected of wanting to introduce TRIPS-plus rules which would give the Swiss pharmaceutical corporations a tool for putting pressure to bear on the Indian patents system.

We think that Switzerland conducts a foreign policy in matter of health which is not coherent in the sense

18. 3D (2009a).

19. DB (2008a).

20. Exports of pharmaceutical products increased sharply in 2008 and reached 55 billion Swiss francs, i.e. a quarter of the total of Swiss exports. Interpharma (2009).

21. DB (2008a).

where commitments for development come into conflict with commercial logic.

In 2006 the Federal Council published a contract document [22] so that its foreign policy in matter of health be more coherent and coordinated; it was approved by the Foreign Affairs Federal Department (DFAE) and by the Federal Interior Department (DFI). The implementation of the political goals is under the management of the Swiss Agency for Development and Cooperation (SDC) and of the Public Health Federal Office (OFSP) which have to work with SECO and other departments. In this contract document the intention of improving the access to essential medicines [23] is mentioned twice. If one considers the recent accusations and suspicions levelled at Switzerland in its negotiations in view of free trade agreements with India and the pressure put to bear on the Thai Government as to compulsory licences the goals of this contract document appear to us to be sweet talk…

What is the present position of Switzerland vs. WTO's future? In a recent interview [24] the Swiss ambassador towards WTO, Marie-Gabrielle Ineichen-Fleisch, declared that « although it is urgent to take the Doha round out of its dormant state, Switzerland must nevertheless continue operating bilaterally. The exchange of goods with countries with which a bilateral agreement was signed increases twice as fast as with the WTO partners ». Regarding WTO « a revision of the institution based in Geneva is necessary » and « this is a trade organization and it has to stick to it »; « it is neither destined to development, nor environment nor finance » the ambassador went on. In other terms Switzerland will carry on with its policy of bilateral agreements; is it going to demand an increased protection of IP? In which international institution is it going to act so that the goals of its Contract Document in matter of health in developing countries be respected? In the Development Agenda of WIPO?

22. CH (2008a).

23. CH (2008a), under Point 3.9: « Ameliorate on the international level the access to essential medicines – whether they have proved their efficacy or have just been developed. » and under Point 4.13: « One of the priorities must be to guarantee a non discriminatory access, at affordable prices, to health care and medicines ».

24. Lieberherr (2009).

CHAPTER 2

SWITZERLAND, IP AND ACCESS TO ESSENTIAL MEDICINES

Here we shall limit ourselves to commenting on some positions taken or not taken by Switzerland with respect to the intentions laid out in its Contract Document for a foreign policy in matter of health.

The Contract Document states that: « The industrial sectors concerned by measures aiming at protecting health like the pharmaceutical industry and the food industry established long ago their international network. (…) For example one can quote the improvement of access to basic medicines at an affordable price for developing countries, which is also one the *Millenium development goals*. (…) Let us notice that the industrial sector is getting more and more conscious of its social responsibility at the world level in the field of health, which presents more cooperation possibilities. » [1]

If the recent saga of repeated court cases initiated – and lost – by Novartis against the Indian Government (see Ch. 1 and 2, DB(2007b), (2009a), (2009c) Novartis boycott (2009), is examined the sentence on the *awareness* of the Swiss private sector seems peculiar if not involuntarily ironical. Until today as far as we know there has been no intervention (neither official nor informal) of the competent Swiss institutions towards Novartis so that this multibillion multinational corporation gives up its relentless struggle against the Indian

1. CH (2008a).

Government and accepts the goal of supplying India with « basic medicines at an affordable price ».

It is also reasonable to doubt that Switzerland, as was written in its Contract Document, can « quote the improvement of access to medicines at an affordable price for developing countries » as an example of coherent and long term policy. Indeed how to judge the actions undertaken by the Swiss Government after compulsory licences were granted by the Thai Government [2] for medicines patented by Roche, Novartis and Sanofi-Aventis [3] ? In a memorandum of February 2008 « Switzerland expressed its preoccupation that a systematic use of compulsory licences be likely to make totally ineffective a system of patent protection which would not in any case be in the long term of public health. Switzerland invited the Thai Government to find through negotiations and together with the industries concerned a satisfactory solution which would enable supplying Thai patients with high quality original medicines at prices remaining accessible » [4] (this term original is delicious and hides an aristocratic contempt for generic medicines !).

The positions which Switzerland will take in the future on the fate of the Development Agenda (Chapter 2.4, part 1) can also convince, or on the contrary cast doubt, of the sincerity of the Swiss Administration as far as the statements found in the Contract Document are concerned that « the questions of health have gained in importance not only in the home policy but also in the foreign policy » [5]. Indeed a greater awareness to the development problems in the DCs with respect to the obsession of the defence, if not of the reinforcement of IP rights could only improve public health conditions in these countries. But between 2004 and 2009 the projects related to the Development Agenda moved from one commission to another, from one committee to another and were discussed endlessly in all WIPO general assemblies without reaching binding decisions

2. Rivière (2007).

3. CH (2008), DB (2008), (2008a).

4. Letter from Mrs Doris Leuthard, DFE, of the 23 May 2008 to the Déclaration de Berne, DB (2008b).

5. CH (2008a).

for member states[6]. It is fair to think that the main cause of this situation lies in the systematic obstruction by industrialised countries of which Switzerland is often the spokesperson.

Finally it would be better to probe the Swiss Government's position after the recent arbitrary seizures of generic medicines carried out under the accountability of the World Customs Organization of which Switzerland is a member; WCO claimed these generic medicines were suspected of being counterfeited[7]. Did the services quoted in the Contract Document as responsible for the Swiss foreign policy in the field of health react to these seizures? In the framework of WCO, did they ask for these arbitrary actions to stop (as they jeopardize the exchange of generic medicines between DCs)?

6. IPW (2006), WIPO (2007), (2007a), (2007c), (2007d).

7. Chapter 1 and IPW (2009g).

CHAPTER 3

PATENTING LIVING SPECIES, BROADENING THE BASES WHICH ENABLE PATENTING ANIMAL SPECIES AND PLANT VARIETIES

Here we reconsider the essential elements of the present debate on the possibility of patenting living species which were presented in chapters 2 and 3 of the first part and we shall examine them as regards to the situation of Switzerland.

The article 1a of the revised Swiss law on patents of 1976 says that a patent can be granted neither on plant varieties nor on animal races. In a message of March 1976, the Federal Council explained clearly that organisms themselves cannot be patented. But in 1986 the Federal Office of Intellectual Property (FOIP) [1] issued internal guidelines according to which it is possible to patent any form of life provided that neither the race nor the variety is specified in the registered patents. This corresponded to a reinterpretation of the law.

In 1986 in view of adapting the legislation to these FOIP directives, a revised version of the law was requested but no project came out. Some ten years later the Federal Council tackled a new revision of the Swiss patents law so as to comply to the EU directives (directive 98/44/EC of 1998 issued by the European Patent

1. In 1996 the Federal Office of intellectual property was renamed Federal Institute of intellectual property: its status changed in the sense that it could from then on give (remunerated) advice to the private sector about all that concerns IP and its legislation.

Office, EPO), which governs the patenting of inventions and genes in the field of biotechnology (see Chapter 2.3, part 1). In Spring 2006 after numerous proposals and debates, a revised version of the patents law was submitted to the Federal Parliament for examination. But the project still foresaw clearly the possibility of patenting living species. This caused reactions from the Bern declaration supported by associations of farmers, consumers, environment defenders, mutual aid structures and researchers [2].

In Summer 2007, the National Council and the Council of States adopted the revised patents law proposed by the Federal Council. « So from now on it will be possible to patent a gene sequence ». This innovation is a moot point but went along the line requested by the pharmaceutical industry. The project was « the result of a compromise between the interests of research and those of the pharmaceutical industry » ; that was the argument put forward by Christoph Blocher, Justice Minister in charge of the matter [3].

In this chapter we shall limit ourselves to discuss the case of plant varieties, the standards of which are defined within the framework of UPOV, but the patentability of animal races generates the same problems.

Let us recall that UPOV was initiated by a first Convention signed in 1961 in Paris and which came into force in 1968. It was then revised in 1972, 1978 [4] and 1991 [5] in Geneva. The 1991 Convention allows the crop material to be re-used (for example it is the case of wheat). On the other hand it generally forbids using multiplication material (for example for vegetables, fruits and berries). As far as crop material is concerned, UPOV 91 lets the member states free to authorize or forbid using seeds by legislating. For example Swiss farmers could re-use certain seeds but under the condition that they are on a list established by the Federal Council.

2. DB (2006d).

3. *Swissinfo.ch* of the 12 June 2007.

4. UPOV (1978).

5. UPOV (1991).

Today any country wishing to join UPOV must adopt the text of the 1991 Convention. Switzerland signed and ratified the 1978 Convention. Subsequently it also signed the 1991 Convention but only ratified it on the 1st August 2008. We wonder why such a long delay occurred between signature and ratification. Did the Swiss Government undergo pressure from agricultural producers concerned by certain conditions found in the text or from Swiss agro-businesses or pharmaceutical industries? Which arguments did in the end convince the Swiss Parliament to ratify the Convention seventeen years after it was signed?

It is rather surprising to notice that Switzerland, despite its own hesitations, has no scruple requesting that countries with which it establishes free trade agreements sign the 1991 UPOV Convention. Strange contradiction …

Now, we shall scrutinize essentially two problems. The first one is related to the 1991 UPOV Convention and to the absence of use by Switzerland of the flexibilities allowed. And the second one deals with Switzerland's passive attitude vs. the more and more systematic drift of plant varieties considered non patentable until a few years ago towards varieties to which EPO granted patents.

– The first problem is related to the attempts to prevent farmers from resowing seeds protected by a patent. Indeed Art. 1.4 of UPOV (1991)[6] defines the scope of the breeder's right which introduces for the first time the possibility of granting (against remuneration) to farmers the authorization to reproduce a seed protected by a patent:

  « 1) a) (…) the following acts in respect of the propagating material of the protected variety require the authorization of the breeder: i) production or reproduction (multiplication), ii) conditioning

6. These articles do not exist in the first version of these conventions, UPOV (1978).

for the purpose of propagation, iii) offering for sale, iv) selling or other marketing, v) exporting, vi) importing (…). »

However Art. 15 offers a certain flexibility to the different member states :

« 2) [Optional exception] (…) each member of the Union may « within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, restrict the breeder's right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety or other variety covered by the protection (…). » [7]

Therefore Switzerland like any other member and signatory of UPOV 1991 may decide that farmers keep their rights in particular that of resowing their crop of plant varieties protected by a patent. However this flexibility does not appear anywhere as a clear and unambiguous statement.

The problem is probably of little importance in Switzerland, considering the increasing use of varieties strictly defined by the market and hybrid varieties which cannot be resowed. But perhaps it is essential in DCs where very small farms undergo a strong pressure in favour of using varieties protected by a patent (with arguments of profitability, resistance to diseases or parasites, products standardization to satisfy the market forces), whereas resowing a part of their crop is in fact necessary to their survival.

In such cases one does not understand Switzerland's policy when signing free trade bilateral or multilateral treaties. Indeed the 1978 UPOV Convention, contrary to that of 1991, does not consider any scope of the breeder's right ; why does then Switzerland requested in the free

7. UPOV (1991).

trade treaty with Colombia that the latter adheres to « either UPOV (1978) or UPOV (1991) » whereas in the treaty negotiated with Vietnam (1999) Switzerland demands that the former « joins UPOV (1991) » ? [8]

When the Swiss Contract Document for a foreign policy states : « the progress achieved during these last decades at the health level of populations testify of the usefulness of international standards and rules and of the positive interactions between health and economic development as well » in reality the economic development of rural areas of certain DCs and consequently the health of their populations could be jeopardized by the economic demands related to adhesion to UPOV 1991 which Switzerland imposes in the free trade agreements.

– The second major problem lies in the progressive drift of the notion of patentability of plant varieties obtained through *non essentially biological* methods towards the notion of patentability of varieties whose methods of production and selection do not differ from what a naive biologist would define as *essentially biological* and therefore not patentable (see Chapter 3 of the first part of this work). Does Switzerland have to accept without any resistance this drift which only favours big multinational corporations and generates a vague situation in which tomatoes (non-GMO) which do not wrinkle up and brocoli (non-GMO as well) rich in anticancerous substance obtain a patent ?

In 1998, 50 genetically modified varieties (GMO's) had obtained their patent but none non-GMO : essentially biological still seemed to play an important role in preventing drifts. In 2001 there were 5 non-GMO varieties submitted to a patent and 45 in 2006. On the other hand the number of registered patents regarding GMO varieties was in sharp decrease (550 in 2001 but 300 in 2006) [9].

8. The situation is much harder and the blackmail more explicit in most of the free trade treaties between the USA and DCs : « must join UPOV (1991) by the year 2008 » (Colombia, 2006), « no law that excludes plants and animals from the possibility of obtaining a patent » (Mongolia, 1991), « must join UPOV (1991) ; no law that excludes plants and animals from the possibility of obtaining a patent » (Nicaragua, 1998), (…) ; vaguely less tyrannical than the EU : free trade treaties : « must make the best efforts to join UPOV (1991) by the year 2006 » (Bangladesh, 2001). Tnasey et al. (2008).

9. No-patents (2007).

The confusion was apparently semantic but in reality it was the result of a question of force and power among the big protagonists of plants and animals protection and cannot be attributed to EPO and WIPO; it is important that IPI takes position and defends – if necessary refusing patents accepted by EPO – a broad and common sense interpretation of this famous *essentially biological* term so that no non-GMO variety gets granted a patent.

CHAPTER 4

HEALTH IN THE WORLD

The Contract Document for Switzerland's foreign policy in matter of health states:

« So health protection acquires an ever more international dimension notably at the level of food safety, reliability of therapeutic products, chemical safety, radioprotection, safety at work and many other fields of environmental policy. (…) Switzerland has a real economic and political interest in the health improvement in the world particularly in developing or emerging countries. »

However this commitment is mitigated: « Switzerland must also defend the interests of the pharmaceutical industry, which is important for the national economy, and ensure its presence on its territory. » [1]

In this Contract Document Switzerland's intentions are translated into an ensemble of *mid-term eighteen goals and priorities* (horizon at five years) out which the ninth one:

« 9. On the international level improve access to essential medicines – whether they have proved effective or have just been developed. »

And the thirteenth:
« 13. Perfect, reform and harmonize the health systems in the developing countries, those in a crisis or in a transition state. One of the priorities must be to guarantee a non discriminatory access to health benefits at affordable prices. » [2]

1. CH (2008a).
2. *Op. cit.*

Here it is presumed that among the *health benefits* at affordable prices there are also those which refer to access to essential medicines.

Reaching these goals demands a direct commitment by Switzerland in the framework of its international cooperation activities ; but we believe that it also calls for an explicit and possibly polemic commitment by Swiss representatives in WHO's management and various directions. Here we shall limit ourselves to two aspects presented in detail in Chapter 4 of the first part.

On one hand WHO's weight decreases steadily among the global health decision-makers : budget constraints, difficulty in finding funds for specific activities ; and especially proliferation of international or private bodies which cover more and more particular sectors of this field with big economic means. This tendency is dangerous in the sense that whoever has got money has the power to choose priorities and preferential fields. A global vision essential for modifying health benefits in the world and in particular in DCs, becomes impossible.

But how does the Swiss Contract Document describes the present situation ?

« The main international organizations which coordinate or define the standards of the health sector are WHO and other UN bodies (UNICEF, UNFPA etc.) the World Bank and OECD. The EU influences in numerous ways the health systems of its Member States and their respective health policies through regulations or through its Agencies (European Food Safety Authority [EFSA], European Centre for Disease Prevention and Control [ECDC]). And the Council of Europe as well sets quality standards in the health sector (e.g. European Pharmacopea). At the implementation level of public health measures the most influential organizations are the World Bank and WHO. These last years new international financing mechanisms appeared (e.g.

Global Fund to fight AIDS, tuberculosis and malaria) and private/public partnerships (e.g. Global Alliance for Vaccines and Immunization). » [3]

As can be seen all this seems normal : there is nothing to say, that's how the world runs. But does one really believe that one can « guarantee a non discriminatory access to health benefits at affordable prices » in this world of fragmented strategies often dominated by interests of national prestige, by advertisements for large multinational corporations and big private wealth, by purely commercial interests ? Will the Swiss policy makers who sincerely wish to reach the goals of the Contract Document not feel the necessity to fight against this dispersive proliferation and be in favour of a central organizing role for WHO ?

On the other hand in Chapter 4 we put in evidence, perhaps naively, how WHO was dragged into international organizations fighting against counterfeit medicines. Once the practice and goals of these organizations have been analysed it appeared quickly they were strongly geared on the defence of IP rights ; generic medicines produced with fewer means and in less attractive wrappings than the corresponding original products have sometimes been seized by zealous customs offices [4]. From Swiss representatives active in WHO's high level management, one would expect a greater rigour in the type of international collaboration to which WHO is committed.

3. CH (2008a).

4. TWN (2008).

CHAPTER 5

COMMITMENT OF SWITZERLAND IN BILATERAL AND MULTILATERAL AGREEMENTS

The Swiss economy bases its growth on three pillars:

- bilateral agreements with the EU;
- agreements signed by Switzerland alone or by EFTA (Norway, Iceland, Liechtenstein and Switzerland) and other countries;
- multilateral agreements implemented in the framework of WTO.

The European Union is by far the principal trade partner of Switzerland. The free trade agreement creates a free trade area for industrial products which are exempted from quotas and customs duty. This agreement signed in 1972 lies at the origin of strong economic relations between Switzerland and the EU [1]. Generally speaking, the agreements with the EU countries do not seem to cause many problems, the partners being close on the technical level and on the economic level as well.

The implementation of agreements signed within the framework of WTO was often laborious: as soon as the national legislations were made to comply with the TRIPS system, a power struggle took place through the technical expertise brought by the competent organizations and by the DCs internal tensions.

1. Bureau de l'intégration DFAE/DFE, August 2009 – see *www.europa.admin.ch/themen/00499/index.html?lang=en*.

As for the Free trade Agreements (FTA) they generally contain TRIPS-plus [2;3] dispositions making them more binding than the TRIPS standards of multilateral agreements. Arguing that the Doha round, which would give a green light to fairer multilateral agreements, is partially paralysed, countries sign more and more bilateral agreements and Switzerland does so as well : these free trade agreements are now here not only to stay but to still increase in numbers.

When these free trade agreements are signed with countries that are not members of the European Union, it is legitimate to have fears as the « Contract Documents for goals in the foreign policy in matter of health » [4] seems to fade away behind the commercial Realpolitik, especially when it concerns developing countries.

So the last agreement signed with Colombia was ratified in September 2009. A part of the Parliament wanted to introduce a disposition in favour of human rights since Colombia is far from being a model in this field. The majority did not want to mix trade and human rights and ratified the agreement [5].

In an intervention of 2007 [6] Francine John Calame, national councillor representing the Green Party, questioned the Federal Council on the TRIPS-plus measures of the Agreements passed between EFTA and Peru and Colombia on one hand and with Indonesia and India on the other hand. She referred to the recommendations of Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) [7] which advised industrialised countries not to seek in bilateral trade agreements to set up an intellectual property protection going beyond the TRIPS Agreement. In its answer the Federal Council did not give any guarantee on these points. It seems that a meticulous attention

2. See Deere (2009).

3. See GRAIN (2001).

4. *Op. cit.*

5. To consult the report on the foreign economic policy 2009 and its critical commentary supported by arguments : follow the links given on : *www.alliance-sud.ch/fr/politique/autres-sujets/rapport-politique-economique-exterieure-2009.*

6. *www.francinejohn.ch/web/index.php?view=article&id=108%3A073683-accord-aele-avec-le-perou-la-colombie-lindonesie-et-linde&option=com_content&Itemid=100021.*

7. OMS/CIPIH (2006).

must be given to these characteristics of FTA's in our countries whereas in the countries concerned the persons affected will not be able to do away with a clear minded analysis of the local situation and the concrete consequences of these agreements terms.

SWISS EXTERNAL TRADE : SOME FIGURES

- 70 % of Swiss exports are carried out through free trade agreements (*La Vie Economique*, November 2009).
- Switzerland earns one franc out of three in its exchanges with the European Union (August 2009, Bilateral Agreements Switzerland-EU, Bureau de l'intégration DFAE/DFE).
- Two thirds of Swiss exports are destined to the EU and 80 % of our imports come from it.
- End 2008, eighteen free trade conventions were already in force. In the framework of EFTA, or on its own the Confederation does not intend to stop at that point : it is notably in contact with India, China, Hong-Kong, Russia Ukraine and Mercosur (Brazil, Argentina, Venezuela, Paraguay, Uruguay) (*Bilan*, 29th June 2009, Switzerland multiplies free trade agreements).

CHAPTER 6

ACTIONS OF NGOs IN SWITZERLAND IN THE FIELD OF ACCESS TO MEDICINES

In Switzerland before 1950 only mutual aid confessional organizations were active in the field of development cooperation. Indeed in this era the Confederation considered that it was an activity up to private initiatives and not to the State. Only in 1950 did the Swiss Government decide to include development cooperation in its foreign policy. Therefore the State started financing its own projects while still providing help to private organizations. From then on according to Werner Külling, former secretary general of Helvetas, development cooperation « became a public task of central importance the volume of which has only increased (…). This evolution caused somewhat also a weakening of the solidarity which Swiss NGOs were enjoying »[1]. However it appears that the importance of the funds raised by Swiss NGOs has risen constantly.

A report of the UN Department of economic and social affairs regarding the economic aspects of sustainable development in Switzerland argues « Switzerland's help programme enjoys a strong popular support which is partly related to the existence of an important community of NGOs, which are very active and wield a strong influence on Swiss policy, playing a complementary role to that of the authorities. NGOs are central in making the Parliament and the public opinion aware

1. *www.edinter.net/docs/BOL_6theses.pdf.*

of questions of coherence and development education »[2]. According to a 2004[3] study carried out at the IUED (University Institute of Development Studies) on the financing of NGOs in development cooperation and humanitarian aid in Switzerland, several offices of the Federal Administration keep relations with Swiss NGOs. The latter dispose of different mechanisms for obtaining public finances for their activities, notably contributions from the SDC (Swiss Development and Cooperation Agency). If the Federal Council considers that NGOs are « precious partners »[4] with which it keeps a « constructive and lively » dialogue, the Confederation does not have a unified policy as far as relations with NGOs are concerned.

In Switzerland the relations between State and NGOs also shows a phenomenon of *externalization* or *subcontracting* (like in the private sector) : the State finances more and more the Swiss NGOs (via the SDC, the cantonal federations and also the communes), what enables it to keep high contributions without the state agencies having to manage the projects, follow them up administratively, to look after salaries, etc.

The questions relative to the extension of access to medicines caused a variety of initiatives from NGOs active in Switzerland.

In this sense, Médecins sans frontières (MSF) and the Bern Declaration (DB) exhorted the pharmaceutical industry to commit itself more for developing countries in facilitating access to medicines (notably for AIDS treatment)[5;6]. These two NGOs also asked Swiss industries to orientate R&D towards neglected diseases like malaria or the sleeping sickness[7;8;9;10].

In parallel the Medicus Mundi[11] network canvassed in favour of a lowering of sale price of anti-HIV/AIDS medicines. Among the other initiatives launched by Swiss NGOs let us note :

2. *www.un.org/esa/agenda21/natlinfo/countr/swiss/eco.htm*.

3. Perroulaz (2004).

4. Message about the continuation of technical cooperation and financial aid in favour of developing countries of the 28 May 2003, point 4.4.2. p. 4199.

5. *www.msf.ch/Archives-2001.66.0.html*.

6. On the 25 April 2003 DB launched a campaign « to look after one's health : a right for all, for poor countries as well ! » with the support of 48 organizations. This action urged everyone to protest towards the Federal Council and Roche by sending postcards. Thousands of postcards were sent testifying of the expectation of Switzerland's inhabitants for a change of attitude towards developing countries ; DB (2003a).

7. MSF (2001).

8. MSF/DNDi (2009).

9. MSF/DNDi (2009a).

10. *www.evb.ch/fr/p25014645.html*.

11. *www.medicusmundi.ch/mms-fr/network*.

– In January 2000 after the world mobilization which took place at Seattle against WTO's liberalization policy different Swiss NGOs active in the field of human rights created the Switzerland-WTO Coordination [12] in view of making their claims more effective; the message of the Coordination to the Federal Council is formulated so: « Switzerland must choose an alternative way in favour of reforming deeply WTO to

SWISS NGOs COMMITTED TO FACILITATE ACCESS TO ESSENTIAL MEDICINES

Several NGOs active in Switzerland's political arena undertook actions and published material in view of a facilitated access to essential medicines for DCs and LACs. Among these:

3D->Trade-Human Rights-Equitable Economy
www.3dthree.org

Alliance Sud
Alliance Sud regroups six associations (Swissaid, Action de Carême, Pain pour le prochain, Helvetas, Caritas and Eper).
www.alliancesud.ch

Centrale sanitaire suisse romande (CSSR)
www.ccs-romande.ch

Déclaration de Berne (DB)
www.evb.ch

Le centre Europe-Tiers monde (CETIM)
www.cetim.ch

MSF-Suisse
www.msf.ch

12. The Switzerland-WTO Coordination Committee regroups Alliance Sud, the Bern Declaration, Pro Natura, the Swiss farmers, the Swiss Trade-Union and Uniterre. *www.alliancesud.ch.*

II-6. ACTIONS OF NGOs IN SWITZERLAND IN THE FIELD OF ACCESS TO MEDICINES

give it the means to meet the real challenges of globalization.» [13] Thanks to regular contacts with SECO the Coordination succeeded in forwarding its positions on topics such as agriculture, services, environment, investments, relations with developing countries and access to medicines. «For example the pressure exerted by the Coordination contributed to Switzerland giving up for the time being any liberalization of services related to the public sector. The Swiss negotiators rejected notably the European Union's request in favour of opening the Swiss market for drinking water supply and distribution.» [14]

– A CETIM booklet entitled «The right to health» (2006).

– A series of documents published on the website of the 3D THREE NGO pertaining to intellectual property and access to medicines. They include notably information notes on the impact of IP rules on the access to medicines and human rights in Botswana, Denmark and Italy (EU), Ecuador, Marocco, Salvador, Philippines Thailand and Uganda [15].

– A book on the impact of the TRIPS Agreement on essential medicines published in 2006 by CSSR (Intellectual property and access to medicines) [16].

– In 2007 after EFTA proposed to launch negotiations for new free trade agreements with Colombia, India, Indonesia and Peru, a group of several Swiss NGOs (among which are those quoted here) cosigned with NGOs from other EFTA countries and with diverse associations of the Colombian, Indian, Indonesian and Peruvian civil society an open letter to the ministers of commerce and foreign affairs of the EFTA member states in which it was requested inter alia: «No TRIPS-plus dispositions on medicines in the free trade agreements with EFTA» and «no TRIPS-plus dispositions in agriculture in the free trade agreements» [17].

13. Joerchel-Anhorn (2003).

14. *Op. cit.*

15. *www.3dthree.org/fr/page.php?IDpage=14&IDcat=4.*

16. CSSR (2006).

17. *www.evb.ch/fr/p25012925.html.*

In October 2006 at the initiative of France and Brazil, joined by Chile, Norway and the United Kingdom UNITAID was created; it is a purchasing pool for medicines. Its funding will be assured in a sustainable way by a tax on plane tickets. Many international organizations [18], NGOs and foundations (among which the Clinton Foundation) support this initiative. UNITAID's goal is to improve access to medicines in developing countries to fight against three pandemics such as AIDS, tuberculosis and malaria. UNITAID's Trust Fund has been based at WHO in Geneva since the 19th September 2006. MSF International welcomes the setting up of this organization which puts into place a community of patents for certain medicines like the anti-HIV/AIDS ones, which answers the NGOs wish. Thanks to this new system recent versions of medicines could be put on the market at accessible prices for developing countries. Production of generics could thus start before the expiry of the 20 years duration of a patent [19].

Several of the international NGOs which are in favour of such a project remain nevertheless vigilant as to its running [20]. For example on the 13th December 2009 the civil societies organizations of India rebut UNITAID's decision to exclude China, Brazil and India from the patents community [21].

As far as we know UNITAID's creation did not arouse a great interest among Swiss NGOs. Is it due to the fact that Switzerland declared not to be interested in the financing of UNITAID? Indeed in 2005 Carlo Sommaruga, member of parliament, was answered: « the Federal Council had already considered more innovative financing mechanisms – among which was the tax on plane tickets ». During the reflection session of May 18, 2005, « the Federal Council decided in a general way against Switzerland participating in a world taxing system or an international financing facility (IFF) » [22]. It would be interesting to know the opinion of Swiss NGOs active in the field of access to

18. Among which: WHO, UNAIDS, UNICEF, the Global Fund to fight HIV/AIDS, tuberculosis and malaria.

19. To know about the functioning of UNITAID, see *www.ambafrance-cn.org/Un-fonctionnement-simple-et-transparent.html?lang=fr.*

20. See the article of C. Raimbeau, in DATAS, *www.datas.ch/article.php?id=439.*

21. *www.essentialdrugs.org/emed/archive/200912.*

22. *www.datas.ch/article.php?id=439.*

medicines about UNITAID. Would it not be a mean of putting pressure to bear on our Authorities and pharmaceutical industries? Should we – as a Swiss NGO – try to work more closely with our members of parliament who are already well aware of the problem of access to medicines and/or draw the attention of those who are not yet aware?

CONCLUSION

In the first part of this book we wished to show how on the different scenes of international relations the stakes of access to medicines caused a variety of initiatives, debates and contradictions.

As was seen several international organizations mobilised over this question and important events followed triggered by the variety of initiatives adopted by different organizations.

Following the ratification of the TRIPS Agreement at WTO, the attention was then focused towards the Doha round of negotiations, which are at present in a deadlock because of important disagreements between member states. Subsequently at the initiative of Brazil and Argentina some debates took place at WIPO in order to incite this organization to adopt a more balanced approach to IP rights. In this sense the Development Agenda and the supporting declarations which followed contributed to the creation of a Development and Intellectual Property Committee inside this organization. WIPO also set up an *intersectorial* plan of action the ambition of which is to take into consideration the development goals in all its activities.

For its part WHO gave preference to a reflective approach as was materialised in the work of the CIPIH commission, which was concluded by a series of relevant recommendations marking a certain progress ; however these were not translated into formal commitments.

After CIPIH was dissolved WHO set up an intergovernmental working group (IGWG) with the task of examining again the questions of intellectual property, innovation, public health and access to medicines. In the first report of the group (presented to the World Health Assembly in May 2008) one noticed the absence of explicit criteria for the protection of access to medicines [1]. A more recent report caused a controversy at WHO's top management, some countries feeling they were urged to adopt it without even having had the opportunity to consult it. On the NGOs side interested in public health this report was found disappointing [2].

At the UN, the Human Rights Council nominated a special rapporteur on the right of all persons to benefit from the best possible state of physical and mental health. During the commission's eleventh meeting in March 2009, the new rapporteur, Mr Anand Grover, handed over a report analyzing the obstacles impeding the improvement of access to medicines in DCs [3]. This report presents in detail the problems of using the flexibilities contained in the TRIPS Agreement and analyses the dangers of the TRIPS-plus clauses contained in the free trade agreements. Indeed the rich countries have been progressively able to bypass the TRIPS Agreement by signing free trade treaties which include more important demands in matter of IP protection (see Chapter 5, part 1).

To cut a long story short, since the TRIPS Agreement was ratified the problems of access to medicines moved from WTO to WIPO, then to WHO [4] and progressively outside any multilateral framework via trade relations *à la carte* between countries (or groups of countries).

In these meanders where many protagonists are active the access to medicines appears like a field of a considerable complexity. Its fate is determined notably in a series of international organizations with different mandates and approaches – their way of functioning

1. See Chapter 4.2 (part 1), and Forman (2009) for a critical review of the IGWG report.

2. Parsons (2009).

3. Grover (2009). This report can be consulted online: *www2.ohchr.org/english/bodies/hrcouncil/docs/11session/A.HRC.11.12_fr.pdf.*

4. Musungu (2007).

is not always intelligible the more many negotiations, decisions, arrangements and discussions take place outside the formal channels. Let us also remark that international organizations are variously interrelated and this influences the decisions taken in a matter of access to medicines.

Outside international treaties, intellectual property rights and all that is discussed and decided top down the access to medicines is also intricately tied to the social and political complexity (like for example the dangers related to the privatization of health services). In other words if we treated mainly this problem through an institutional approach we are well aware that the fate of access to medicines depends on the multiple levels of the social, political and economic arena.

In fact we think that it is not relevant to consider the actions determining the access to medicines as a set of isolated decisions with their own dynamics. Indeed all that concerns in one way or the other public health can modify the quality, the efficiency and the access to medicines.

In the second part of this book we did want to underline the contradictions which arise between the declarations of intent of the Swiss Authorities and their actions on the international scene.

Let us mention that this approach is a watered down measure in comparison with our initial ambitions : we initially planned to unravel the Swiss decision making structures which influence the access to medicines and public health in the DCs. This ambition could not be fully satisfied notably for reasons of insufficient information in this matter.

Which role does the Secretariat of Economy (SECO) play in the positions taken by Switzerland towards international organizations ? In which measure can – or wants – the Office of Public Health (OFSP) intervene

to defend the interests of public health? What about the apparent non-commitment of the Swiss Agency for Development and Cooperation (SDC) vs. the conservative positions taken by the Swiss Government and which can potentially harm public health in DCs? How to describe the links between the Swiss Parliament and the national pharmaceutical industry? These questions remain largely unanswered and some point at the lack of transparency in which our authorities operate.

Nevertheless we were able to confront declarations of intent of our Government with a series of positions taken in the international arena. So it appears that Switzerland generally takes positions which coincide with those of industrialised countries[5]. Therefore as representatives of industrialised countries, submitted to the demands of the country's economic powers, the persons in charge of the Swiss Government act in view of reenforcing IP rights.

When these positions represent a danger to the DCs public health or to the interests of their poor classes we think that it is time to organise meetings with the NGOs and other organizations of the civil society in view of common actions of information and protest.

Indeed we are convinced that development aid must be accompanied by a political consciousness of international power structures and relations of domination: International solidarity in its material form is indeed useful and necessary but it cannot implement ambitious declarations for the development of poor countries as they are formulated in the Millenium Development Goals which UN Member States are supposed to reach by 2015.

Without tackling the political context which lies at the origin of unequal access to health care and medicines the ambition of social and health development will remain unfulfilled. It is a fundamental field of action

5. The industrialised countries correspond to Group B of WIPO (a group formally defined, but apparently not in a rigid way) (see Chapter 2, part 1). During the WIPO meetings Switzerland often spoke up « on behalf of Group B ». From the 2 October 2009 Switzerland took over the chairmanship of the group for one year.

for people of the civil society concerned by development policy, particularly in Switzerland because of the importance attached by our authorities to the protection of intellectual property and of dangers for the DCs marginalised populations.

From then on, calls for increasing Switzerland's financial contributions to public aid to development as formulated during the campaign *0,7 % Ensemble contre la pauvreté (*The aim of which was to raise development aid to 0,7 % of Swiss GDP) relegate to the back ground the question of commitment modalities and political investment of the representatives of the Swiss civil society. The commitment coherence cannot be measured in percentage of GDP. It is our duty to make known the chains of responsibility which relate the situations of distress in the South to the powers in the North. It is time to adopt the maxim Act local, think global. Should we need to be convinced, let us quote finally the first lines of the 2005-2006 report of Global Health Watch[6]:

« The present crisis of global health reflects the increasing inequalities between and inside countries. When the rich get richer and the poor poorer scientific and technological advances enable a longer life and in better health for a small fraction of the world population. At the same time children die of diarrhea through lack of clean water, persons die of Aids through lack of affordable medicines and poor populations in all regions are more and more remote from political, social and economic means which they might use for their health and well-being.

The real scandal is that the world lacks neither financial resources nor necessary know-how to solve most of these problems. Nevertheless the leadership of the conservative thinking and of the neoliberal economy led the established institutions which are to promote social justice to impose policies and practices which achieve the contrary. »

6. GHW (2005).

APPENDICES

BETWEEN THE WTO COMMERCIAL RULES AND THE PUBLIC HEALTH RECOMMENDATIONS OF WHO

BY GERMÁN VELÁSQUEZ

FORMER DIRECTOR OF SECRETARIAT ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY, WHO GENEVA SENIOR ADVISOR AT THE SOUTH CENTRE

« The question of medicines and of their production by large pharmaceutical conglomerates is part of this senseless industrial and commercial monster that men have created to get the largest profits in the shortest possible time. As long as this quick enrichment « logic » prevails efforts (in favour of access to medicines) will falter. Because it is not a logical approach but a sophism which will lead to the destruction of mankind. This logic leads us into destroying our own environment : we destroy our vital living space, we pollute the water we drink and the oxygen we breathe. (…) As long as this logic rules the best trade will remain illicit. (…) Consequently the claim to humanize an unjust trade will be as inefficient as humanizing war. Injustice does not come from private property at all cost but depends on the balance between human beings in the face of available resources. » [1]

1. Abstract from the preface of Alejandro Angulo Novoa S.J. to the recent publication by Germán Velásquez and Carlos Correa El acceso a los medicamentos en el contexto de los acuerdos internacionales de comercio y las nuevas reglas de propiedad intelectual, Ediciones Antropos Ltda, Bogota, Colombia, November 2008.

Never before did the world have at its disposal such large therapeutic facilities as today to face the diseases affecting mankind. But equally millions of persons die through lack of medicines from which everybody should benefit (at least theoretically) thanks to the technical and financial tools we have. Only three out of the nine million persons who need an antiretroviral treatment (ARV) in the developing countries effectively benefit from it [2], and, according to WHO, about eight out of ten million deaths of children under five years of age which take place in developing countries could be avoided if these populations had access regularly to medicines [3]. All the efforts made at present by States, international organizations, industry, non governmental organizations and charity institutions are insufficient [4].

These last years the debate on access to medicines has gone beyond national and international bodies (health ministries and World Health Organization) to reach national organizations in charge of trade and intellectual property and international organizations such as the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO). For this reason the countries and interested observers ask for more and more collaboration between WHO and WTO, which is a good thing. However to optimise this collaboration it is worth reflecting upon the nature and functions of these two organizations.

Since the winds of liberalization and deregulation have swept over international organizations and industrialised countries WHO has not been spared with respect to the development model we are going through.

The majority of the industrialised countries have introduced mechanisms for controlling the price of medicines so as to make sure their social security systems are viable, but most developing countries do no longer control the price of medicines … with the agreement or at least the tacit agreement of WHO.

2. Cf. Report of WHO/UNAIDS/UNICEF 2008.

3. Cf. J. Quick, H. Hogerzeil, G. Velásquez, L. Rago, Twenty-five years of essential medicines, Bulletin of the World Health Organization, 2002, 80 (11).

4. Resolution WHA61.21 of the World Health Assembly, Public health, innovation and intellectual property: global strategy and plan of action, Geneva, May 2008.

Confronted with the present crisis the rich countries announced the injection of colossal sums of money into their banks, their financial institutions and some private sector industries, like that of car making; once more the developing countries will have to tighten their belt. And what will organizations like WHO do? Will they continue promoting the policies which were proposed as a development model now under reexamination, or will they reformulate their policies to grant to health the place it deserves… by putting the market and its rules into their right place and putting health at the level of rights and equity?

WTO and WHO have not been outside the crisis now affecting the world. Let us put it this way: WTO has been and is a symbol of liberalization and market hegemony and that WHO, either accomplice or at least timid and silent witness, have known how to adapt to the model imposed. Both will have to draw their own conclusions and adapt to the new economic international context.

THE CREATION OF WTO AND WHO: A BRIEF HISTORY

THE CREATION OF GATT, ANCESTOR OF WTO[5]

GATT (General Agreement on Tariffs and Trade) was born after the Second World War in answer to three big questions which were essential for the reconstruction of the world economy: exchange rates, reconstruction and organization of the international trade in goods. In 1944 the allied powers were considering three international organizations to deal with this problem. In July 1944 the IMF (International Monetary Fund) and the World Bank were created by the Bretton Woods Agreements, signed by 44 allied nations.

5. G. Velásquez, C. Correa, El acceso a los medicamentos en el contexto de los acuerdos interna- cionales de comercio y las nuevas reglas de propiedad intelectual, Ediciones Antropos Ltda, Bogota, Colombia, November 2008.

In parallel with the Bretton Woods Conference the idea of creating an international trade system based on free trade was born in view of setting up a world trade organization. Finally the World Trade Organization was not born in 1948 because the country which proposed it did not accept it and so the GATT became the main international trade institution. In order to promote liberalization several negotiation « rounds » were organized, like the « Kennedy Negotiations (1964-1967) or the Tokyo Round (1973-1979) where the majority of agreements on non-tariff barriers were signed , up to the final act creating the World Trade Organization (Marrakech, 1994) ; this was the result of multilateral and plurilateral negotiations in the Uruguay Round. Today 153 nations are members of WTO. Other countries have applied for membership and negotiations are carried out during assemblies or inside working groups.

A framework Convention was agreed upon at the Uruguay Round ; it was the Agreement setting up the WTO, which encompasses several multilateral sector agreements. A member signing this Agreement implies compulsorily that he abides by all the multilateral agreements (multilateral agreements on trade in goods, general Agreement on trade in services and trade-related aspects of intellectual property rights (TRIPS)) whereas abiding by plurilateral agreements (civil aircraft and government procurement) is optional.

« Essentially, the World Trade Organization (WTO) is a place where member governments go, to try to sort out the trade problems they face with each other. At its heart are the WTO agreements, negotiated and signed by the bulk of the world's trading nations. Its main function is to promote as much as possible the smooth running, predictability and freedom of trade. » [6]

6. Cf. internet site of WTO, 2009.

THE TRIPS AGREEMENT

This Agreement, and in particular the sections relative to makes and patents is certainly the WTO tool likely to have the biggest repercussions on public health, especially regarding access to medicines in developing countries.

The TRIPS agreement is meant to reinforce and harmonize some trade-related aspects of intellectual property on a world scale. In the case of pharmaceutical products the agreement establishes a patent protection (of the product and process) during a period of at least twenty years.

Since 1998-99, WHO has stated[7] that pharmaceutical products must not be considered as mere goods although in practice they still are. The point of view proposed by WHO was confirmed in 2001 by the Declaration on the TRIPS Agreement and public health adopted at the WTO ministerial Conference which was held at Doha. In approving a declaration which was only partially relative to health the Ministerial Conference in truth granted a special status to medicines.

In the present debate it is more and more admitted that medicines play an important social role as they are essential for exercising a right to health although in practice, as was mentioned above, medicines remain « captive » of commercial rules which apply to all consumer goods.

The preamble and the general dispositions of the TRIPS Agreement underline the necessity of promoting an efficient and sufficient protection of intellectual property rights, but also of taking into account a series of larger economic objectives. The protection of intellectual property rights is not an absolute obligation.

Article 7 (Objectives) and Article 8.1 as well indicate clearly that the protection of intellectual property rights comes under public policy objectives.

7. Cf. Political perspectives of WHO on medicines N° 3. Globalization, TRIPS and access to pharmaceutical products, Geneva, 2001.

Article 7 : « The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation (…) to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations. »

Article 8 : « The members to adopt measures for public health and other public interest reasons (…) »

The TRIPS Agreement foresees that the patent protection for any invention and in particular for pharmaceutical products must apply to all members (taking into account some exceptions agreed upon such as the transition periods granted to less advanced countries).

Though the patent system did in the past have a certain positive effect on public health in enabling research and development of new pharmaceutical products essential for health we wish to mention that, as indicated by the recent World Strategy for public health, innovation and intellectual property approved by the 193 WTO member states in May 2008, the intellectual property rights are an incentive which cannot stimulate pharmaceutical innovation for fighting diseases when the potential market is « restricted or uncertain ». [8]

The most important aspect of all the dispositions of the TRIPS Agreement is perhaps the possibility for WTO to make these agreements binding.

« The WTO's procedure for resolving trade quarrels under the Dispute Settlement Understanding is vital for enforcing the rules and therefore for ensuring that trade flows smoothly.

A dispute arises when a member government believes another member government is violating an agreement or a commitment that it has made in WTO. The authors of these agreements are the member governments

8. Cf. Resolution WHA61.21, *op. cit.* point 7, p. 6.

themselves – the agreements are the outcome of negotiations among members. Ultimate responsibility for settling disputes also lies with member governments, through the Dispute Settlement Body. » [9]

THE WORLD HEALTH ORGANIZATION

The World Health Organization (created on the 7th April 1948) is the specialized United Nations organization as a coordinating authority on international questions of public health.

As a governing and coordinating authority for health action within the United Nations WHO is responsible for managing the world health action, for defining health research programmes, for presenting political options based on relevant data, for providing a technical support to countries and for monitoring trends in matter of public health. [10]

Article 19 of the WTO Constitution states: « The Health Assembly shall have authority to adopt conventions or agreements with respect to any matter within the competence of the Organization. A two-thirds vote of the Health Assembly shall be required for the adoption of such conventions or agreements, which shall come into force for each Member when accepted by it in accordance with its constitutional processes. In May 2003 after 3 years of work the World Health Organization unanimously adopted the Framework Convention on Tobacco Control (FCTC) aimed at curbing tobacco-related deaths and disease. This is the first international treaty negotiated under the auspices of the World Health Organization (WHO). » [11]

« WHO fulfils its objectives through its core functions:

– providing leadership on matters critical to health and engaging in partnerships where joint action is needed;

9. Cf. internet site of WTO, Disputes settlement.

10. Cf. internet site of WHO: *www.who.int/about/fr/index.html*.

11. Cf. Seuba Hernández, Xavier. Thesis of doctorate La protección de la Salud ante la Regulación Internacional de los Productos Farmacéuticos, p. 75, Barcelona, 2008.

- shaping the research agenda and stimulating the generation, translation and dissemination of valuable knowledge;
- setting norms and standards and promoting and monitoring their implementation;
- articulating ethical and evidence-based policy options;
- providing technical support, catalysing change, and building sustainable institutional capacity;
- monitoring the health situation and assessing health trends.

These core functions are set out in the 11th General Programme of Work, which provides the framework for organization-wide programme of work, budget, resources and results. Entitled « Engaging for health », it covers the 10-year period from 2006 to 2015. » [12]

The WHO functions set out in the eleventh general work programme (2006-2015) seem to limit themselves to adopting technical texts and recommendations. The adoption of binding texts has remained limited [13] and only took place exceptionally like in the case of the framework convention on tobacco control, of the International Health Regulations or perhaps some elements of the « World Strategy for public health, innovation and intellectual property » recently approved (May 2008) [14]; or as it would be the case for an international treaty on research and development of new pharmaceutical products, discussed within this strategy.

COMPARISON BETWEEN WTO AND WHO

Comparing WTO and WHO (see table on page 159) seems to show that WHO is in a better position, considering its objectives, its mode of operation, its technical means, its location in many countries and its relations

12. Cf. internet site of WTO: *www.who.int/about/role/fr/index.html*.

13. Cf. Seuba, X, *op. cit.* p. 487.

14. Cf. *op. cit.* Resolution WHA61.21 of the World Health Assembly.

with non governmental organizations, to tackle the problem of access to medicines, with an important exception : point 12 on the compulsory dispositions of the TRIPS Agreement. WHO should look at what WTO does or the countries concerned should modify or apply the dispositions of WTO's constitution to make its « recommendations » binding when the issue is an important public health question.

WTO has at its disposal a powerful tool for compelling its members to apply thoroughly the rules they have approved. The Memorandum of understanding on the rules of dispute settlement defines a complete framework in view of settling disputes amiably but as a last resort it offers a quasi-juridical mechanism and sets the delays for every step in the procedure. The dispute settlement body is the only one entitled to setting up special expert groups examining the disputes and accepting or rejecting the conclusions of these groups or the results of appeals.

The dispute settlement procedure is the corner stone of the present commercial multilateral system. The existence of this mechanism means that all WTO members have committed themselves to abide by all the rules and concessions granted and that they will use the dispute settlement procedure instead of unilateral decisions when one or several members consider that another member has adopted measures which are not in conformity with the above mentioned rules and concessions. This is what regards commercial decisions. In a matter of public health, sometimes questions of life and death, would these decisions be less important ?

It is strange and even difficult to admit that the international community empowered an organization like WTO with a mechanism for applying binding decisions. The application of WTO rules relative to international trade, like those contained in the TRIPS Agreement, depend on a dispute settlement body which is nothing

but a tool for imposing these rules. At WHO one talks about optional recommendations … And vaccination against poliomyelitis, a humiliating and incapacitating disease, is in the 21st century not yet compulsory.

The future of WHO, in particular in the field of medicines, will depend upon the means at our disposal to make compulsory the measures in favour of public health promotion and defence within a framework of equity and justice. When decisions of international organizations like WTO are binding for their members, WHO resolutions and directives remain simple recommendations for the time being though WHO has the possibility of adopting binding resolutions. WHO will only be able to give its advice in the field of medicines if the international community wishes to give it proper binding mechanisms, like recently in the case of the framework convention on tobacco control or the International Health Regulations. Will it be the same case for the World Strategy for public health, innovation and intellectual property[15] (approved in May 2008) ?

Do the commercial juridical rules negotiated in the WTO framework enable the whole population to access essential medicines equitably and regularly ? This is the fundamental issue. This is why any form of collaboration, interaction and complementarity between WHO and WTO will have to take clearly into account this « starting point » which is also somehow the « arrival point ».

15. Cf. *op. cit.* Resolution WHA61.21 *op. cit.*

TWELVE POINTS OF COMPARISON BETWEEN WTO AND WHO

	WTO	WHO
1.	Sets and supervises international trade regulations.	Sets, promotes and supervises the right to health.
2.	Takes decisions by « consensus » and according to the « single undertaking » principle. [16] 16. WTO single undertaking principle: at Doha the ministers agreed that no final decision would be taken on an element of the Doha development round before results were « established » in all other fields of the round. This principle, referred to as « single undertaking » means that nothing is agreed upon before everything is agreed upon.	Takes decisions by simple majority vote.
3.	Meetings are « formal », « informal », « informal with groups of countries » or of the « green Salon ». [17] 17. Rather than a place the green Salon designates a process by which the delegation chiefs seek informally a consensus under the chairmanship of the Director General.	The meetings of the governing bodies are not limited in their composition (open to all) and also those of the working groups (editorial groups) of the Executive Council of the World Health Assembly.
4.	The staff of the Secretariat is fairly small: 629 persons present in Geneva only.	The staff of the Secretariat is fairly large: more than 2500 persons in Geneva, 6 regional offices and more than 100 country offices.
5.	The Secretariat has a limited role.	The Secretariat enjoys a large autonomy to take initiatives, formulate recommendations in the spirit of the Constitution and of the resolutions of the World Health Assembly.

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6.	The staff claims not to be entitled to interpret any agreement.	Great freedom of adapting and/or interpreting policies and recommendations in the spirit of the Constitution and of the resolutions of the World Health Assembly.
7.	153 members (in 2009).	193 members in (2009).
8.	Industrialised countries carry a lot more « weight ».	Developing countries carry much weight.
9.	Non governmental organizations and news reporters play a fairly limited role : they are admitted neither in the formal nor in the informal meetings and no non governmental organization obtained the observer status.	The meetings of the governing bodies are open to NGOs and the public including news reporters and professional associations of the private or public sector. A large number of NGOs have official relations with WHO. The Organization and NGOs have common projects.
10.	Must apply the clause of the most favoured nation. [18]	A particular treatment granted to a country is not compulsorily extended to all the others…
11.	The developed countries are anxious about WHO's role in the field of intellectual property.	Recommendations are not binding (except the framework Convention on tobacco control and the international health regulations).
12.	Decisions are binding and the Dispute Settlement Body is entitled to apply them.	Recommendations are not binding (except the framework Convention on tobacco control and the international health regulations).

18. According to the first Article of the GATT (1947) : « With respect to customs duties and charges of any kind imposed on or in connection with importation or exportation or imposed on the international transfer of payments for imports or exports, and with respect to the method of levying such duties and charges shall be accorded immediately and unconditionally to the like product originating in or destined for the territories of all other contracting parties. » In other terms it is forbidden to grant a product a different treatment according to its origin. Any advantage granted to a country must be extended to all the other WTO members.

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LOGOS AND ACRONYMS

Logos and acronyms are translated and presented in two languages in the following order: French/English.

Accord DR-CAFTA	Accord entre l'Amérique centrale, les États-Unis et la République Dominicaine/Central America Free Trade Agreement
ACP	Afrique, Caraïbes, Pacifique/African, Caribbean and Pacific Group of States
AD/DA	Agenda du développement/Development Agenda
ADPIC/TRIPS	Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce/Trade-Related Aspects on Intellectual Property Rights
AELE/EFTA	Association européenne de libre-échange/European Free Trade Association
AGOA	African Growth and Opportunity Act
AIEA/IAEA	Agence internationale de l'énergie atomique/International Atomic Energy Agency
AIPPI	Association internationale pour la protection de la propriété intellectuelle
ALE/FTA	Accord de libre-échange/Free Trade Agreement

APTA	Andean Trade Preference Act
BM/WB	Banque mondiale/World Bank
CBE/EPC	Convention sur le brevet européen/European Patent Convention
CDPI	Comité du développement et de la propriété intellectuelle/Committee on Development and Intellectual Property
CETIM	Centre Europe-Tiers monde
CFE	Commission fédérale d'éthique
CIEL	Center for International Environmental Law
CIPIH	Commission sur les droits de propriété intellectuelle, l'innovation et la santé publique/Commission on Intellectual Property Rights, Innovation and Public Health
CNUCED/UNCTAD	Conférence des Nations Unies sur le commerce et le développement/United Nations Conference on Trade and Development
CSSR	Centrale sanitaire suisse romande
CPTech	Consumer Project on Technology
DB	Déclaration de Berne
DDC (DP)/SDC	Direction du développement et de la coopération (Direction politique)/Swiss Cooperation and Development Agency
DFAE	Département fédéral des affaires étrangères
DFE	Département fédéral de l'économie
DFI	Département fédéral de l'intérieur

DFJP	Département fédéral de justice et police
DNDi	Drugs for Neglected Diseases Intiatives
DUDH	Déclaration universelle des droits de l'homme
EU/USA	États-Unis d'Amérique/United States of America
FAO	Food and agriculture organization
FFI/IFF	Facilité financière internationale/International financial facility
FMI/IMF	Fonds monétaire international/International Monetary Fund
FNUAP/UNFPA	Fonds des Nations Unies pour la population/United Nations Population Fund
GAD/FOD	Groupe des amis du développement/Group of Friends of Development
GATT	Accord général sur les tarifs douaniers et le commerce/General Agreement on Tariffs and Trade
GAVI	Alliance mondiale pour les vaccins et l'immunisation/The Global Alliance for vaccines and immunization
GFAM	Le fonds mondial de lutte contre le sida, la tuberculose et le paludisme/The global fund to fight AIDS, tuberculosis and malaria
GHW	Global Health Watch
HAI	Health Action International
ICTSD	International Center for Trade and Sustainable Development

IMPACT	International Medical Products Anti-Counterfeiting Taskforce
IPI	Institut fédéral de la propriété intellectuelle
MSF	Médecins sans frontières
NPF/MFN	Nation la plus favorisée/Most Favoured Nation
OAPI	Organisation africaine de la propriété intellectuelle/ African Intellectual Property Organization
OCDE/OECD	Organisation pour la coopération économique et le développement/Organization for Economic Cooperation and Development
OEB/EPO	Office européen des brevets/European Patent Office
OI/IO	Organisation internationale/Intergovernmental Organization
OFAG	Office fédéral de l'agriculture
OFSP	Office fédéral de la santé publique
OGM	Organisme génétiquement modifié
OIT/ILO	Organisation internationale du travail/International Labour Organization
OMC/WTO	Organisation mondiale du commerce/World Trade Organization
OMD/WCO	Organisation mondiale des douanes/World Customs Organization
OMPI/WIPO	Organisation mondiale de la propriété intellectuelle/ World Intellectual Property Organization

OMS/WHO	Organisation mondiale de la santé/World Health Organization
ONG/NGO	Organisation non gouvernementale/Non Governmental Organization
ONUSIDA/UNAIDS	Programme commun des Nations Unies sur le VIH/SIDA/Joint United Nations Programme on HIV/AIDS
ONU/UN	Organisation des Nation Unies/United Nations Organization
OTAN/NATO	Organisation du traité de l'Atlantique Nord/North Atlantic Treaty Organization
OXFAM	Oxford Committee for Famine Relief
PED/DC	Pays en développement/Developing Countries
PHI	Groupe intergouvernemental sur la santé publique, l'innovation et la propriété intellectuelle/Intergovernmental Working Group on Public Health, Innovation and Intellectual Property
PI/IP	Propriété intellectuelle/Intellectual Property
PIB/GDP	Produit intérieur brut/Gross Domestic Product
PMA/LAC	Pays les moins avancés (désignés comme tels par l'Organisation des Nations Unies et actuellement au nombre de 50)/Least Advanced Countries
QUNO	Quaker United Nations Office
R&D	Recherche et développement/Research and Development
SECO	Secrétariat à l'économie et au commerce
SECURE	Normes provisoires appliquées par la douane aux fins du respect uniforme des droits

SIDA/AIDS	Syndrome de l'immunodéficience acquise/Acquired Immuno Deficiency Syndrome
TIC	Techniques de l'information et de la communication
TLE/FTA	Traité de libre-échange/Free trade agreement
TWN	Third World Network
UE/EU	Union européenne/European Union
UNESCO/UNESCO	Organisation des Nations Unies pour l'éducation, la science et la culture/ United Nations Educational, Scientific and Cultural Organization
UPOV	Union pour la protection des obtentions végétales/ Union for the Protection of New Varieties of Plants
USD	Dollar américain/US Dollar
VIH/HIV	Virus de l'immunodéficience humaine (causant le SIDA)/Human Immunodeficiency Virus
WERO	WIPO Evaluation and Research Office
AMS/WHA	Assemblée mondiale de la santé/World Health Assembly

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[*n*] indicates a reference to a note.

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Most of the information regarding the goals and structure of WTO can be found on the site *www.wto.org/indexfr.htm*, and in Hoekman et al. (2007) as well.

World Intellectual Property Organization (WIPO)
34, chemin des Colombettes, c.p. 18,
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www.wipo.int

WIPO is an intergouvernemental organizazion of the United Nations, established in 1967 (WIPO (1979)).

International Union for the Protection of New Varieties of Plants (UPOV)
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Printed in November 2010 by Médecine et Hygiène (Groupe M+H)
46, chemin de la Mousse
1225 Chêne-Bourg (Switzerland)