4. Conclusion

The TRIPS Agreement causes a lively discussion that this document has attempted to explain and illustrate by digging deeper into it and denouncing the unfair aspects. The questions asked, the different domains examined and the various actors involved make this Agreement one of the main problems of economic and health policy at the beginning of this millenium. The topic complexity justifies coming back briefly on this problem before formulating some responses. Some useful links will be given for those who wish to find some more detailed information.

4.1 The actors and their role

An "invisible" confrontation takes place between WTO, WIPO and the pharmaceutical industry on one hand and the DC's health ministries on the other hand. "Invisible" because there is no clearly stated opposition. WIPO, the World Intellectual Property Organization, lets WTO and WHO play the first role in trade and health respectively. WHO sees its programme for Essential Drugs severely threatened considering the delay imposed by the new IP rules for reproducing original medicines in the form of generics. The dispositions of the Agreement which might offer the DC's solutions in case of health emergency are poorly known and difficult to implement in these countries when they are not prevented by the signature of bilateral agreements with industrialised countries; such agreements compel governments of the South to reinforce their legislation in matter of IP related to medicines.
For the attention of readers in the field we come back hereafter on the different actors involved in the globalisation affecting the population's health and their respective roles.

4.1.1 WTO, WIPO and their joint actions

WTO comes first. During the negotiations leading to the creation of WTO the Agreement was negotiated and finalised[185] and its successive transformations and adaptations were decided[186]. Its Internet page proves very useful to access the official texts of the most important documents and get informed about the ongoing negotiations[187].

The collaboration programmes and responsibilities distribution regarding the Agreement application, in particular with WIPO and the national organizations for IP, are worked out and defined within WTO. WTO remains a prime actor in any action pertaining to access to essential drugs since the problems related to patents for medicines and vaccines are part and parcel of the vast domain of patents and IP protection following any discovery and industrial invention.

Even if WIPO[188] seems to play a minor role in the ongoing discussions on the Agreement modifications wanted by the DC's it is present in the TRIPS Council and in all the other bodies concerned by the Agreement and having a decision making or consultative power. WIPO could have a very important position in the sense that IP constitutes the common denominator between the pharmaceutical companies and the access to their products by the population, between R & D protection and Right to health. At a local level the role of WIPO is played by the different national organizations for IP; in Switzerland, for example,

[185] The TRIPS Agreement was published as an IC Appendix to the Marrakesh Agreement creating WTO, 15th April 1994; see WTO (1994).
[186] In particular the Doha Declaration on the TRIPS Agreement and public health; see Doha (2001); and the Declaration on the implementation of Paragraph 6 of the Doha Declaration; see WTO (2003).
[187] Information about TRIPS: www.wto.org/french/tratop_f/trips_f/trips_f.htm
[188] The Convention creating WIPO is available at: www.wipo.int/treaties/fr/agreement/index.html.

by the Federal Institute for Intellectual Property (IFPI) which gives out on its Internet site a very complete information on the Agreement and the ongoing *rounds of discussion* (Doha, Cancún, Hong-Kong, etc.)[189].

On the 1st January 1996 a cooperation agreement between WTO and WIPO came into force via the TRIPS Council. This agreement foresees a cooperation in three big fields, i.e. «the notification and translation of national laws and regulations, and the access to these texts as well, the implementation of procedures in view of protecting national emblems and the technical cooperation»[190]. Two years later the task is more clearly stated: it is to "help" the DC's to abide by the end dates of the Agreement: «WTO and WIPO unite their efforts in helping the DC's to conform to the deadline of year 2000 set for respecting the commitments regarding IP[191]». Three years later the task remains unchanged: «(A joint initiative of WTO and WIPO) launched in 2001 aims in the same way at helping the less advanced countries to respect their deadline date of January 1st , 2006 [...]», but it is added «[...] and to use the IP protection for their economic, social and cultural development»[192].

[189] www.ifpi.ch.
[190] www.wto.org/french/tratop_f/trips_f/trips_f/intel3_f.htm.
[191] www.wto.org/french/news_f/press98_f/pr108_f.htm.
[192] www.wto.org/french/tratop_f/trips_f/trips_f.htm.

4.1.2 WHO

The position of WHO is totally different from those of WTO and WIPO; rather than «helping the less advanced countries to abide by their deadline date of January 1st, 2006» it proposes to «offer the necessary technical assistance and support to the Member States so as to stimulate an implementation of the TRIPS Agreement which is coherent with the protection of public health and the development of access to medicines. This activity is guided by the political prospect of WHO, which considers public health and access to medicines a priority[193].

Hence the meetings between WHO and WTO and their joint study on the *WTO agreements and public health*[194], and the 2004 Workshop (with WIPO) on *IP rights and vaccines in the DC's*[195]. Within this framework defined by WHO it was possible to reach in 2001 the ministerial Doha Declaration, which stipulates that the Agreement «should be interpreted and implemented in such a way as to protect the public health and promote the access to medicines for all. [...] The Declaration safeguards the principle which was preconized by WHO during the last four years, i.e. restating the right of WTO members to use fully the dispositions of the TRIPS Agreement to protect the public health and improve the access to medicines»[196].

But the most interesting WHO initiative likely to stimulate reflection and dialogue on the problem of access to medicines in the DC's was the recent implementation of the Commission on intellectual property rights, on innovation and public health (CIPIH).

In the CIPIH are grouped experts from WHO, UNCTAD, UNAIDS, WIPO, WTO, the pharmaceutical industry and the civil society. Launched by WHO in February 2003 on the basis of a resolution of its world Assembly it has the task to collect data and proposals coming from different concerned parties and to work out an analysis of IP rights, of innovation and public health; this analysis must include the question of adequate financing and of mechanisms facilitating the creation of new medicines and other active products against the diseases which affect the DC's in a major way. The final status report of CIPIH was presented in its final form during the world Assembly of WHO in May 2006.

[193] www.who.int/medicines/press/policy/globtrade/en/print.html.
[194] See WHO/WTO (2002).
[195] See WHO-IVB (2004).
[196] Correa (2002); see also WTO (2003).

The CIPIH aims at «collecting data and proposals coming from different concerned parties and at working out an analysis of IP rights, of innovation and public health; this analysis must include the question of adequate financing and of mechanisms facilitating the creation of new medicines and other active products against the diseases which affect the DC's in a disproportionate way»[197]. The life span of CIPIH seems to be limited to presenting its final report; however, its existence could be extended, in particular if a large number of NGO's considers its activity useful and efficient and makes it known.

During its first years of existence the CIPIH activity was intense; the Commission went to several countries and promoted a large variety of «discussion and analysis forums» on its Internet site and in thematic meetings[198]. Let us note in particular the contributions stimulated by CIPIH and relative to "ignored diseases"[199] or to the frequent practice of *evergreening* which enables a pharmaceutical firm to extend a patent simply by changing the appearance or the colours of its product[200]. Other institutional actors expressed themselves on the topics put under discussion by CIPIH; in particular WIPO which formulated some «preliminary comments» on the activities and proposals of CIPIH[201] which are worth examining.

CIPIH has no decision making power but it is our opinion that it should play a precious role of go-between among the actors most directly related to the power structures on one hand and the governments, the health ministries of DC's and the NGO's which represent the interests of the civil society on the other hand. The DC's NGO's in particular would be well advised to register themselves on the CIPIH's site[202] to remain well informed about all the activities proposed, to participate via Internet in its forums and studies, to benefit from the possibility of submitting proposals and to share their experience.

[197] See for example CIPIH (2004), (2005); it is clear that the task assigned to CIPIH is much larger than the reflections and analysis of the Agreement and its consequences on the access to medicines.
[198] Consult the CIPIH site (in English); www.who.int/intellectualproperty and its specific pages: /events, /documents, /forum, /links, /studies, /seminars, /submissions, /topics.
[199] See Smith (2005) and Towse (2005); see also Lanjouw (2005) and Musungu *et al.* (2005).
[200] See CIPIH (2005a), for example.
[201] WIPO (2004).
[202] Interested organizations and individuals can visit the site: www.who.int/intellectualproperty/contact/form/.

4.1.3 The governements and health ministries of DC's

Despite their role and the weight of their decisions the governments and health ministries of DC's often seem indifferent to the health problems of their country. In accepting the Agreement they pay little attention to the restrictions and obligations it implies. One could expect that they use all the exception possibilities foreseen by the Agreement, which is far from being the case. More interested in signing free-trade agreements with industrialised and rich countries, whereby they explicitly renounce the safeguard clauses of the Agreement[203].

This calls for a more vigilant action by local NGO's versus their governments through a direct action or through contacts with the health institutions of DC's.

However, there are some cases of consultation between government and civil society, as proposed by governments, like Chile for example:
«The general Direction of economic international relations of the Chilean

[203] Several such cases were presented in Chapter 2.

[204] *Convocatoria permanente a la sociedad civil* (2005): www.direcon.cl/index.php?accion=sociedad_civil_05.

ministry of foreign affairs invites all institutions and organizations of the Chilean socitey (among other the academic, professional, women's, indigenous people's organizations [...]) to present their opinion on the commercial topics relative to the negotiation and implementation of the free-trade agreements.»[204]

4.1.4 NGO's

The NGO's of industrialised countries – the most influential representatives of the civil society – can often put pressure to bear in a stronger and better coordinated way than the DC's on the international institutions and on their own government as well.

In Switzerland the Bern Declaration (DB)[205] is an interesting example. It intervened about the free-trade agreements negotiated by Switzerland with the DC's: «Obtain from the five South African countries the most severely affected in the world by HIV/AIDS [...] that they reinforce their legislation in matter of intellectual property on medicines beyond the already binding rules set by the TRIPS Agreement of WTO? This is what Switzerland is trying to obtain through a bilateral free-trade treaty. However, this is not what these countries need of which 20 to 40 % of the adult population carries the AIDS virus. To treat their whole population they must, on the contrary, have a sufficient manoeuvering latitude to obtain the cheapest anti-retroviral generics [...]. Far from public view and without a true parliament control Switzerland concludes with developing countries bilateral free-trade agreements containing dispositions in matter of intellectual property which reduce further the access to essential and vital medicines in developing countries. [...] This is a grave and poorly known problem in which the DB is actively engaged»[206]. Oxfam[207] takes similar initiatives.

For several years Médecins Sans Frontières (MSF) has been organizing a *Campaign for access to essential medicines*[208] and acts in the field during its interventions in the DC's and at an international level by stimulating the collaboration with other NGO's and the organization of joint meetings with other institutional actors[209].

On the 28 August 2003 MSF called upon the countries of America «to reject the United States' efforts aiming at reinforcing the protection measures of intellectual property beyond the global standards in the negotiations of the Free-Trade Area of the Americas (FTAA). MSF launched a campaign asking the signatory countries to exclude from this Agreement any disposition relative to intellectual property – a position which was put forward publicly by Brazil as well. The ongoing FTAA negotiations aim at creating the largest free-trade area in the world, which represents a market worth one thousand billion dollars and covers 34 countries distributed over North America, Central America, South America and the Carribean. The FTAA draft agreement also includes proposals of clauses on intellectual property which would reduce drastically the access to affordable medicines by imposing rules on intellectual property much stricter than in other regions of the world [...] However, the FTAA draft agreement goes much further than the standards established in the TRIPS Agreement. For example the United States propose to extend the monopoly duration of a patent beyond the 20 years foreseen in the TRIPS Agreement and to limit the granting of compulsory licences. These «TRIPS-plus» clauses would have as a consequence to limit drastically the access to essential medicines at affordable prices in the Americas.»[210] Recently MSF has been very active during the first consultation phase started by CIPIH (February 2005), through a *Technical briefing document* on the effects of a deadline date (2005) for the Agreement implementation and through a contribution presented at a meeting organized by WIPO (April 2005)[211].
During a collaboration between several NGO's a *Geneva Declaration on the future of WIPO* was recently worked out which underlines clearly what are the present emergencies and which defines the role that the civil society organizations have to play with respect to the institutional bodies: «The delegations representing the WIPO member states and the WIPO secretariat are being asked to choose a future. We want a change in orientation, new priorities and better results for mankind. We cannot wait one more generation. It is time to seize the opportunity and move forward»[212].

[205] Site of the Déclaration de Berne: www.evb.ch
[206] www.evb.ch/cm_data/public/viderdoha.pdf; see WTO *et al.* (2002) and Reinhard (2004).
[207] www.oxfam.org; see Oxfam (2004).
[208] www.msf.be/fr/news/access_campaign/news; see mainly Pecoul (2002), (2005).
[209] See for example the Proceedings of the meeting organized in collaboration with Consumer Project on Technology, Oxfam, and Health International on the implementation of the Doha Declaration, 27th February 2002, in Moon (2002).

[210] www.msf.be/fr/news/access_campaign/news/ftaa.htm.
[211] MSF (2005a), (2005b).
[212] www.cptech.org/fp/wipo/futurompi.doc.

4.1.5 The regional pressure groups of Latin America and Africa

A. Latin America

The Oficina de Coordinación para la Salud en América Latina y el Caribe (which is part of the Acción Internacional por la Salud (AIS)[213] is an international network which seeks to promote a universal access to essential medicines and their rational use[214].

B. Africa

In Africa an important mobilisation exists, often directly related to the devastating problem of AIDS on this continent and to the very limited access of the population to extremely costly treatments, a situation which has grown worse after the Agreement implementation.

The example of Kenya can be quoted where the flexibility of the Agreement was included in the IP Act 2001 partly through technical assistance and pressure on the government exerted by local NGO's and in particular by the Kenya Coalition for Access to Essential Medicines (KCAEM), a group of local and international NGO's. These organizations studied different intellectual property laws and published a report putting in evidence the different flexibilities and means of safeguard, most of which were eventually included in the IP Act 2001. It is to be noted that the government also received a technical assistance from WIPO and WTO but that, according to a case study published by the DFID Health Systems Resource Centre in September 2004, it consisted essentially in putting models of laws at the government's disposal and was therefore without any real meaning in the local context[215,216,217].

At a regional level (South-East Africa) the Southern and Eastern African Trade Information and Negotiations Institute (SEATINI) based in Zimbabwe is an important example of a network in a civil society

[213] Responsible Roberto López Linares, Oficina de Coordinación AIS LAC, Aptdo. 41-128, Lima Perú); robertolopez@aislac.org.
[214] www.aislac.org.
[215] Lewis-Lettington *et al.* (2004).
[216] AFP (2001).
[217] SAPA-AFP (2001).

having played a key role in the domain of intellectual property and public health. SEATINI makes an effort to inform and make the public and the institutions concerned aware of the pressures exerted by industrialised countries on the African governments and to help those to resist them; they do so in supplying them with technical aid. The network promotes actively the regional coordination and organizes many international conferences for the different parties concerned[218,219].
The Regional Network on Equity in Health in Southern Africa (EQUINET) is also important. It is a network composed of individuals from all concerned parties and whose general aim is the promotion of equitable health systems.

SEATINI and EQUINET collaborate tightly over many projects from which can be quoted a recent programme carried out with the Center for Health Policy in South Africa. Its aim is developing the promotion and protection of equitable health systems in Tanzania and Zimbabwe, in a context of political pressures for trade and investment liberalisation (*Promoting health in trade agreements*), which are related to the TRIPS Agreement and the access to medicines (in particular to ART). After two years of activity the results of this programme were judged satisfactory, even if the relevant information for the local context is sometimes lacking and the dissemination of adequate information to the parties concerned remains problematic. To overcome these weak points the participants wish at present to:

a) develop new educational supports, better suited and destined either to the general public or to the different actors concerned;
b) translate these documents into the different indigenous languages;
c) develop the communication media (radio, etc.). The participants also wish to be involved more concretely in actions and to intervene henceforth at the political level (ministers, members of Parliament). They also want to extend the programme to the neighbouring countries of South-East Africa[220,221,222].

218 Masungo *et al.* (2004).
219 www.seatini.org/.
220 CHP (2005).
221 www.equinetafrica.org/.
222 Training and Research Support Centre, www.tarsc.org.

4.1.6 The regional pressure groups of Asia

In Asia the case of India can be quoted where the civil society has been and continues being active in protecting the benefits of a well developed and of quality generics industry, which is not only indispensable to India but also to numerous DC's. In the framework of revising the patents law in view of making it compliant with the TRIPS Agreement by the 1st January 2005 a national and international campaign, the Affordable Medicine and Treatment Campaign (AMTC) was launched; it aims at protecting the access to medicines and treatments at affordable prices. In India and in the countries importing medicines from India organizations of the civil society, NGO's, groups of patients and health staff participate in this campaign. The participants watch continually the evolution of discussions and denounce the dangerous aspects for public health by intervening with the decision-makers on the basis of solid and broad knowledge of the different domains and stakes.

AMTC denounced the project of adopting dispositions going well beyond what was demanded by the TRIPS Agreement and exercised some pressure to obtain:

1) simplified procedures for granting a compulsory licence;
2 the suppression of provisions allowing the granting of new patents to products already known under the pretext of a new use or new dosage of these products;
3) the adoption in its totality of Paragraph 6 of the Doha Declaration and of the *30th August Decision* regarding this paragraph (determining the export modalities to countries without a capacity for local production) [223,224225].

The fight of India to save its generic medicines flourishing industry was studied in detail in Chapter 3 «Case studies».

In Thailand some NGO's, two of which are active in the defense of AIDS patients, got together to lodge a complaint against Bristol-Myers Squibb (BMS) regarding the didanosine ARV for which the firm had registered a new patent only on the basis of a different dosage of constituants. In October 2002 the Thai Central Intellectual Property and International Trade Court (CIPITC) rendered its judgement in favour of the plaintiffs and the patent was withdrawn. This judgement was a first event in the sense that it referred explicitly to the Doha Declaration and to the safeguard of public health according to the TRIPS Agreement. However, not only BMS but also the Thai Department of Intellectual Property (DIP) appealed against the verdict[226].

223 Healthgap (2005).
224 Independent Media Center India, http://india.indymedia.org/en/.
225 See CL (2004).
226 Ramachandran (2003).

4.2 Prospects

The Agreement signed during the Uruguay Round of WTO which was held from 1986 to 1994 introduced for the first time rules relative to intellectual property in the multilateral commercial system. This WTO Agreement aims at attenuating the differences in the way these rights are protected throughout the world and to submit them to international common rules. In the case of medicines it extends the life span of patents up to twenty years; this is done – officially – to guarantee to R & D a return on investment and protect it from the dangers of counterfeiting. But as this document has shown this Agreement generated more problems than it has brought solutions. In certain cases it caused a medicines price increase, complicated supply, marginalised further the less privileged in the DC's, sabotaged the local production of generics and jeopardised the WHO programme for essential medicines. The intrusion of WTO in the health domain has weakened the role played by WHO in matter of public health at the international level. Moreover the technology transfer towards the DC's which was to be assured by the Agreement has not taken place. A confrontation surged between public health and profit, the main victim being the access to medicines. It was mentioned before in which way the adoption of this Agreement has widened the gap between South and North. In the long term it is difficult to see efficient solutions since the priorities of different parties diverge without much hope of conciliation. In the most deprived countries where most of the time there is no health system and where health costs are the responsibility of users it can be noticed a marginalisation of the poorest, an indebtedness of most households, a reduction in the access to health care and in parallel an encouragement to corruption.

In order to avoid negative consequences for the populations of DC's, as far as the supply of products indispensable for their survival is concerned, a real willingness of collaboration between all the concerned parties is mandatory. One can understand the necessity of financing R & D and protecting the medicines market from counterfeiting, the more this activity has nefarious effects for the producing countries of the North and for the DC's populations as well. However, this does not justify the race to profit in the indifference to vital needs and the negligence of R & D for specific diseases of DC's. Despite the difference of interests and influence of the actors present on the scene where The Agreement is played the general interest would be better served by guaranteeing the access to medicines up to the DC's populations and at the same time protecting IP rights and consequently R & D.

At all levels there exist possibilities to act in this direction. We invite for example the responsible persons of NGO's based in the DC's to participate actively in discussion forums on Internet (in particular *[e-med]*[227], French-speaking forum on essential medicines where many health professionals of DC's exchange information and opinions, or – in English – *Ip-health digest*[228] which reports on discussions and events at the world level). These instruments enable to follow-up the implementation of the Agreement and its avatars, to collect data relative to actions taken by organizations of the civil society, to bring together NGO's of DC's working in a same region on common themes and to provide any individual interested in this topic with information. In its capacity the Centrale Sanitaire Suisse Romande will contribute to this work of information, prevision and counsel and will try to answer the questions it receives[229]. So all these protagonists contribute to a thorny discussion where different interests conflict with each other, but the outcome could prove positive if all parties did recognise the principal subject: man.

[227] http://list.healthnet.org/mailman/listinfo/e-med.
[228] http://lists.essential.org/mailman/listinfo/fp-health.
[229] Centrale Sanitaire Suisse Romande, 15 Rue des Savoises, CH – 1205 Genève tél./fax +41 22 329 59 37 info@css-romande.ch www.css-romande.ch.