Deprive Doha of all substance

How through bilateral agreements EFTA states impose to developing countries intellectuel property rules on medicines that are beyond the WTO obligations and that restrict access to medicines

Julien Reinhard/Berne Declaration (Switzerland) August 2004

The 1995 WTO Trade-Related Aspects of Intellectual Property Rights agreement (thereafter "TRIPS agreement") has established high and uniform standards of patent protection, industrialized and developing countries as well. This agreement has strengthened the rights of patent holders worldwide and has made more difficult access to cheap and affordable generic version of new medicines in poor countries. Therefore the safeguard mechanisms provided by the TRIPS agreement (in particular the compulsory licences) have become very important for developing countries in order to counter-balance the exclusive rights of the patent holders, During the WTO ministerial conference in November 2001 WTO Member States have recognized in a declaration that the TRIPS agreement could be interpreted and implemented in a manner supportive of the "right to protect public health and, in particular, to promote access to medicines for all". (thereafter "Doha Declaration").[1]

However the USA and other industrialized countries negotiate with developing countries free trade agreements with intellectual property provisions on medicines which goes beyond the TRIPS agreement obligations (thereafter "TRIPS-plus" provisions). Those TRIPS-plus provisions delay and make more difficult generic competition or limit the use of the TRIPS safeguards (in particular the compulsory licences). They have consequences for the public health of millions of people in the poor countries. Agreement with TRIPS-plus provisions reduce the implementation space left by the TRIPS agreement which was reaffirmed in the 2001 Doha Declaration. In fact, gradually the Doha Declaration is deprived of its substance. That web of bilateral agreements is part of a global strategy to by-pass WTO multilateral negotiations and to continuously raise international standards on intellectual property.

Smaller states like Switzerland, Norway, Iceland and Liechtenstein are also concluding free trade agreements with TRIPS-plus provisions.The Berne Declaration asks EFTA states to stop negotiate TRIPS-plus provisions on medicines in its free trade agreements with developing countries.

1. Free trade agreements from the EFTA with third countries

The European Free Trade Association (EFTA) is a free trade area established in 1960. Today it has four member states left: Iceland, Liechtenstein, Norway and Switzerland. The EFTA states have concluded and are concluding many free trade agreements. For a long time EFTA followed a so-called "one step behind the European Union" (EU) policy, meaning that it was concluding free trade agreements only with countries negotiating similar agreements with the EU. The alleged purpose was to avoid that EFTA states would be commercially disadvantaged vis-à-vis the EU. It was mainly agreements with Eastern European and Mediterranean countries. However the situation has changed today: EFTA states are sometimes negotiating bilateral agreements out of the wake of the EU. Moreover they are obtaining provisions on intellectual property rights that are going further from what had been obtained by the EU. For instance the free trade agreement concluded between Chile and

[1] Declaration on the TRIPS agreement and public health adopted on 14 November 2001 (WT/MIN(01)/DEC/2)

EFTA on 26 June 2003 is going further regarding intellectual property on medicines than the association agreement between Chile and the EU from 18 November 2002. On 26 June 2002, EFTA concluded a free trade agreement with Singapore with TRIPS-plus provisions on medicines before than the USA concluded an agreement with Singapore on 6 May 2003.

Since 1995, EFTA has concluded free trade agreements with different categories of countries:
- developing countries: Morocco (1997), the Palestinian Authority (1998), Mexico (2000), Jordan (2001), Chile (2003), Lebanon (2004);
- Central and Eastern European countries: Macedonia (2000), Croatia (2000);
- high income countries: Singapore (2002).

Other agreement are under negotiations with Tunisia, Egypt, Southern Africa Customs Union (i.e. Botswana, Lesotho, Namibia, South Africa, Swaziland), Canada.
(For details about their respective TRIPS-plus provisions on medicines, see in attachment the list of the free trade agreements between EFTA and third countries since 1995).

Agreements with other countries or other groups of states are under project at different stage of development: Albania, Algeria, Gulf Cooperation Council (Bahrein, Kuwait, Oman, Qatar, Saoudi Arabia, United Arab Emirates), South Korea, Mercosur (Argentina, Brazil, Paraguay, Uruguay), Serbia-Montenegro, Thailand, Ukraine.[2]

2. TRIPS-plus provision on medicines in the EFTA's free trade agreements with third countries

Most free trade agreements between the EFTA states and third countries have provisions that strengthen the intellectual property rights in those countries further than the TRIPS agreement obligations (TRIPS-plus provisions). Although this pattern is well advanced for intellectual property provisions in agriculture (limitation of the farmers' rights, provisions enabling patenting on life, restriction on free access to seed, etc.)[3], it gains more and more importance regarding intellectual property provisions on medicines.

Among the four EFTA states Switzerland plays a particular role in this TRIPS-plus diplomacy with third countries. Switzerland bears a special responsibility since it is the only EFTA member state where world class pharmaceutical and agrobiotech companies are located. Those transnational companies are the direct beneficiaries of the TRIPS-plus provisions in agriculture and on medicines.

Countries which are not WTO member yet are also subject to those TRIPS-plus provisions on medicines. Such provisions are added to provisions requesting them to have their legislation in conformity with existing WTO rules. The free trade agreement that EFTA concluded in June 2004 with Lebanon (which is not a WTO member yet) provides a good example of those "TRIPS-like" provisions.[4]

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[2] Cf Press release of the EFTA ministerial meeting in Montreux on 24 June 2004. Press release of the EFTA ministerial meeting in Geneva on 15 December 2003; p. 2. EFTA's Third Country Relations. Factsheet of the EFTA. June 2004; 32 p.

[3] For more details on this agricultural aspect, see: Bernhard HEROLD. TRIPS-plus through EFTA's back door. How Free Trade Agreements concluded with EFTA-States impose much stronger rules on Developing Countries for IPRs on life than the WTO. Zurich: Berne Declaration, December 2003; 8 p.

[4] Lebanon committed itself: to become a contracting party of the TRIPS agreement before 1st March 2008, to grant an adequate and effective patent protection in all fields of technology on a level corresponding to the one in the TRIPS Agreement, and to grant compulsory licenses in compliance with the conditions of the TRIPS Agreement (see articles 3(a) and 3(b) of the EFTA-Lebanon free trade agreement from 24 June 2004).

At present EFTA free trade agreements contain 3 types of TRIPS-plus provisions on medicines:

(1) Protection of data on clinical tests for registration of pharmaceutical products

During the market approval (registration) of a pharmaceutical product by a drug national authority the pharmaceutical company which has developped the product shall provide data of clinical tests in order to prove the effacity and the safety of the pharmaceutical product. The protection of data means that during a certain period (e.g. 10 years in Switzerland)[5] other producers (i.e. generic producers) cannot access and rely authomatically on those data to get market approval for the same substance. They will be obliged to receive an authorization from the original producers and may have to give him a remuneration in order to use its data. In case there is no agreement with the original producer, the generic producer will be forced to make again efficacity and safety tests by its own in order to get market approval. Repeating the clinical tests is expensive. It's also unethical because patients are submitted to tests while the efficacity and safety of a substance has already been proved. Such data protection gives an advantage to original manufacturers and is a restriction for generic manufacturers. Since every pharmaceutical medicines has to be approved by the relevant national drug regulatory authority, this provision provides a protection to the original producer even if a pharmaceutical product is not patented or if it is subject to a compulsory licence. It may be very problematic in emergency situations.

The wording in the free trade agreements with Morocco, Macedonia, Croatia, Jordan is vague ("adequate and effective protection of undisclosed information ") and open to interpretation. The more recent free trade agreement with Chili goes further because it provides 5 years data protection. The agreement concluded with Lebanon on 24 June 2004 provides a longer period of data protection (6 years) and introduces the principle of adequate compensation for the use of such data with the consent of the original producer during the period of protection.

Such provisions are clearly TRIPS-plus. In its 19 September 2003 factsheet on the EFTA-Chili free trade agreement, the Swiss State Secretariat for Economic Affairs (seco) recognizes it openly: "The level of protection in the free trade agreement is superior to the one in the WTO TRIPS agreemement, in particular regarding complementary certificates of protection for medicines and phytosanitary products, as well as for the period of protection for the results of tests provided in procedure of market approval"[6]. The UK Commission on Intellectual Property Rights in its 2002 report on intellectual property rights and developpement policy is also very clear:
" TRIPS [in its article 39] does not require the imposition of data exclusivity, as such, on these test data, only protection against unfair commercial use. (...) In the light of the above, we take the view that developing countries should protect test data against unfair commercial use in order to protect the legitimate interests of the originators of data and their “considerable effort”. But TRIPS allows considerable freedom in how this may be done. Countries may allow health authorities to approve equivalent generic substitutes by “relying on” the original

[5] See article 12 of the Swiss Medicines Act (Loi fédérale sur les produits thérapeutiques).
[6] Unauthorized translation by the author. Original text in French: "Le niveau de protection de l'accord de libre-échange est supérieur à celui de l'accord ADPIC de l'OMC notamment en ce qui concerne les certificats de protection complémentaires pour les médicaments et les produits phytosanitaires, ainsi que pour la durée de protection des résultats de tests fournis dans le cadre de procédure d'admission au marché." From seco. "Fact sheet: l'accord de libre-échange entre les Etats de l'AELE et le Chili." Berne, 19 September 2003; p. 4.

data. Developing countries should implement data protection legislation that facilitates the entry of generic competitors, whilst providing appropriate protection for confidential data, which may be done in a variety of TRIPS-compatible ways. Developing countries need not enact legislation the effect of which is to create exclusive rights where no patent protection exists or to extend the effective period of the patent monopoly beyond its proper term." [7]

(2) Additional extension of patent protection beyond 20 years

Extending the period of patent protection beyond 20 years delays the introduction of generic medicines.[8]
The agreements with Jordan, Macedonia and Croatia allow up to 5 years patent extension without mentioning any conditions. The agreement with Singapore allows up to 5 years patent extension if the market approval procedure with the national drug regulatory authority lasted more than 5 years. The agreement with Chile allow patent extension to compensate for unreasonable curtailment as a result of the marketing approval for a pharmaceutical product without indicating any maximum period.
Nothing in the TRIPS agreement obliges the States to grant such patent extensions, even in connection with the duration of market approval procedures.

(3) Restrictions affecting compulsory licences

Compulsory licences enable a State to allow third producers to produce a medicine without the consent of the patent owner. Article 31 of the TRIPS agreement details certain conditions but leaves policy space to the State to determine the grounds for example.

The agreements with Morocco, Macedonia, Croatia, Jordan state that compulsory licenses granted on the grounds of non-working of a patent will be limited to the satisfaction of the domestic market and according to reasonable commercial terms.
This limitation goes further than article 31.f of the TRIPS agreement that only states that compulsory licences will be used "predominantly for the supply of the domestic market".

Moreover, as mentioned earlier, the protection of data on tests for market approval may be a problem when a compulsory licence is granted.

3. Problems with the free trade agreements with TRIPS-plus provisions on medicines

(1) Restricting access to medicines for all

The TRIPS-plus provisions hinder the introduction of generic medicines or limit the use of the safeguards of the TRIPS agreement (in particular compulsory licences) in developing countries. This is ignoring the need of developing countries for cheap medicines as well as their right to implement the TRIPS agreement in a manner supportive and adjusted to their

[7] Commission on intellectual property rights. Integrating Intellectual Property Rights and Development Policy. London: September 2002; p. 70. cf: www.iprcommission.org On the same topic, see also: Carlos CORREA. Protection of data submitted for the registration of pharmaceuticals. Implementing the standards of the TRIPS agreement. Geneva: South Centre published in collaboration with the Department of Essential Drugs and Medicines Policy of the World Health Organization, 2002; 46 p.
[8] In Switzerland a patent holder on active ingredients or compostion of active ingredients for a medicine is entitled to ask an additional certificate of protection ("certificat complémentaire de protection") available up to 5 years after the date of expiry of a patent (art. 140a to 140m of the Swiss Patent Act (Loi fédérale sur les brevets d'invention).

public health needs. The case of HIV/AIDS medicines has proved that generic competition is the most efficient tool to lower the price of medicines and therefore to improve access to medicines. This is particularly important in developing countries where the majority of the population lives in poverty and has to pay its medicines out of its own pocket. On the contrary TRIPS-plus provisions profit giant pharmaceutical companies that hold patents or exclusive licences but not the sick in the poor countries.

Such provisions might be particularly detrimental to countries which are negotiating free trade agreements with the EFTA.

EFTA is negotiating now with the countries of the the Southern African Customs Union (SACU). Those countries have the highest HIV prevalence rate among their adult population in the world: South Africa (20.1%), Namibia (22.5%), Lesotho (31.0%), Swaziland (33.4%), Botswana (38.8%)[9]. Those countries give highly active antiretroviral treatments to their people if they want to avoid massive deceases and the consecutive collapse of theirs societies. However in view of the scale of the epidemics and of their limited ressources those countries shall be able to use generic competition in order to get the most affordable medicines. They countries don't need TRIPS-plus provisions that make more difficult to access to generic medicines.

Switzerland is exploring a possible free trade agreement with Thailand[10]. However Thailand is also facing a serious HIV /AIDS epidemics: there are more 755'000 people living with HIV (2.15% HIV prevalence rate among a population of 62.8 millions inhabitants)[11]. Thailand does not need to strengthen intellectual property on medicines too.

The problem is not limited to HIV/AIDS. Egypt is negotiating with EFTA a free trade agreement. Egypte has one of the highest prevalence rate for hepatitis C in the world: more than 14% of its population is affected. The new treatments against the disease that combine ribavarin and peg-interferon (both produced by Switzerland-based Hoffmann-La Roche) remain out of reach of the sick because of the high price of treatment (almost 6000 US dollars per patient for a 24 weeks treatment)[12]. It is in Egypt's interest not to restrict the policy space left by the TRIPS-agreement if it wants to treat its population.

The UK Commission on Intellectual Property Rights has recommended that developing countries take advantage of all flexibilities of the TRIPS agreement by using the safeguard mechanisms of the agreement like the compulsory licence and by facilitating the rapid introduction of generic medicines once a patent has expired. For instance the Commission recommends that developing countries introduce the « Bolar Exception » (or « early working exception ») that "makes it legal for a generic producer to import, manufacture and test a patented product prior to the expiry of the patent in order that it may fulfil the regulatory requirements imposed by particular countries as necessary for marketing as a generic. The WTO legality of this exception was confirmed in 2000 by the dispute settlement case brought by the EU against Canada.".[13]

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[9] Data for end 2001. World Report on Human Development 2003. New York: UNDP, 2003.
[10] See declaration of Swiss Federal Councelor reported in the *Neue Zürcher Zeitung* from 19 March 2004.
[11] MSF. Surmounting Challenges: Procurement of Antiretroviral Medicines in Low- and Middle-Income Countries. The Experience of Médecins Sans Frontières. Geneva: MSF-WHO-UNAIDS, 2003.
[12] Oxfam briefing paper. Robbing the Poor to Pay the Rich. How the United States keeps medicines from the world's poorest. London: Oxfam, November 2003; p. 8.
[13] Commission on intellectual property rights. Integrating Intellectual Property Rights and Development Policy. London: September 2002; p. 50.

(2) Raising intellectual property rights worldwide

The final purpose of TRIPS-plus bilateral agreements with developing countries is to continuously raise intellectual property rigths level worldwide. The strategy is quite clear. It is easier to get concessions through bilateral agreements with isolated developing countries than to negotiate with all developing countries in the WTO. The proliferation of TRIPS-plus bilateral agreement makes the TRIPS intellectual property standards (which have already been raised in 1995) look more and more like minimum standards. At the end TRIPS-plus bilateral agreements will open the way to review up the TRIPS agreement and to further strengthen intellectual property rights worldwide.

One should not misunderstand the fact that EFTA countries (Switzerland, Norway, Iceland, Liechtenstein) obtain from developing countries lesser TRIPS-plus provisions than countries with a stronger negotiating power like the USA or the EU. The small concessions that the EFTA countries obtain open the way to more concessions by more powerful states. There are always a "Most Favoured Nation" clause in the intellectual property provisions of the EFTA free trade agreement with third parties. This means that every concession that a country makes in a free trade agreement with a country is also extended to third countries which have concluded similar agreements with him. For instance through their free trade agreement with Chili they concluded on 26 June 2003, EFTA countries benefit of the additional concessions that the USA obtained from Chile through their free trade agreement concluded on 6 June 2003.

Provisions on intellectual property rights in free trade agreements obliges the countries to change their national legislation accordingly. This a bitter pill for poor countries: in exchange of few concessions by rich countries allowing more export of some agricultural products (e.g. fore Lebanon olive oil) developing countries have to adopt domestic laws that permanently make more difficult access to affordable medicines needed to treat their people.

There are no rational for developing countries to implement intellectual property law as high as in Switzerland or in other industrialized country. If the Swiss government wants to implement an high patent protection that hinders generic medicines in Switzerland because it thinks that it is in its interest to support the Switzerland-based pharmaceutical industry and that its population can afford expensive medicines, it is a choice that matters only for Switzerland. But it is unacceptable that the Swiss governement seeks to impose that choice to developing countries that have neither its richness nor its level of development, and that are facing difficult public health challenges.

With their TRIPS-plus bilateral diplomacy EFTA states are denying the letter and the spirit of the Declaration on the TRIPS agreement and public health they have adopted in Doha in November 2001[14]. All WTO member, including the four EFTA states (Switzerland, Norway, Iceland, Liechtenstein), have signed this Declaration. It states that the TRIPS Agreement "does not and should not prevent [WTO] Members from taking measures to protect public health " and that it "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all". By seeking and obtaining from developing countries TRIPS-plus provisions through bilateral free trade agreements, EFTA countries effectively restrict the

[14] Declaration on the TRIPS agreement and public health adopted on 14 November 2001 (WT/MIN(01)/DEC/2)

policy space of all countries they have recognized in Doha. As consequence of this TRIPS-plus diplomacy the Doha Declaration is deprived of its substance and is made meaningless.

UN Special Rapporteur on the Right to Health, Paul Hunt, has made clear that this TRIPS-plus diplomacy has consequence on the right to health: "The use of trade presure to impose TRIPS-plus style of intellectual property legislation could lead member states to implement intellectual property standards that do not take into account the safeguards and flexibilities included under the TRIPS Agreement, which in turn could constrain States from implementing intellectual property systems that provide adequate policy space for the promotion of the right to health."[15]

The UK Commission on intellectual property rights made a very clear recommendation too: "More specifically, we believe that developed countries should discontinue the practice of using regional/bilateral agreements as a means of creating TRIPS-plus intellectual property regimes in developing countries as a matter of course. Developing countries should be free to choose, within the confines of TRIPS, where to pitch their intellectual property regimes. Though developing countries have the right to opt for accelerated compliance with or the adoption of standards beyond TRIPS, if they think it is in their interests to do so, developed countries should review their policies in regional/bilateral commercial diplomacy with developing countries so as to ensure that they do not impose on developing countries standards or timetables beyond TRIPS."[16]

(3) Lacking transparency and democratic control

The negociations of bilateral agreements are not public and their results are known only once the text has been signed. The members of parliaments are informed lately of the precise content and implications of those agreements. Only the advantage gained for the economic actors are mentioned without considering their impact on access to medicines for all in developing countries. In Switzerland for instance, the annexes where stand the TRIPS-plus provisions are not always published or accessible on the internet[17]. This is a problem for provisions like provisions on intellectual property that oblige the states to change their domestic legislation.
This is also a problem for the public since the public is kept in ignorance of what is being negotiated in its name.

4. Demands of the Berne Declaration

-EFTA states shall abstain from seeking from developing countries provisions that hinder the introduction of generic medicines or that limit the safeguard mechanisms of the TRIPS Agreement (in particular the compulsory licences). They shall respect the letter and spririt of the 2001 Doha Declaration on the TRIPS Agreement and public health.

[15] Report of the Special Rapporteur of the Commission on Human Rights on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Paul Hunt. Addendum: Mission to the World Trade Organization. E/CN.4/2004/49/Add.1. 1 March 2004; p. 19.
[16] Commission on intellectual property rights. Integrating Intellectual Property Rights and Development Policy. London: September 2002; pp. 163-4.
[17] The annexes of the EFTA free trade agreements with third countries are accessible on the internet (in English) on: http://secretariat.efta.int/Web/LegalCorner/

-EFTA states shall renounce to introduce intellectual property provisions on medicines in bilateral free trade agreements with developing countries.

-The negotiations and results of the bilateral agreement shall be made public. The Members of Parliament shall be better informed (in particular about the consequence of those agreements on access to medicines for all in the developing countries). Parliaments shall be integrated in the negotiation process. The text of the agreements (including the annexes) shall be made public and accessible to all.

For more information:

- Commission on intellectual property rights. Integrating Intellectual Property Rights and Development Policy. London: September 2002; 178 p. (www.iprcommission.org)
- CORREA, Carlos. Protection of data submitted for the registration of pharmaceuticals. Implementing the standards of the TRIPS agreement. Geneva: South Centre published in collaboration with the Department of Essential Drugs and Medicines Policy of the World Health Organization, 2002; 46 p.
-HEROLD, Bernhard. TRIPS-plus through EFTA's back door. How Free Trade Agreements concluded with EFTA-States impose much stronger rules on Developing Countries for IPRs on life than the WTO. Zurich: Berne Declaration, December 2003; 8 p.
-MSF. Access to Medicines at Risk accross the Globe. What to Watch Out For in the Free Trade Agreements with the United States. MSF: May 2004; 12 p.
-Oxfam briefing paper. Robbing the Poor to Pay the Rich. How the United States keeps medicines from the world's poorest. London: Oxfam, November 2003; 34 p.
-Oxfam Briefing Note. Undermining access to medicines: Comparison of five US FTA's. A technical note. June 2004; 21 p.

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Annexe: EFTA free trade agreements concluded after 1995 and TRIPS-plus provisions on medicines (developing countries and other countries).

Contracting state [particular status]	***Date (signature)***	***Status (coming into force)***	***TRIPS-plus provisions on medicines***
Morocco	19.06.1997	In force. (01.12.1999)	Adequate and effective protection of undisclosed information (Annexe V art. 3.1), compulsory licenses granted on the grounds of non-working limited to the extent necessary to satisfy the domestic market and according to reasonable commercial terms (Annexe V, art. 3.1)[18]
Palestinian Authority	30.11.1998	In force. (01.07.1999)	Implementation and enforcement of "the highest international standards" of intellectual property rights (art. 15)[19]
Macedonia [country in transition; lower middle-income country]	19.06.2000	In force. (01.05.2002)	Up to five years additional protection for pharmaceutical products (Annexe V art.3), adequate and effective protection of undisclosed information (Annexe V art 3), compulsory licenses granted on the grounds of non-working limited to the extent necessary to satisfy the domestic market and according to reasonable commercial terms (Annexe V art 3)[20]
Croatia [country in transition, upper middle-income country]	19.06.2000	In force. (19.09.2002)	Up to five years additional protection for pharmaceutical products (Annexe VII art.3), adequate and effective protection of undisclosed information (Annexe VII art 3), compulsory licenses granted on the grounds of non-working limited to the extent necessary to satisfy the domestic market and according to reasonable commercial terms (Annexe VII art 3)[21]
Mexico	27.11.2000	In force. (01.07.2002)	[22]

[18] http://secretariat.efta.int/Web/ExternalRelations/PartnerCountries/MA/Annexes/14-Annex_V.pdf
[19] http://secretariat.efta.int/Web/ExternalRelations/PartnerCountries/Palestinian_Authority/PLO/PLO_FTA.pdf
[20] http://secretariat.efta.int/Web/ExternalRelations/PartnerCountries/MK/Annexes/10-Annex_V.pdf
[21] http://secretariat.efta.int/Web/ExternalRelations/PartnerCountries/CR/CR_RUAP/Annexes/17-Annex_VII.pdf
[22] http://secretariat.efta.int/Web/ExternalRelations/PartnerCountries/MX/Annexes/30-Annex_XXI.pdf

Contracting state(s) [particular status]	*Date (signature)*	*Status (coming into force)*	*TRIPS-plus provisions on medicines*
Jordan	21.06.2001	In force (01.09.2002)	Adequate and effective protection of undisclosed information (Annexe IV art. 3), compulsory licenses granted on the grounds of non-working limited to the extent necessary to satisfy the domestic market and according to reasonable commercial terms (Annexe IV, art. 3)[23]
Singapore [high income country]	26.06.2002	In force. (01.03.2003)	Extension of the patent term up to 5 years maximum if the marketing approval process had lasted more than 5 years (Annexe XII, art. 3.b.i)[24]
Chile	26.06.2003	In force. (01.07.2004)	Extension of the patent term to compensate the patent owner for unreasonable curtailment of the patent term as a result of the marketing approval (Annexe XII, art. 3.b); prohibition to transmit to third persons undisclosed informations on new chemical entities without the consent of their for a period of at least five years from the date of approval for a pharmaceutical product (Annexe XII, art. 4.2)[25]
Lebanon	24.06.2004	Will enter into force soon.	Prohibition to applicants for marketing approval from relying on or referring to undisclosed test or other undisclosed data submitted by prior applicants to the approval authorities for a periode of at least six years unless the first applicant is adequately compensated (Annex V, art. 4)[26]

[23] http://secretariat.efta.int/Web/ExternalRelations/PartnerCountries/JO/Annexes/10-Annex_VI.pdf
[24] http://secretariat.efta.int/Web/ExternalRelations/PartnerCountries/SG/SG_RUAP/Annexes/35-Annex_XII.pdf
[25] http://secretariat.efta.int/Web/ExternalRelations/PartnerCountries/CL/CL_RUAP/Annexes/CL_FTA_Annex_XII.pdf
[26] http://secretariat.efta.int/Web/ExternalRelations/PartnerCountries/LB/LB_RUAP/annexes/LB_Annex_V.pdf

Contracting state(s) [particular status]	***Date (signature)***	***Status (coming into force)***	***TRIPS-plus provisions on medicines***
Tunisia		Negotiations have ended. Not signed yet.	Not known yet.
Egypt		Under negotiation.	Not known yet.
SACU (Southern African Customs Union: Botswana, Lesotho [LDC][27], Namibie, South Africa, Swaziland)		Under negotiation.	Not known yet.
Canada [high income country]		Under negotiation.	No intellectual property provisions.

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[27] Least Developed Country