Occasional Paper 1

Protection of Intellectual Property and Public Health within the framework of the Chile-U.S. Free Trade Agreement

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October 2004

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Protection of Intellectual Property and Public Health within the framework of the Chile-U.S. Free Trade Agreement[1]

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After long negotiations, the Government of Chile signed a Free Trade Agreement (FTA) with the United States, achieving one of the most cherished ambitions of its commercial policy of the last decade. Chile, however, has had to pay a very high price for the greater access to the U.S. market that the FTA promises: higher standards of intellectual property protection that go beyond the minimum levels required by the World Trade Organisation's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Higher standards may result in significant costs for the Andean country, especially with regard to the protection of public health and access to technologies that would accelerate its economic development.

The intellectual property (IP) component of the FTA is, paradoxically, adopted at a time of growing scepticism about, and criticism of, the overprotection of intellectual property rights (IPRs) that the United States is actively pursuing bilaterally or at the regional level[3]. Compliance with the agreed standards under the TRIPS Agreement imposes significant restrictions and high costs on developing countries. There are no reasonable grounds for these countries to adopt "TRIPS-plus" levels of protection. On the contrary, these levels reinforce the advantages — based on monopolies rather than on free competition — of companies in the U.S. and other developed countries, as well as impose barriers on developing countries in terms of access to the products and technologies originating in developed countries.

The TRIPS Agreement laid down new and higher standards of IP protection, particularly with respect to patents, for all WTO member countries regardless of their level of development and technological capacity. However, as members of the WTO confirmed in the Doha Declaration on the TRIPS Agreement and Public Health ("Doha Declaration"), adopted at the Fourth WTO Ministerial Conference (November 2001), the Agreement includes some flexibilities or safeguards, which allow Member states to limit the extent of the monopoly conferred by patents. Under the agreement with the U.S, Chile has given up an important number of such flexibilities.

More room for patents

The FTA does not provide for Chile's right to implement exceptions to patentability for reasons of public interest, as recognised by the TRIPS Agreement, for diagnostic, therapeutic and surgical methods for the

[1] This paper was originally published in March 2004, in *Le Monde Diplomatique* (Spanish edition), under the title "Mal negocio de Chile con Estados Unidos" and has been translated with permission

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[3] See, e.g., the report of the Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy*, 2002, available at www.iprcommission.org

treatment of humans or animals. Even though Chile may legitimately state that these methods do not constitute inventions (due to the lack of technical contribution), there is more room to force the patent office to grant patents on new *uses* of already known products — such as the drug AZT for HIV-infected individuals and sildenafil for erectile dysfunction. These patents have become increasingly common due partly to the declining capacity of the pharmaceutical industry to develop products that represent a real therapeutic advance.

Under the FTA, each Party shall provide that a patent may be revoked or cancelled only on grounds that would have justified a refusal to grant a patent, including fraud in obtaining it. This provision abolishes the right, granted under the Paris Convention, to set the revocation of a patent on the grounds of failure to work or insufficient working after a compulsory licence has been granted (Article 5A), or on the grounds of lack of payment of the annual maintenance fees. The possible cancellation of a patent is further limited by precluding the use of other grounds, such as the deliberate lack of information on the origin of biological resources claimed in the patent. The implementation of an obligation to disclose the origin of biological resources — through the amendment of Article 29 of the TRIPS Agreement — is actively sought by many developing countries in the TRIPS Council of the WTO.

Longer duration of rights

As we all know, the prices of pharmaceutical products drop dramatically at the expiration of the patent that grants them protection. Many countries have consequently adopted exceptions and procedures to accelerate the entry of generic products into the market. The possibility of extending the term of pharmaceutical patents, provided for in the agreement, poses a serious threat to Chile's public health policies (a country in which patents are still granted for 15 years from the date of issuance of the patent) for two cumulative reasons.

Firstly, the term of a patent could be extended (Article 17.9.6) "to compensate for unreasonable delays that occur in granting the patent". An unreasonable delay in the sense of this paragraph shall include a delay in the issuance of the patent of more than five years from the date of filing of the application in the territory of the Party, or three years after a request for examination of the application has been made, whichever is later, provided that periods attributable to actions of the patent applicant need not be included in the determination of such delays. In signing this agreement, Chile places itself among the most protectionist countries of patent rights. As Álvaro Díaz, the Chairman of the IP negotiating group from Chile, admitted, this concession, together with some others in the accord, "satisfies the aspirations of the foreign pharmaceutical industry"[4].

Secondly, pursuant to Article 17.10.2 (a) — only applicable to pharmaceutical products — Chile shall make available an extension of the patent term to compensate the patent owner for unreasonable curtailment of the patent term as a result of the marketing approval process. The agreement does not specify, as in the previous case, the circumstances under which the curtailment of the patent term should be considered "unreasonable". Under the agreement, it seems that any curtailment is to be considered

[4] Submission before the Commission of Foreign Affairs, Interparliamentary Affairs and Latin American Integration of the Chamber of Deputies of the Congress of Chile, session of 4 September 2003

unreasonable. In addition, no mention is made as to whether said curtailment shall apply only to delays in the approval process in Chile (though it would be legitimate to consider it so) or whether the delay in the first country where the marketing approval had been sought should be taken into account. Even when the approval process for pharmaceutical products has been reduced during the last few years, it may still take five, eight or more years.

No maximum period is provided for the extension of the patent term in relation to either of the two cases mentioned above. This constitutes a remarkable difference when compared to the current situation in the United States where the extension on grounds of delays in the marketing approval process shall not exceed five years and where, in no case, shall exclusivity exceed fourteen years from the date of approval by the Food and Drug Administration (FDA). Since the grounds for the extension of patent terms under the Chile-U.S. FTA are *independent*, *cumulative* and with *no maximum period*, nothing seems to prevent a patent from being extended, for example, for two years due to a delay in its granting process and five more years due to a delay in the marketing approval process of the pharmaceutical product. In other words, Chile would have the rare privilege of being one of only a few countries to grant patents on pharmaceutical products for 25 or more years! This measure has obvious consequences: the delay in the introduction of competing products with the ensuing loss of consumer welfare and increased barriers to drug access for the poor.

Exclusive protection of data

The FTA also entails another serious loss of flexibility derived from the inclusion, in the agreement, of the obligation— not required under the TRIPS Agreement— to confer a term of exclusivity in relation to test data submitted for marketing approval of pharmaceutical or agro-chemical products. While Article 39.3 of the TRIPS Agreement only bans unfair commercial use of submitted undisclosed information, the FTA does not permit third parties to refer to the marketing approval granted to the party submitting the information. In accepting the TRIPS-plus interpretation of the U.S., the Chilean government agreed, in the treaty, that the national authority could not rely on a previous approval to approve a similar pharmaceutical product for a period of five years. This will exclude from the market any competing product, with inevitable consequences for the price of drugs.

The exclusivity of test data will operate in *the absence of* a patent protecting the product. Where such a patent exists, this exclusivity would, however, create barriers to the execution of a compulsory licence since Chile could not allow third parties (including the compulsory licensee) that do not have the consent of the person providing the information to market a product based on a previous drug marketing approval. In contrast, it should be noticed that, in the United States, the grant of compulsory licences includes the test data with a view to permitting the execution of a licence. For example, in the case of the acquisition of shares of Rugby-Darby Group Companies by Dow Chemical Co., the Federal Trade Commission required Dow to license to potential entrants into the dicyclomine market, formulations, patents, trade secrets, technology, know-how, specifications, processes, quality control data, the Drug Master File, and all information relating to the FDA approvals.

Denial of marketing approval

The FTA also provides for the health authorities to deny, to any third party, the marketing approval in relation to a patent-protected "pharmaceutical product" before the expiry of the patent term, except with the consent and the acquiescence of the patent holder. Such refusal of the application for the approval of a pharmaceutical product will be applicable *even when the applicant fully complies with the requirements for such approval*. Once the mere existence of a patent is confirmed, the pharmaceutical approval requested will be denied.

According to the Chilean negotiator, there would, however, be a way out of the restriction agreed to by the government. A procedure enabling the Public Health Institute to grant "sanitary permits" and not "marketing approvals"[5] would be defined. It is not clear, however, whether such a distinction will outlive U.S. claims of a breach of the FTA if the expectations created by the agreement to increase the U.S. monopolisation of the Chilean pharmaceutical market, embraced by the U.S. industry, are not realised.

A provision similar to that of the FTA was adopted by the Mexican Decree of 19 September 2003, which added paragraph (iv) to Article 167 and Article 167bis to the Regulation for Health Care Products (Reglamento de Insumos para la Salud). However, this Decree makes reference to "valid patents on the substance or on the active ingredient", whereas the Chile-U.S. FTA applies to any "pharmaceutical product". This implies that, in the Chilean case, not only patents on the active ingredient but also other product patents, such as patents on pharmaceutical salts and polymorphs[6], isomers, etc. — patents that are aggressively used to block the entry of competing products — would impede obtaining a marketing certificate.

This provision of the FTA constitutes an important concession made to the powerful lobby of the U.S. pharmaceutical industries. With this regulation, *the State directly takes on the defence of the rights of pharmaceutical companies patenting in Chile.* It substitutes for patent holders in exercising their rights. The FTA ignores the fact that, as is clearly laid down in the Preamble of the TRIPS Agreement, the rights over a patent are *private rights*, the exercise and defence of which are the exclusive responsibility of the holder. If a third party illegally exploits a patent, it falls to the holder, and not to the State, to request the necessary administrative and judicial measures to avoid infringements.

The FTA consequently ignores the right of any legally established pharmaceutical company to obtain the marketing approval for a product with proven therapeutic benefits. It also ignores the specificity and complete separation of the functions of the patent office and of the health authority in charge of marketing approval. The function of the patent office is to examine and grant patents on the basis of compliance with patentability requirements, payment of fees, etc. The role of the health authority is to grant approval when the product fulfils the corresponding sanitary requirements. If the product complies with such requirements, it must be approved since the health authority's *sole function is to protect public*

[5] Idem

[6] Polymorphysm is a property of some chemical compounds by virtue of which the same molecule crystallizes in different forms. The U.S. Food and Drug Administration, on 12 January 2003, adopted new regulations to discourage the approval of polymorphs as a way to hinder the entry into the market of generic products, and required the submission of test data on bioequivalence, among other elements (*Journal of Generics*, vol 1, No 1, p. 86)

health and not to protect the eventual property rights of third parties. To tie the activity of the health authority to the assessment of the patent situation amounts to the creation of a barrier that is completely counterproductive from a public health policy perspective.

This "linkage" also constitutes a serious breach of the basic principles of patent rights. The FTA establishes the legal presumption that the simple existence of a patent makes a request of marketing approval a violation of the patent, in contradiction to the basic principle requiring proof and assessment of the facts. This presumption ignores the fact that a high number of patents granted are ruled partially or totally invalid. The U.S. Federal Trade Commission itself, in a report dated October 2003, has drawn attention to the deficiencies of the patent examination and approval processes in the United States, and has suggested that "an overly strong presumption of a patent's validity is inappropriate" and that "it does not seem sensible to treat an issued patent as though it had met some higher standard of patentability"[7].

Thus the FTA lays down a TRIPS-plus requirement that is not even present in the NAFTA, of which Canada, Mexico and the United States are signatories. The agreement also contradicts the letter and the spirit of the Doha Declaration on the TRIPS Agreement and Public Health. Paragraph four of this declaration states: "We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement 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. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose".

The FTA will have, hence, negative consequences for public health since it may be used to block the legitimate introduction of pharmaceutical products — which could be competitive and accessible to Chilean patients — simply based on the existence of patents on a certain product. Chile, in accepting this obligation and the ones mentioned above, relinquishes its right to use the flexibilities provided for in the TRIPS Agreement, which does not require the strict and overly-demanding form of patent protection laid down by the FTA.

It is ironic to note that the patent-sanitary approval linkage, as established by the FTA, **does not exist at present either in the United States or in Europe**. Chile will, consequently, grant foreign pharmaceutical companies more rights than they have had so far in their own countries.

In the United States, companies obtaining patents can list them in the Orange Book, which gives them *the right to be notified by the FDA of a third party request for approval of a product covered by a patent* in order to take legal action, if the holder so desires, against a third party. The FDA is **not** empowered, however, to deny the approval requested by the third party as long as this party complies with the applicable health requirements. In Europe, the European Medicines Agency (EMEA) grants approval irrespective of the

[7] Federal Trade Commission. *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, October 2003, htpp://www.ftc.gov

patent status of the medicine whose approval is sought. Approval can even be granted to an *infringer*. The basic concept is that the protection of intellectual property is entirely independent of compliance with the technical health standards. In addition, the EMEA deliberately avoids the responsibility it would have to assume if it denied approval on the basis of the alleged existence of a patent, with the ensuing significant legal consequences if the affected party claimed damages.

Preserving flexibilities

Nothing is said in the FTA about the possibility of permitting *parallel imports*, even when these imports originate in the United States. Parallel imports — permitted under the TRIPS Agreement in accordance with the principle of "international exhaustion" — take place when patent-protected products are imported without the intervention or consent of the patent holder in order to benefit from the lower prices at which these goods could have been (legally) sold in a foreign country. In the absence of regulations on the subject, it is desirable that Chile secures, in its national legislation, the admissibility of these types of imports.

The FTA omits any reference to the grant of compulsory licences, that is to say, the authorisation the State can confer on a third party to use a patented invention without the holder's consent in the case of failure to exploit a patent, of an emergency or of other circumstances. This may mean Chile has not limited its capacity to grant these licences, thus preserving an essential right to ease the monopoly conferred by a patent, which is particularly important for the protection of public health. The law presently in force in Chile, however, provides for the issuance of compulsory licences only under very limited circumstances relating to anticompetitive practices.

The TRIPS Agreement does not impose any restrictions on the reasons for which a State may confer a compulsory licence, as confirmed by the Doha Declaration on the TRIPS Agreement and Public Health. Among the most common reasons found in comparative law are patent abuse, such as the failure to exploit an invention (expressly authorised by the Paris Convention), governmental use, emergencies, health or public interest, and the correction of anticompetitive practices. Chile should definitely provide for these grounds in order to protect its public interests, especially in the field of public health.

The FTA includes the so-called "Bolar provision", that is to say, the possibility for a third party to request regulatory approval, from health authorities, of a pharmaceutical product before the patent protection expires. This provision constitutes, however, no concession by the United States since it has been provided for in its own legislation since 1984.

A risky model

It is clear that the United States took part in the negotiation of the FTA with the aim of satisfying the needs of its national industries, especially of the pharmaceutical and copyright-based industries. It is not clear, however, why a country with limited industrial development and with the current poverty levels agreed, after the adoption of the Doha Declaration, to the implementation of standards of intellectual property protection that will encumber the process of industrialisation and the access to essential goods, such as education and public health.

It is true that other developing countries have accepted similar conditions to the ones imposed on Chile. Jordan accepted higher standards of IP protection in a bilateral agreement with the United States, but this was prior to the controversy leading to the adoption of the Doha Declaration and in a very different political context. It is also true that Singapore signed, almost simultaneously with Chile, a similar accord, but the Asian city-state has a higher *per capita* income and a stronger capacity to face the costs derived from higher levels of protection.

It should be noted that, in implementing the Most Favoured Nation clause, to which Chile is obligated under the TRIPS Agreement, the benefits gained by U.S. companies under the FTA are automatically and unconditionally extended to the companies of the other WTO member countries. This means that, in particular, the companies of the European countries, firmly committed to keeping their agricultural markets closed to Latin-American products, will benefit, for free, from the more favourable conditions that Chile has granted to the United States.

According to the Chairman of the Chilean IP negotiating group, Álvaro Díaz, in spite of the important concessions made and their likely negative effect on public health, "the success of the negotiation was more obvious on the issue of patents and regulated products, where a balance among the interests of national drug manufacturers, foreign laboratories and consumer rights was achieved"[8].

It is difficult, however, to share this feeling of success. The FTA is another example of a TRIPS-plus agreement, imposed on a developing country, in contradiction to what the WTO members approved in the Doha Declaration in an effort to strike a balance in the implementation of intellectual property. It sets a dangerous precedent for future negotiations. Developing countries currently involved in bilateral negotiations with the United States should prevent the Chile-U.S. FTA from becoming the *model* for any new agreement on intellectual property. This model satisfies the needs of U.S. pharmaceutical companies and not of the public health sector of the countries that have to implement it. It limits rather than promotes free trade and reduces governments' room for manoeuvre in implementing policies to develop their local pharmaceutical production capacities and to provide full access to medicines.

[8] Submission before the Chamber of Deputies of the Congress of Chile, session of 4 September 2003