

RECENT INTERNATIONAL DEVELOPMENTS IN THE AREA OF INTELLECTUAL PROPERTY RIGHTS

This paper examines some of the recent international developments in the area of IPRs: the *interim* implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, copyright and the expansion of “open access” options, the negotiations on the harmonization of substantive patent law and the protection of traditional knowledge (TK). It does not address other equally relevant issues, such as the proliferation of TRIPS-plus bilateral and regional agreements, which have been dealt with elsewhere¹, nor issues still subject to negotiation in WTO, such as geographical indications and the review of article 27.3 (b) of the TRIPS Agreement.

I. IPRS AND PUBLIC HEALTH

The relationship between TRIPS and public health has dominated the agenda of the TRIPS Council since 2001. Patents are particularly important for the pharmaceutical industry and their interests are well represented by some governments in that Council². At the same time, many developing countries have realized that the broad and strong IPRs protection in that field, and the aggressive patenting and enforcement strategies of large pharmaceutical companies, generates costs that had not been duly anticipated at the time of the adoption of the Agreement .

The Doha Declaration on the TRIPS Agreement and the Public Health, adopted in November 2001, was one of the most important international developments in the area of IPRs in WTO since the adoption of the Agreement in 1994.

The Declaration has indicated that in cases of conflict between IPRs and public health, the former should not be an obstacle to the realization of the latter. In affirming that the TRIPS 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”, paragraph 4 gives guidance to panels and the Appellate Body for the interpretation of the Agreement's provisions in cases involving public health issues. In doing so, Members have developed a specific rule of interpretation that gives content to the general interpretive provisions of the Vienna Convention on the Law of the Treaties on which GATT/WTO jurisprudence has been built up.

The confirmation that the TRIPS Agreement has left room for flexibility at the national level, namely with regard to the determination of the grounds for compulsory licensing and the admission of parallel imports, has important political and legal implications. It indicates that the pressures exerted by some developed countries to impede the use of available flexibilities run counter to the spirit and purpose of the TRIPS Agreement, especially in the light of the recognized “gravity of the problems”³ faced in the area of public health by developing countries

¹ See, e.g., US bullying on drug patents: One year after Doha, Oxfam Briefing Paper 33, November 2002.

² As illustrated by the USA rejection to the Chair's proposed solution for the problem described in para. 6 of the Doha Declaration on TRIPS and Public Health, due to US pharmaceutical industry's concerns about the scope of the mechanism to be approved under that paragraph.

³ See paragraph 1 of the Declaration.

and LDCs. In legal terms, such confirmation means that panels and the Appellate Body must interpret the Agreement and the laws and regulations adopted to implement it in light of the public health needs of individual Members States. Therefore, in cases of ambiguity, or where more than one interpretation of a provision is possible, panels and the Appellate Body should opt for the interpretation that is effectively “supportive of WTO Members' right to protect public health”.

The Doha Declaration instructed the Council for TRIPS to address a delicate issue: how can Members lacking or with insufficient manufacturing capacities make effective use of compulsory licensing. The Declaration requested the Council for TRIPS “to find an expeditious solution to this problem and to report to the General Council before the end of 2002” (paragraph 6).

On August 30, 2003, an agreement was reached at the Council for TRIPS⁴ for the implementation of its paragraph 6. This “solution” is based on a compromise developed by the Chair of the Council and on a “Statement by the Chair” requested by the USA as a condition to accept the compromise. The Decision takes the form of an *interim* waiver, which allows countries producing patented products under compulsory licenses to export the products to eligible importing countries, provided that a compulsory license has also been granted in the importing country and that various other conditions are met. The waiver would last until the TRIPS Agreement is amended.

The conditions established in both the text of the Decision and the Statement for allowing exports of patented medicines, are hardly compatible with the idea of an “expeditious” solution (see Box 1).

Box 1: Conditions for the operation of the “solution” under paragraph 6

- In order to get the supply of drugs under this mechanism the following steps must be followed⁵:
- (1) unless the prior request of a voluntary license does not apply, an entity in the importing country must seek a voluntary license from the patent owner;
 - (2) failing this an application for a compulsory license must be submitted and the license be obtained in the importing country;
 - (3) the importing country must assess its generic industry's capacity to produce the medicine locally;
 - (4) if capacity is insufficient, it must notify the WTO of its decision to use the paragraph 6 “solution”;
 - (5) the interested importing country or party must identify a potential exporter;
 - (6) that exporter must in turn seek a voluntary license on commercially reasonable terms for a commercially reasonable period of time;
 - (7) if the voluntary license were refused, the potential exporter must seek a compulsory license (to be granted on a single-supply basis) from its own government;
 - (8) if a license is granted, the exporter will have to develop the chemistry and formulate the drug (when produced by the licensee for the first time), and to investigate products' shape, coloring, labeling and packaging of the patent-holder's product in the importing country in order to differentiate the product for export;
 - (9) the exporter will also need to seek product registration and prove bio-equivalence based and bioavailability, when required by national law⁶;

⁴ See IP/C/W/405.

⁵ See, e.g., Brook K. Baker, “Vows of Poverty, Shrunken Markets, Burdensome Manufacturing and Other Nonsense at the WTO”, Health GAP, Sept. 27, 2003.

- (10) if in the importing country exclusivity (as promoted by the USA and EU) is granted with regard to data submitted for the registration of a medicine, the supplier will have to obtain authorization by the possessor of those data to use them, or to develop its own studies about toxicity and efficacy, unless the use of such data is included in the compulsory license;
- (11) before shipment begins, the licensee shall post on a website information about the quantities being supplied and the distinguishing features of the product;
- (12) the exporting Member must notify the Council for TRIPS of the grant of the license, including the conditions attached to it.

The process described in Box 1 must be fulfilled over and over since only the amount necessary to meet the needs of one particular eligible importing Member may be manufactured under the licence, and the entirety of this production shall be exported to the Member that has notified its needs to the Council for TRIPS.

In addition to all these steps, and as a pre-condition for the operation of the system, eligible countries may have to amend their national patent laws to allow the granting of licenses for export, or for import. The waiver of the obligations under article 31 (f) only means that a *WTO Member* will not complain against another Member using the system, but it does not prevent a *private party* from blocking the exportation or importation of drugs, if the national laws do not specifically permit such exports or imports under compulsory licenses.

Though the intent of the majority of the WTO Members in drafting the Decision was to facilitate the export of affordable drugs produced under compulsory license, the Chair's Statement added further constraints to the already cumbersome Decision. The Statement indicates that the special conditions (as set out in paragraph 2(b)(ii) of the Decision) apply not only to formulated pharmaceuticals but also to active ingredients produced and supplied under the system and to finished products produced using such active ingredients. The Statement also adds (though there is no evidence to support this statement), that it "is the understanding of Members that in general special packaging and/or special colouring or shaping should not have a significant impact on the price of pharmaceuticals. In addition the Statement introduces a monitoring system clearly aimed at facilitating challenges to another Member's use of the system, including on how the Member in question has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector.

The Statement also indicates that Members recognize that the system "should be used in good faith to protect public health and, without prejudice to paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial policy objectives". This ignores that the only sustainable way of providing a credible alternative to the supply by patent owners is the creation of incentives for other commercial companies to supply the required drugs and, ultimately, the development of a viable domestic industry.

⁶ If in the importing country exclusivity (as promoted by the USA and EU) is granted with regard to data submitted for the registration of a medicine, the supplier will have to obtain authorization by the possessor of those data to use them, or to develop its own clinical studies.

As discussed elsewhere⁷, in order to be effective, a solution to the problem described in paragraph 6 should be economically viable, and not only diplomatically acceptable. This agreement fails to provide an effective means of increasing competition and lowering drug prices. The adopted “solution” is so cumbersome for potential suppliers that they will be hardly encouraged to use the Decision, “because it is so designed that no generic manufacturer would be able or willing to comply with its provisions”⁸. Such a complex and burdensome system does not create a serious risk to the patent owners’ position; hence, they will have little or no incentive to lower their prices or to negotiate voluntary licenses.

In sum, the adopted “solution” is largely symbolic in view of the multiple conditions required for its application. It is unlikely to lead to any significant increase in the supply of medicines, particularly for the poor. In any case, developing countries now face two important tasks in relation to the adopted Decision:

(1) developing an interpretation of the Decision and Statement that clarify both the constraints and the flexibilities for the application of this “solution”. Many ambiguities in the text, as well as the legal status of the “Statement” need to be clarified.

(2) elaborating and proposing a *permanent* solution to the problem affecting countries with limited or without manufacturing capacities in this field, in order to reach an amendment of the TRIPS Agreement, as necessary. Such an amendment may be based on a fresh conceptual start, including a possible clarification to article 30 of the Agreement. It should aim at a simple and effective solution both in legal and economic terms.

Finally, it should be noted that *paragraph 6 only describes one of the problems* arising in the context of the TRIPS Agreement with regard to public health. The IPRs protection of pharmaceutical will continue to pose significant challenges to public health policies in developing countries, even if the agreed “solution” were proven to be viable and effective. The agreement on paragraph 6 does not mean an end to the controversies around IPRs and public health. They are likely to continue, especially as developed countries seek TRIPS-plus protection via interpretation⁹ or the negotiation of bilateral and regional agreements¹⁰, and as patents on marginal or trivial developments (sometimes called “ever-greening” patents) are granted and used to block or delay generic competition¹¹.

⁷ See e.g., Carlos Correa, IMPLICATIONS OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH, World Health Organization, Geneva (2002) at 33; Commission on Intellectual Property Rights, Integrating intellectual property rights and development policy London, 2002 (available at www.iprcommission.org)

⁸ Comments by D. G. Shah, Indian Pharmaceutical Alliance (mail of August 26, 2003, on file with the author).

⁹ The USTR, for instance, interprets that article 39.3 of the Agreement requires the granting of an exclusive period of protection for data submitted for the marketing approval of pharmaceuticals and agrochemicals.

¹⁰ See, e.g. the recent US-Chile and US-Singapore bilateral agreements.

¹¹ See, e.g., Carlos Correa (2001), Trends in drug patenting. Case studies, Corregidor, Buenos Aires.

II. DEVELOPMENTS IN PATENT LAW

Important developments (albeit with unpredictable outcomes) are taken place in the area of patent law. In September 2001, the WIPO Assemblies approved an initiative by the Director-General aimed at simplifying the acquisition of patent rights globally and at the further harmonization of patent law. The ‘WIPO Patent Agenda’ includes three components ultimately oriented to develop a framework for a “global patent”:

- (a) efforts to promote the ratification of the Patent Law Treaty (PLT), which harmonized procedures for patent applications;
- (b) the reform of the Patent Cooperation Treaty (PCT); and
- (c) negotiations on a Substantive Patent Law Treaty (SPLT).

The Patent Agenda is supposed to address the failure of the system to adequately respond to the international nature of business activities, the high costs of obtaining patents, the workload crisis in patent offices and time consuming procedures.¹²

While the reform of the PCT is intended to reduce patent offices’ overload, it would also blur the separation between Chapter I (international search) and Chapter II (international assessment of patentability) and extend the period for initiating the national phase of patent applications.

The SPLT, if adopted, may have far reaching consequences for developing countries, as it may dramatically limit the space available for designing patent policies at the national level. The TRIPS Agreement left great flexibility with regard to the crucial issues of what is patentable and how the requirements for patentability are defined and applied. This flexibility would disappear or be substantially eroded if the harmonization exercise is successful.

The TRIPS Agreement, in effect, only indicates what the requirements of patentability are (novelty, inventive step or non-obviousness, and industrial applicability or usefulness)¹³, but it neither defines such concepts nor what an “invention” is. TRIPS, moreover, does not contain rules on the modalities and interpretation of patent claims, which are essential to establish the scope of protection.

Discussions on the SPLT include, inter alia, key issues such as whether an invention should show a “technical character” in order to be patentable¹⁴. The United States seeks to internationalize its legislative model, which does not require such a character and thereby allows the patenting of computer programs, business methods¹⁵ and research tools¹⁶. Proposals have also been made to

¹² See Memorandum of the Director General, Agenda for Development of the International Patent System, August 2001, WIPO A/36/14, Geneva, para. 17 – 28.

¹³ See article 27.1 of TRIPS.

¹⁴ See SCP/6/9, para. 184.

¹⁵ “Business methods” include methods applied to business activities such as buying and selling, marketing techniques, financial schemes and strategies, generally supported on computer software and networks.

establish a harmonized standard of inventive activity based on the *general* knowledge of a person skilled in the art (as obtained, for instance from handbooks)¹⁷, and for the adoption of a “doctrine of equivalents” in a form that significantly limits the scope for inventing around a patented invention.

Progress towards the possible harmonization of the patent law may be blocked by differences between USA and EU on issues such as the grace period and the technical effect of patents. If these differences were overcome, however, developing countries would face the risk of being under pressure to adopt harmonized rules that would limit the possibility of defining what an invention is, applying strict standards of patentability and designing, according to their interests and levels of development, other aspects of substantive patent law.

III. COPYRIGHT AND THE CHALLENGE OF OPEN ACCESS

The TRIPS Agreement reinforced the protection of copyright, especially for computer programs and data bases. It also strengthened the protection of neighboring rights, particularly in relation to phonograms. However, the copyright section of the Agreement did not go as far as other sections (like the section on patents) in terms of developing new international standards of protection. Shortly after the adoption of the Agreement, two international conventions on copyright-related issues were successfully negotiated under the auspices of WIPO¹⁸.

While these conventions were designed to expand and strengthen copyright protection, several initiatives have been launched since the 1990's on the basis of the concept of “open access”. They include, for instance¹⁹, the initiative for a freely accessible software under a legal mechanism called “copyleft”. This mechanism aims at protecting free available software from being modified and then protected by a third party under IPRs.

Open access initiatives may be particularly appropriate in fields where decentralized creation is efficient, like in academic research and software development. It may be also applied in agriculture, where the improvement of seeds may be leveraged by access to a wide pool of materials. Farmers have, in fact, traditionally improved seeds and shared them with other farmers for cultivation, multiplication and further improvement.

Open access offers an alternative to the restricted access model based on the exercise of IPRs. It is gaining a growing number of adepts in the software area. In the United States, the European Union and many developing countries, governments are considering measures to encourage the

¹⁶ “Research tools” are methods or substances (such as Expressed Sequence Tags - ESTs) used to undertake research, notably in the biological field.

¹⁷ This means that specialized journals should not necessarily be taken into account to assess inventiveness.

¹⁸ WIPO Copyright Treaty and WIPO Treaty on Performances and Phonograms (1996). WIPO also convened a Diplomatic Conference to develop a treaty on databases in December 1996. One of the basic proposals considered by the Conference was the protection of non-original databases the production of which entailed a “substantial investment” (see document WIPO CRNR/DC/6, 30.8.96). This initiative, however, has found considerable resistance (including from the scientific and librarian communities in the USA) and no further negotiations have taken place so far.

¹⁹ The “Budapest Open Access Initiative”, the “Scholarly Publishing and Academic Resources Coalition” (SPARC) and, most notably, the Human Genome Project, are also examples of free access schemes.

public procurement of open-source software, such as the Linux operating system, already adopted by major hardware producers.

Creators or innovators under an open access model have no expectation of direct monetary gain. Access is easy and the dissemination of information/products is faster and more cost-effective than under IPRs. Open access, however, operates within the current legal framework of copyright law. It deals with information susceptible of appropriation under IPRs, that is made openly and freely available by the right holder who retains some or all of the exclusive property rights that are granted under statutory IP laws²⁰. Despite that open access is based on a restricted use of IPRs, WIPO has refused to deal with this kind of initiatives²¹.

IV. TRADITIONAL KNOWLEDGE

WIPO's General Assembly established in 2000 an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (ICGRTKF), with the mandate of discussing (a) access to genetic resources and benefit sharing, b) protection of TK and c) protection of expressions of folklore. The ICGRTKF held five sessions that provided an opportunity for discussion of legal, policy, economic and scientific issues relating to TK protection, including the analysis of *sui generis* forms for TK protection²².

While informative and technically solid, the analysis undertaken by the WIPO Secretariat for the ICGRTKF has attempted to explain traditional and indigenous practices of conservation and transmission of knowledge under established IP concepts²³, thereby ignoring the traditional and indigenous communities' views on the creation, use and sharing of knowledge.

WIPO has addressed the possible development of a *sui generis* regime for TK. The recognition and enforcement of customary law as a form of protection that respects cultural diversity, has been largely overlooked. For instance, a draft legislation prepared by the WIPO Secretariat for Venezuela proposes the granting of a set of exclusive rights essentially similar to those required under article 28 for patents, and makes protection of TK dependent on a disclosure requirement and the registration of knowledge²⁴. A similar approach inspired the law for the protection of TK adopted by Panama (Law No. 20, June 26, 2000 and Executive Decree No. 12, March 20, 2001).

²⁰ See, e.g. Paul Uhler (The National Academies), summary report of the Meeting on Copyright, Science, and the Public Interest, Science and Intellectual Property in the Public Interest (SIPPI), Directorate for Science and Policy Programs, American Association for the Advancement of Science (AAAS), (Washington D.C., 20 June 2003).

²¹ WIPO Secretariat accepted last July a suggestion from a group of lawyers and economists to convene an international meeting on the subject in 2004. The US Patent and Trademark Office objected the decision (thereby echoing the opposition of some U.S software companies and the Business Software Alliance). It argued that open-source software was contrary to WIPO's mission to promote intellectual property rights, and that to hold a meeting to disclaim or waive such rights would be "contrary to the goals of WIPO". WIPO Secretariat subsequently announced that the meeting will not be convened. See Declan Butler NATURE|VOL 424 |28AUGUST 2003 |www.nature.com.

²² For a summary of the IGC's discussions, see WIPO, Overview of Activities and Outcomes on the Intergovernmental Committee (WIPO/GRTKF/IC/5/12).

²³ See, e.g. WIPO, Intellectual property needs and expectations of traditional knowledge holders, Geneva, 2001.

²⁴ See Secretaría de la OMPI, "Proyecto de ley sobre la protección de los conocimientos tradicionales de los pueblos indígenas de la República Bolivariana de Venezuela y comentarios de las principales disposiciones".

In order to be protectable, TK²⁵ must be capable of commercial use (Law, Article 1) and based upon tradition, although it need not be 'old' (Law, Article 15). The knowledge must be registered and published, and protection is granted upon examination. Collective rights under the Panama's law are exclusive. They allow titleholders to authorize or prevent use and commercialization (Article 15) and industrial reproduction (Law, Article 20), for an indefinite time.

The extent to which WIPO Secretariat approach to the protection of TK would serve the interests of its intended beneficiaries is doubtful. Little consideration seems to have been given, in addition, to the *costs* that such a system would create, if operative. For instance, the granting of exclusive rights on products used in traditional medicine (TRM) systems may have high social costs via a reduction of access to medicines and treatment.

There are also other limitations and gaps in WIPO's work on the matter. For instance, no serious analysis has been made of the standards for patentability applied by WIPO members (such as the differential novelty standard applied in the USA with regard to inventions disclosed in non-written form outside the country) which allow the patenting of genetic resources and TK. Work done has also overlooked the role of customary law as a basis for TK protection.

During the fifth (and last) session of the IGCGR TKF (July 7-15, 2003), a very clear split between developed and developing countries emerged about the possible renewal of the Committee's mandate. Developed countries aimed at prolonging the current mandate, limited to technical analysis, for another two-years period or more. The USA, in particular, proposed to prolong the current mandate unchanged for another 4 years. The African Group, in contrast, demanded an immediate start of negotiations on "a legally binding international instrument on genetic resources, traditional knowledge and folklore". Developing countries from Asia and Latin America did not go so far, and suggested an action-oriented agenda, not limited to further studies, aiming at "norm-setting" of some kind, in particular to develop rules about bio-piracy and misappropriation of TK. The final decision is to be taken late this year by WIPO's General Assembly. A likely outcome is that it will simply prolong the mandate for another two years without major change²⁶.

The indigenous organisations that intervened at the last Committee meeting presented a coherent message. They supported the developing countries' request to pass from analysis to action, but "strongly emphasised the limited relevance of IPRs to the protection of TK, and consequently that any future work must 1) involve other intergovernmental organisations with more relevant mandates, and 2) take customary law rather than intellectual property law as a starting point"²⁷.

²⁵ The law protects customs, traditions, beliefs, spirituality, cosmovision, folkloric expressions, artistic manifestations, traditional knowledge and any other type of traditional expressions of indigenous communities which are part of their cultural assets (cultural heritage) (Law, Article 2). It also covers TK embodied in creations such as inventions, models, designs and drawings, innovations contained in images, figures, graphic symbols, petroglyphs and other material, cultural elements of history, music, arts and traditional artistic expressions (Decree, Article 1).

²⁶ See Peter Einarsson (2003), Report WIPO GRTKF5 (mimeo).

²⁷ Ibidem.

Depending, in sum, on the decision to be taken later this year about the future of the ICGRTKF, it may continue as a forum of discussion and study, as it was so far, or evolve into a negotiating or standard setting forum, as requested by some developing countries. Both options present some advantages and disadvantages. On the one hand, the extension of the mandate of the Committee as a discussion and study forum, may neutralize developments in other organizations, as some developed countries argue that work on TK should wait for the outcomes of the ICGRTKF²⁸. These outcomes may not be expected soon, given the complexity of the issues under consideration and the broad mandate of the Committee.

On the other, the negotiating or standard-setting option may allow the development of international rules on the matter. It is unclear, however, whether developing countries have a clear strategy and an articulated position to initiate negotiations. A logical approach would be, as suggested by some countries during the Committee's meeting, to concentrate as a first step on the development of misappropriation rules. While developing countries' governments have actively proposed the protection of TK, it is unclear to what extent there has been sufficient dialogue between governments and traditional/indigenous communities so as to ensure that their vision and customary law approaches are duly taken into account.

There is also a risk that the general philosophy of WIPO and its narrow mandate to promote intellectual property, influence such development in a way that ignores the multiple facets and implications of intellectual property protection, such as the restrictions on access to TRM and derived products, and the ensuing consequences for equity and human development. WIPO has been strongly led by a legalistic approach, without adequately consider other equivalent economic and social dimensions.

²⁸ For instance, the EC and its Member States have stated that they "support the development of an international model for the legal protection of traditional knowledge" and expressed their hope that the issue be taken by the WIPO Intergovernmental Committee referred above in cooperation with the CBD, and that "once a model is in place, attention can then be focused on how and to what extent the protection of traditional knowledge can be included in the TRIPS Agreement". See IP/C/W/254, 3.4.01.