FRIENDS WORLD COMMITTEE FOR CONSULTATION
Quaker United Nations Office – Geneva

tel: + 41 22 7484800
fax: +41 22 7484819
email: quno@mbox.unicc.org

Quaker House
Avenue du Mervelet 13
1209 Geneva Switzerland

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TRIPS Disputes: Implications for the Pharmaceutical Sector

Carlos M Correa
University of Buenos Aires
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Introduction

The adoption of the TRIPS Agreement has entailed significant changes for the protection of pharmaceutical products and processes. The Agreement not only made product patent protection binding to all Member countries (article 27.1); it also strengthened, inter alia, process patents (articles 28 (b) and 34), narrowly defined the conditions for establishing exceptions to patent rights (article 30), and limited the possibility of applying especial modalities of compulsory licenses to pharmaceuticals (e.g. as provided for in Canada until 1993).

The TRIPS Agreement became a crucial tool for the universalization of high standards of protection of pharmaceuticals, actively sought by large pharmaceutical companies and the governments of some developed countries. The Agreement dealt with a number of significant IPRs issues in a manner that no prior international convention had done before, including both substantive and enforcement rules, in some area (notably in the case of patents) with considerable detail.

However, the Agreement only incorporates minimum standards for the protection of intellectual property; it neither constitutes a uniform law nor an exhaustive codification of IPRs law. It has not addressed all possible issues to be dealt with under intellectual property laws, but only a number of issues on which it was possible to reach consensus. This means that the Agreement left a wide number of issues without any international standard[1]. In addition to these deliberate "gaps", there are many ambiguities in the text that were the result of difficult compromises made during the negotiations.

[1] For instance, in the area of patents, the issue of the "first to file" or "first to invent" principle was left out.

Unlike previous international conventions on intellectual property rights, under the TRIPS Agreement non-compliance with the obligations stipulated in the Agreement may lead to trade sanctions by other Member States, after the procedures provided under the Dispute Settlement Understanding (DSU) have been exhausted. The Understanding sets out a unified mechanism of dispute settlement covering all the multilateral trade agreements.

The adoption of the TRIPS Agreement as a component of the WTO system means that any controversy relating to compliance with the Agreement's minimum standards should be solved under the WTO multilateral procedures. The adoption by another Member of unilateral trade sanctions would be incompatible with the multilateral rules. Any complaint should be brought to and settled according to the rules of the Dispute Settlement Understanding (DSU).

Despite this, some countries have continued to be under unilateral demands by some developed countries, notably the U.S.A and the EU, in the area of IPRs, aiming not only at the implementation of the TRIPS Agreement standards, but often asking for "TRIPS-plus" protection[2]. In several cases, developing countries were persuaded to admit "TRIPS-plus" standards in order to benefit from other trade concessions under bilateral agreements[3].

The consistency of the authorization given to the US government to retaliate under several sections of the US Trade Act (such as section "Special 301") was examined by a WTO panel in a case initiated by the European Union. As mentioned below, however, on the basis of a commitment by the US government not to unilaterally apply sanctions, the panel did not find a violation to WTO obligations.

The TRIPS Agreement has been one of the most controversial components of the WTO system; it has given rise to a large number of procedures under the Dispute Settlement Understanding, involving alleged violations by developing and developed countries, even before the core of the Agreement's obligations entered into force in developing countries (1 January, 2000). In 1999 there had already been 16 WTO dispute settlement filings based on the TRIPS Agreement. This amounted to 10 % of all filings under the DSU, a significantly high percentage. 11 of the 16 filings were brought by the United States (Geuze and Wager, 1999). New complaints have been submitted after 1 January 2000, including USA against Brazil on compulsory licenses and parallel imports, and Argentina on various issues regulated under the patent and the trade secrets laws.

There have already been five cases decided, by panels or the Appellate Body specifically on the TRIPS Agreement[4]. In three cases, issues relating to transitional provisions have been dealt with. Two of them related to the implementation of article 70.8 by India. The third one related to the extension of the term of patents granted before the entry into force of the Agreement (article 70.2) This case involved two developed countries, the United States and Canada (Canada was found in violation of the Agreement). There were two other cases also between developed countries, in which the issues of exceptions to patent rights (EU v. Canada) and copyright (EU v. USA) were considered.

[2] An example was the USTR complaint against South Africa, later withdrawn, in relation to parallel imports (which are not disallowed under the Agreement).

[3] For instance, the bilateral agreements entered into between the European Union and South Africa (1999), Tunisia (1998) and the Palestinian Authority (1997) require the latter, in each case, to ensure adequate and effective protection of intellectual property rights "in conformity with the highest international standards".

[4] The Agreement was also incidentally invoked in the *Indonesia-Autos* case, in relation to the protection of trademarks (WT/DS54, 55, 59, 64/R).

The subject of disputes

In the USA-India and EU-India cases[5], the complaining parties argued that India had failed to provide a mechanism for implementing the "mail box" to be established in accordance with article 70.8 of the TRIPS Agreement. India was found to have failed to comply with its obligations under said article, since there was no legal basis –procedurally or substantively- for the grant of exclusive marketing rights when a product which is the subject of a patent application under article 70.8 became eligible for protection under article 70.9 of the TRIPS Agreement[6].

In the USA-Canada case[7], USA challenged section 45 of Canada´s Patent Act. It claimed that the patent protection term of 17 years (counted from the date of grant) accorded to patent applications filed before 1 October 1989 often ended before 20 years from the date filing. USA argued that pursuant to Articles 33 and 70.2 of the TRIPS Agreement, Canada was obligated to make available a term of protection that did not end before 20 years from the date of filing to all inventions which enjoyed patent protection on 1 January 1996, including those protected by the old Patents Act. Inventions enjoying protection under such Act were covered by article 70.2 of the TRIPS Agreement (protection of "subject matter" existing on the date of application of the TRIPS Agreement). USA prevailed; the Canadian law was found inconsistent with the Agreement.

The EU-Canada case[8] addressed the TRIPS-consistency of Section 55(2)(1) and (2) of the Canadian Patent Act, as revised in 1993, regarding the "early working", "regulatory review" or "Bolar" exception. This exception permits the use of a patented invention, without the consent of the patent holder, for testing required for the submission of data to obtain marketing approval for pharmaceutical products. The request for a panel was submitted in November 1998 by the EU and their member States. In March 2000, the panel concluded that Canada was not in violation of the TRIPS Agreement. However, Canada was found to be acting inconsistently with TRIPS in terms of its practice of manufacturing and stockpiling pharmaceutical products during the six months immediately prior to the expiry of the 20-year patent term. The panel report was not appealed.

Lastly, upon a complaint by the European Union, a panel found that section 110(5)(b) of US copyright law -relating to the enjoyment of certain works by customers in business premises-, was inconsistent with article 13 of the TRIPS Agreement[9].

Interpretation of the TRIPS Agreement

What are the lessons that may be drawn in relation to the TRIPS Agreement from the five referred cases and from other cases settled by panels and the Appellate Body? Though panels and Appellate Body's reports have no strict value as a precedent, that is, they do not bind future opinions on the same matter, they provide guidance to both governments and the DSU bodies for future cases. Several issues have been dealt with that require careful consideration.

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[5] See WT/DS50 and WT/DS79/R.
[6] In order to comply with article 70.9 of the Agreement, the President of India, on 31 December 1994, promulgated an Ordinance (the Patents (Amendment) Ordinance 1994) so as to provide a means for the filing and handling of patent applications for pharmaceutical and agricultural chemical products, and for granting of the exclusive marketing rights. The Ordinance was issued on the basis of the President of India constitutional powers to legislate when the Parliament is not operative but, lacking Parliament's confirmation, it lapsed on 26 March 1995.The "exclusive marketing rights" were later implemented by the Patens (Amendment) Act, 1999.
[7] See WT/DS170/R.
[8] See WT/DS114/R.
[9] See WT/DS160/R.

Relationship between TRIPS and the GATT

The panel in the USA-India case on the mail box provision, held that the TRIPS Agreement has a "relatively self-contained, *sui generis* status within the WTO". However, it also held that the Agreement is "an integral part of the WTO system, which itself builds upon the experience of over nearly half a century under the GATT 1947" (para.7.19).

The panels and the Appellate Body have, in practice, extensively applied previous GATT and WTO jurisprudence in the TRIPS-related cases. They have applied to cases involving TRIPS the same method of interpretation applied to cases involving other WTO Agreements, that is, the customary rules of interpretation as contained in Article 31 and Article 32 of the Vienna Convention on the Law of Treaties. No consideration has been given to the fact that while IPRs constitute *private rights*[10] the other components of the WTO system deals with *restrictions imposed on governments*.

The clarification of the relationship between the TRIPS Agreement and the GATT may be crucial for the interpretation of several aspects of the Agreement, such as the extent to which exceptions can be established under article 8.1, the admissibility of banning parallel imports and, more generally, the criteria to be applied to the interpretation of exceptions provided under the TRIPS Agreement. In fact, IPRs constitute themselves exceptions in terms of the GATT (article XX (d)), since by their very nature such rights restrict trade[11].

However, under GATT/WTO jurisprudence the exceptions to States' obligations have been generally construed in a narrow way (Correa, 2000). This also applies to the case of TRIPS, despite that the latter sets forth obligations of private parties vis-à-vis title holders, as illustrated by the panel's opinion on the exceptions to exclusive patent rights conferred article 30 of the TRIPS Agreement in the EU-Canada:

> "As long as the exception is confined to conduct needed to comply with the requirements of the regulatory approval process, the extent of the acts unauthorized by the right holder that are permitted by it will be small and narrowly bounded. Even though regulatory approval processes may require substantial amounts of test production to demonstrate reliable manufacturing, the patent owner's rights themselves are not impaired any further by the size of such production runs, as long as they are solely for regulatory purposes and no commercial use is made of resulting final products" (para. 7.45).

Principles of interpretation

As mentioned, the basic principles of interpretation are, according to the method adopted by GATT/WTO panels and the Appellate Body, those contained in articles 31 and 32 of the Vienna Convention on the Law of the Treaties. In accordance with article 39 (1) of said Convention, "a treaty is to be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose." The Convention also admits as an element for interpretation the "subsequent practice" by the parties to a treaty[12], as well as certain "Supplementary Means of Interpretation"[13].

[10] See the Preamble of the TRIPS Agreement, fourth para.
[11] See also the Preamble of the TRIPS Agreement, first para.
[12] The Appellate Body ruled in *Japan – Alcoholic Beverages* that "the essence of subsequent practice in interpreting a treaty has been recognized as a ´concordant, common and consistent´ sequence of

A corollary of these rules of interpretation, addressed in several GATT/WTO cases[14], is the concept of "effective interpretation" (or "l´effet utile"), which requires that a treaty be interpreted to give meaning and effect to all the terms of the treaty. Accordingly, whenever more than one interpretation is possible, preference should be given to the interpretation that will give full meaning and effects to other provisions of the same treaty.

Panels and the Appellate Body have used the negotiating history of the TRIPS Agreement to confirm the literal interpretation of particular provisions. One interesting feature is that the negotiating history may include the history of the Conventions that are specifically referred to by the TRIPS Agreement, such as the Paris Convention and the Berne Convention, and not only the negotiating history of the TRIPS Agreement as such. Therefore, a negotiation which took place more than one hundred years ago, like the Paris Convention, may be taken as a supplementary means of interpretation of the TRIPS Agreement.

In the EU-India case, for instance, the panel used the history of negotiations to confirm its interpretation of article 70.8:

> "The findings above can be confirmed by the negotiating history of the TRIPS Agreement. We note that in the negotiation of the TRIPS Agreement the question of patent protection for pharmaceutical and agricultural chemicals products was a key issue, which was negotiated as part of a complex of related issues concerning the scope of the protection to be accorded to patents and some related rights and the timing of the economic impact of such protection. A critical part of the deal struck was that developing countries that did not provide product patent protection for pharmaceutical and agricultural chemicals were permitted to delay the introduction thereof for a period of ten years from the entry into force of the WTO Agreement. However, if they chose to do so, they were required to put in place a means by which patent applications for such inventions could be filed so as to allow the preservation of their novelty and priority for the purposes of determining their eligibility for protection by a patent after the expiry of the transitional period. In addition, they were required to provide also for exclusive marketing rights in respect of the products in question if those products obtained marketing approval during the transitional period, subject to a number of conditions..." (para 7.40)[15].

In the EU-Canada ("Bolar") case, the Panel noted that, in the framework of the TRIPS Agreement, which incorporates certain provisions of the major pre-existing international instruments on intellectual property, the context to which the Panel may have recourse for

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acts...which is sufficient to establish a discernable pattern implying the agreement of the parties regarding its interpretation."

[13] Article 32 of the Convention provides that

> "Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of Article 31, or to determine the meaning when the interpretation according to Article 31:
>
> (a) leaves the meaning ambiguous or obscure; or
>
> (b) leads to a result which is manifestly absurd or unreasonable."

[14] See e.g., WT/DS121/AB/R, para. 88. See also Mengozzi, 1999, p. 26.

[15] The panel also stated that "The observation above can be confirmed by the drafting history of the TRIPS Agreement. Exclusive marketing rights were a *quid pro quo* for the delay of the availability of product patents for pharmaceutical and agricultural chemical products until 1 January 2005, based on a careful balancing of obligations between interested parties during the Uruguay Round negotiations (para. 7.72).

purposes of interpretation of specific TRIPS provisions, is not restricted to the text, Preamble and Annexes of the TRIPS Agreement itself, but also includes the provisions of the international instruments on intellectual property incorporated into the TRIPS Agreement[16], as well as any agreement between the parties relating to these agreements within the meaning of Article 31(2) of the Vienna Convention on the Law of Treaties. Finally, in the EU-USA case on copyright, the panel supported its interpretation on the negotiating history of the Berne Convention[17].

There has been so far no formal recognition of State practice subsequent to the adoption of the Agreement, as an element for interpretation of the TRIPS provisions. However, in the EU-Canada case the panel considered comparative law in order to determine whether the interest claimed as "legitimate" by the EU was a "widely recognized policy norm" (para. 7.77)[18]. In addition, as mentioned below, in the EU-Canada case the panel examined the status of the legislation at the time of the negotiation of the Agreement to determine the interpretation of one of the key concepts in article 30.

Object and purpose of the Agreement

The report in the EU-Canada case on the "Bolar" exception was particularly important for clarifying the weight of the "Objectives" (article 7) and "Principles" (article 8) of the Agreement in the interpretation of the Agreement's provisions. The panel stated that

> ".... Article 30's very existence amounts to a recognition that the definition of patent rights contained in Article 28 would need certain adjustments. On the other hand, the three limiting conditions attached to Article 30 testify strongly that the negotiators of the Agreement did not intend Article 30 to bring about what would be equivalent to a renegotiation of the basic balance of the Agreement. Obviously, the exact scope of Article 30's authority will depend on the specific meaning given to its limiting conditions. The words of those conditions must be examined with particular care on this point. Both the goals and the limitations stated in Articles 7 and 8.1 must obviously be borne in mind when doing so as well as those of other provisions of the TRIPS Agreement which indicate its object and purposes".

Though the literal interpretation is the necessary beginning point for an interpretation exercise under article 31 (1) of the Vienna Convention, this article refers to the application of literal, contextual and teleological methods. Though some reports of the Appellate Body have stressed the importance of the literal interpretation, this cannot be seen as a total rejection to teleological interpretations. It is difficult to think of judgments which are absolutely neutral or aseptic in terms of policy objectives.

There is no universally accepted philosophy on the role and objectives of IPRs, and much debate still goes on their impact on welfare, economic growth and equity[19]. The "purpose" of the Agreement may be differently understood depending on the perspective from which it is examined. Thus, developing countries are looking for an application of the TRIPS Agreement which is as pro-competitive as possible, in order to enhance the affordability of protected products and promote local development through the dissemination and transfer of technology.

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[16] In this case, the panel considered the negotiation history of article 9(2) of the Berne Convention, from which part of the text of article 30 of the TRIPS Agreement was drawn (para. 7.70-72).
[17] See WT/DS160/R.
[18] The panel concluded that the extension of the term of patent protection in the case of pharmaceuticals to compensate for delays in obtaining marketing approval "has not been universal" (para. 7.79).
[19] See, e.g., May, 2000.

Panels may be tempted to introduce their own policy views on IPRs. In the referred EU-Canada case, for instance, the panel advanced its own conception about the "policy" of patent laws. It stated:

> "The normal practice of exploitation by patent owners, as with owners of any other intellectual property right, is to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity…Patent laws establish a carefully defined period of market exclusivity as an inducement to innovation, and the policy of those laws cannot be achieved unless patent owners are permitted to take effective advantage of that inducement once it has been defined" (para. 7.55).

Though this statement -developed in the context of the discussion on the concept of "normal exploitation" of a patent- is too simplistic and does not provide elements for a serious elaboration on the justification and objectives of the patent system, it does hint the own panel's conception on a matter that raises considerable debate -specially among economists- and on which different positions and theories have been elaborated (Gutterman, 1997). The panels' view, while emphasizing stimulation to innovation, fails to consider other equally essential objectives of the patent grants. Like other IPRs, patents are granted in the public interest, and not merely to allow the patent owners to obtain the "economic returns anticipated from a patent's grant of market exclusivity". The diffusion of knowledge and its continuous improvement are equally important objectives of that system (Welfens *et al*, 1999, p. 138).

The interpretation of provisions affecting health-related issues, in particular, cannot be based on such a simplistic vision of the patent system as expressed by the panel. The access to health is a major public policy concern, to the point that the right of everyone to the enjoyment of the highest attainable standard of physical and mental health is deemed a Human Right. Moreover, on April 23, 2001 the United Nations Commission on Human Rights called on governments to ensure the accessibility of pharmaceuticals and medical treatments used to treat pandemics such as HIV/AIDS, as well as "their affordability for all," in accordance with international law and international agreements. The resolution also calls on governments "to safeguard access to such preventive, curative or palliative pharmaceuticals or medical technologies from any limitations by third parties."

If the commercial interests of the patent owner were the only ones to be considered, the interpretation of the Agreement would in practice defeat its intended objectives. The TRIPS Agreement must be viewed as a means for the realization of public health via the "inducement to innovation" *and* the access to the results thereof by those who need them. In other words, the objectives of the patent system would not be fulfilled if it only served to induce innovation to the benefit of those who control the innovations. As noted by Abbott, "the TRIPS Agreement is not *only* about protecting pharmaceutical industry profits. It is also about the health of the global economy, and about the health of individuals" (Abbott, 2001, p. 14).

The "purpose" of the Agreement is clearly stated in article 7, which should be read jointly with article 8.1. This is the guidance that panels and Appellate Body should invariably apply. In accordance with said article:

> "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and *in a manner conducive to social and economic welfare, and to a balance of rights and obligations"* (italics added).

A remarkable (and plausible) development was the Appellate Body unambiguous rejection to

the panel's opinion in the USA-India case on the mail box provision, relating to the "reasonable expectations" of the parties. The panel had argued that the complaining party –in this case the United States- had reasonable expectations which were not fulfilled by the Indian legislation, thus relying on the doctrine applied in a limited number of non-violation cases under the GATT[20]. The Appellate Body correctly reversed this aspect of the panel report, and argued that the reasonable expectations were already contained in the TRIPS provisions, so it was not the task of the panel or the Appellate Body to find other expectations outside the text of the Agreement itself. The Appellate Body held that

> "the legitimate expectations of the parties to a treaty are reflected in the language of the treaty itself. The duty of a treaty interpreter is to examine the words of the treaty to determine the intentions of the parties. This should be done in accordance with the principles of treaty interpretation set out in Article 31 of the Vienna Convention. But these principles of interpretation neither require nor condone the imputation into a treaty of words that are not there or the importation into a treaty of concepts that were not intended".

Interpreting domestic law

In the USA-India and EU-India cases on the mail-box provision, the panel and the Appellate Body[21] were confronted with the issue of the interpretation of the national law in order to establish its consistency with the TRIPS Agreement. The Appellate Body stated in this regard, that there was simply no way for the Panel to make a determination without engaging in an examination of the Indian law, and that the Panel was not interpreting Indian law "as such", but only for the purpose of determining whether India had met its obligations under the TRIPS Agreement:

> "to say that the Panel should have done otherwise would be to say that only India can assess whether Indian law is consistent with India´s obligations under the WTO Agreement"[22].

Though the Appellate Body approach was correct, there are many questions which arise in connection with the interpretation, not of a particular provision, but of such provision in the context of a particular legal system. For instance, which would be the solution in cases where, according to the legal system of a country, the TRIPS Agreement were deemed to be self-executing and binding on domestic courts, but the domestic law failed to adequately incorporate certain of the Agreement's standards?

Since Members can determine the method of implementing their obligations (article 1 of the TRIPS Agreement), any inconsistency with the treaty in such a situation would be *de jure* cured by the direct application of the Agreement. Therefore, the panel or Appellate Body should decide on the basis of how the legal system effectively operates, and not on the basis of an isolated provision. This consideration is particularly important for many Latin American countries, where international treaties are deemed self-executing and can be directly invoked by private parties, including in cases where the national law is inconsistent with the treaty obligations.

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[20] See the Note by the WTO Secretariat "Non-violation complaints and the TRIPS Agreement", IP/C/W/124.

[21] Only the report in the USA-India case was appealed.

[22] India was found in violation of the TRIPS Agreement because, according to the AB, under the Indian legislation, there was no legal basis –procedurally or substantively- for the grant of exclusive marketing rights when a product which is the subject of a patent application under article 70.8 (commonly called a "mailbox" application) becomes eligible for protection under article 70.9 of the TRIPS Agreement.

Deference to national States

A very important question is the degree of deference given to national States in cases in which different interpretations of particular obligations are involved. As mentioned, the TRIPS Agreement contains a number of gaps and ambiguities and these were, in most cases, deliberate. It is not just by chance or by accident that they appear in the text.

The basic question is the extent to which a panel or the Appellate Body could make a choice when two or more permissible interpretations are possible for a particular provision[23]. For example, the TRIPS Agreement obliges Members to protect inventions, but the definition of what an "invention" is differs quite significantly among different jurisdictions. For instance, under U.S. law, a microorganism whose function has been identified is patentable, that is, it may be treated as an "invention". This concept, however, is not shared by other countries. For instance, the legislation of Brazil only allows for the patenting of a genetically modified microorganism. If merely found in nature (even if isolated) it cannot be deemed an "invention", but a "discovery". Both interpretations are reasonable.

It would not be within the authority of the panel or Appellate Body to decide in a case like this which of these permissible, reasonable interpretations is the "correct" one under TRIPS. They should not, as stated in the EU-Canada case (para. 7.82), "decide, through adjudication, a normative policy issue that is still obviously a matter of unresolved political debate" and, more generally, panels and the Appellate Body shall not fill in the gaps or cure the ambiguities of the Agreement. Their only competence is to "clarify the existing provisions…Recommendations and rulings of the DSB cannot add or diminish the rights and obligations provided in the covered agreements (article 3.2 of the DSU).

Discrimination vs. differentiation

The TRIPS Agreement expressly contemplates that Members may adopt necessary measures "consistent with" the Agreement to address public health issues (article 27.2). Is it possible to establish in patent laws a specific treatment for pharmaceuticals? In the EU-Canada case the WTO panel held that WTO Members agree that Articles 30 (exceptions) and 31 (compulsory licenses) of the TRIPS Agreement are subject to article 27.1 of the Agreement[24].

However, the panel clarified that the conduct prohibited by Article 27.1 is "discrimination" as to field of technology, and that "discrimination" is not the same as "differentiation", and that WTO members can adopt different rules for particular product areas, provided that the differences are adopted for *bona fide* purposes. The panel held that

> "Article 27 prohibits only discrimination as the place of invention, the field of technology, and whether products are imported or produced locally. Article 27 does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas. Moreover, to the extent the prohibition of discrimination does limit the ability to target certain products in dealing with certain of the important national policies referred to in Articles 7 and 8.1, that fact may well constitute a deliberate limitation rather than frustration of purpose" (para. 7.92).

[23] This issue was addressed under the "standard of review" provision (Article 17, para.6) only under the Anti-Dumping Agreement.
[24] "Patent rights (shall be) enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced".

There are some examples of patent laws that differentiate the treatment of pharmaceutical products on public health grounds. Noticeable is the case of France, whose patent law provides that

> "Where the interest of public health demand, patents granted for medicines or for processes for obtaining medicines, for products necessary in obtaining such medicines or for processes for manufacturing such products may be subject to *ex officio* licenses in accordance with Article L. 613-17 in the event of such medicines being made available to the public in insufficient quantity or quality or at (abnormally high prices) by order of the Minister responsible for industrial property at the request of the Minister responsible for health" (article L. 613-16).

Contemporaneity

Another question relates to the weight that may be given in future cases to the changes in intellectual property law, which continues to evolve, in particular to adapt to new technological developments such as digital technology[25]. Would the panels and Appellate Body be authorized to apply an evolutionary interpretation of TRIPS rules in the light of such developments?

Article 71 of the Agreement provides for a specific mechanism for the Council of TRIPS to review the Agreement "in the light of any relevant new developments, which might warrant modification or amendment of this Agreement". This makes it clear that amendments or adaptations cannot be made via interpretation[26]. The panels and Appellate Body should stick to the meaning of the terms as understood at the time of their adoption[27].

In the EU-Canada case the panel examined the status of the legislation *at the time of the negotiation*[28] of the Agreement to determine the concept of "legitimate interest" as contained in article 30. In the panel's opinion, on balance

> "the interest claimed on behalf of patent owners whose effective period of market exclusivity had been reduced by delays in marketing approval was neither so compelling nor so widely recognized that it could be regarded as a "legitimate interest" within the meaning of Article 30 of the TRIPs Agreement. Notwithstanding the number of governments that had responded positively to that claims. Moreover, the Panel believed that it was significant that concerns about regulatory review exceptions in general, although well known at the time of the TRIPs negotiations, were apparently not clear enough, or compelling enough, to make their way explicitly into the recorded agenda of the TRIPs negotiation. The Panel believed that Article 30's "legitimate interests" concept should not be used to decide, through adjudication, a normative policy issue that is still obviously a matter of unresolved political debate" (para. 7.82).

[25] For instance, in 1996, very shortly after the adoption of the TRIPS Agreement, two new treaties were adopted by the World Intellectual Property Organization (WIPO) relating to copyright and related rights.

[26] On the importance of the principle of "comtempraneity" in treaty interpretation, see Brownlie, 1998, p. 627).

[27] However, the Appellate Body has considered that certain terms in the WTO Agreements are not "static" but evolutionary (in relation to the terms "exhaustible natural resources" adopted more than fifty years ago) (WT/DS58/AB/R, para. 127 and 130).

[28] This approach is consistent with the general principle of treaty interpretation requiring that the meaning of the terms of a treaty be considered at the time of its celebration..

Mandatory vs. discretionary provisions

Another important element for the interpretation of the TRIPS Agreement provisions relates to the mandatory or discretionary nature of a disputed national rule.

Based on GATT/ WTO jurisprudence a panel or the Appellate Body would generally conclude that a law or regulation violates a WTO provision if it *mandates* a WTO-inconsistent behavior. If, instead, the government or the court has the *discretionary* power to apply such law or regulation in a TRIPS-consistent manner, no violation would be found.

This interpretive principle was invoked by USA and confirmed by the panel in the *United States – Section 301* case[29]. The European Union complained about the application of several sections of the US law authorizing the US Executive Power to retaliate against countries which, *inter alia*, did not provide an adequate level of IPRs protection:

> "Without overruling the general principle of the mandatory-discretionary distinction, the panel found that U.S. Section 301 mandated USTR to make a critical determination as to the WTO-consistency of the acts of other WTO members prior (in some cases) to the completion of a decision by the WTO Dispute Settlement Body. Even though USTR was not bound to make an adverse determination, the fact that the determination needed to be made was inconsistent with the terms of the WTO DSU" (Abbott, 2001, p. 13).

However, as mentioned above, the panel did not find USA in violation of the WTO rules based on the assurance given by the US government that the relevant provisions of Section 301 would be administered consistently with the WTO DSU. This commitment was considered by the panel as sufficient to held non-violation of the WTO rules.

Pending cases

USA has requested a panel against Brazil arguing that article 68 of the Brazilian patent law (establishing compulsory licenses in cases of lack of local working of the invention) is in breach of article 27.1 of the TRIPS Agreement. The panel members have not been selected yet. In response to this request, Brazil asked United States for consultations, *inter alia*, with regard to some provisions of the US patent law which limit the right to use or sell any federally owned invention only to a licensee that agrees that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the USA[30]

Consultations have also been requested by USA (joined by the EU and Switzerland) on various aspects of the Argentine patent and confidentiality law. The issues under discussion include areas of considerable importance for the pharmaceutical sector, such as the scope of allowed parallel imports, preliminary injunctions and the protection of data submitted for the approval of pharmaceuticals. On this latter issue, USA and the EU have held that article 39.3 of the TRIPS Agreement requires the granting of a certain period of exclusivity (the term of which is to be determined by national law) after the first commercial authorization of a pharmaceutical (or agrochemical product). In Argentina, no such exclusivity is granted. The Argentine law has interpreted that, in the framework of unfair competition, as regulated by

[29] The United States argued that only legislation that is mandatory in nature, and precludes WTO-consistent conduct, may be WTO-illegal. *United States – Section 301-310oif the Trade Act of 1974, Report of the Panel*, Dec, 22, 1999. paras. 751-54, and note 675.
[30] WT/DS224/1.

article 10*bis* of the Paris Convention, there is no obligation to provide for such an exclusivity in order to protect against unfair commercial practices.

Main conclusions

The WTO dispute settlement system faces a very complex and delicate task in the area of TRIPS, perhaps more difficult then in other WTO agreements. The high sensitivity of the issues involved both for developing and developed countries, indicate that any opinion on the matter will be subject to a very strict scrutiny and may significantly influence future developments in the area of IPRs, particularly within WTO.

An "activist" approach by panels and the Appellate Body in the interpretation of the TRIPS Agreement is likely to imperil the dispute settlement system as such. This Agreement has neither addressed nor resolved all issues in IPRs law. Its gaps and ambiguities were an unavoidable result of difficult negotiations. If the panels or Appellate Body tried to make an expansive interpretation or make choices which the parties have not done during negotiations, the credibility of the dispute settlement system will be certainly undermined.

If confronted with the task (in applying the rules of article 39 (1) of the Vienna Convention) of defining the "purpose" of the treaty in relation to a disputed provision, panels and the Appellate Body should be aware that the role of the TRIPS Agreement is not merely to guarantee the commercial interests of IPRs holders, but to achieve public interest, inter *alia,* in the area of health.

Panels and Appellate Body should recognize that among the WTO members there are basic differences in relation to the role of intellectual property and, in particular, on how can it affect the realization of basic human rights as well as the development prospects of developing countries.

Finally, due attention should be given to the fact that the principal objective of the GATT/WTO system is to promote free trade by ensuring the realization of competitive opportunities on a non discriminatory basis. The TRIPS provisions, hence, should be interpreted bearing in mind that it is the promotion of competition, and not the restriction thereof, the foundation of the trade system.

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