
PART 6: TRANSITIONAL AND INSTITUTIONAL ARRANGEMENTS

33: Transitional Periods**Article 65 Transitional Arrangements**

1. Subject to the provisions of paragraphs 2, 3 and 4, no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the WTO Agreement.
2. A developing country Member is entitled to delay for a further period of four years the date of application, as defined in paragraph 1, of the provisions of this Agreement other than Articles 3, 4 and 5.
3. Any other Member which is in the process of transformation from a centrally-planned into a market, free-enterprise economy and which is undertaking structural reform of its intellectual property system and facing special problems in the preparation and implementation of intellectual property laws and regulations, may also benefit from a period of delay as foreseen in paragraph 2.
4. To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.
5. A Member availing itself of a transitional period under paragraphs 1, 2, 3 or 4 shall ensure that any changes in its laws, regulations and practice made during that period do not result in a lesser degree of consistency with the provisions of this Agreement.

Article 66 Least-Developed Country Members

1. In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under

paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.

2. [...]

1. Introduction: terminology, definition and scope

The notion of transitional periods in the WTO needs to be understood as the time necessary for a WTO Member to bring itself into full conformity with the obligations set out by an Agreement. It has been argued that transitional periods are an important component of Special and Differential Treatment in favour of developing countries. However, it may be borne in mind that in the various WTO agreements, it is not just the developing countries that are given transitional periods. Thus, in the Agreement on Textiles and Clothing, it is the developed countries that are in effect entitled to a transition period of 10 years for the elimination of quotas. Nevertheless, in the context of TRIPS, transition periods basically constitute the amount of time available for a WTO Member (developed, developing or least-developed) to bring itself into full conformity with the obligations of the Agreement.

2. History of the provision

2.1 Situation pre-TRIPS

Under the predecessor of the WTO, the GATT 1947,¹ there were no transitional periods for any Contracting Party, be it developed or not.² This may be explained by the fact that the GATT is mainly about the reduction of tariffs. This has considerably less effect on a country's internal legal system than the TRIPS disciplines, which require the introduction of minimum standards, border controls and domestic enforcement procedures along with the setting up of the respective authorities. Instead of transitional periods, Part IV of the GATT (Trade and Development, Article XXXVI) seeks to boost developing countries' and least-developed countries' (LDCs) export earnings by obligating developed states to open their markets for primary products from those countries³ and to waive reciprocity for tariff reduction commitments.⁴

2.2 Negotiating history

Since TRIPS is a new and unprecedented Agreement in the WTO, and since it was clear that the adjustment of the internal legal regimes of developing and

¹ In the framework of the WTO, the GATT 1947 is replaced by the identical GATT 1994.

² On the other hand, the GATT admits grandfather clauses allowing countries that accede to it to maintain pre-existing domestic legislation inconsistent with GATT provisions. In addition, the GATT in Part IV (Trade and Development) contains some provisions on special treatment for developing countries. For instance, according to Article XXXVI:8 of the GATT, "developed contracting parties do not expect reciprocity for commitments made by them in trade negotiations to reduce or remove tariffs and other barriers to the trade of less-developed contracting parties".

³ See Article XXXVI:4 of GATT 1994.

⁴ See Article XXXVI:8 of GATT 1994.

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least-developed countries would require a very substantial effort,⁵ the question of transition periods assumed enormous importance for those countries. It was not settled until the very end of the TRIPS negotiations. The reason for this was that the developing countries did not agree to the introduction of substantive IPR standards until late in the negotiations. Without having agreed on the substance, there was no question of agreeing to transition periods.

When formal negotiations in the Uruguay Round began in early 1987, about 14 developing countries led by Brazil, India and Argentina resisted the mandate to develop substantial IPR standards. However, it can be stated that the negotiating draft submitted by the Trade Negotiations Committee (TNC) meeting in Geneva in April 1989 for the mid-term review of the Uruguay Round signalled a success for the interests of the developed countries and a setback for those developing countries which had opposed the inclusion of substantive IPR standards. The text agreed to by Ministers specifically mentioned transition periods. This was the first time that ministers explicitly took note of the issue of transition periods in TRIPS. The text makes clear, albeit implicitly, that some transition period would be required if the full participation of all countries in the results of the negotiations was to be ensured.

Following the above-mentioned mid-term review, important changes were made in the negotiating texts between July 1989 and December 1990. However, with respect to the issue of transition periods, neither the Anell Draft nor the Brussels Draft brought about a final agreement.⁶ The differences between those drafts and the final versions of TRIPS Articles 65 and 66.1 will now be analysed.⁷

2.2.1 The Anell Draft⁸

"1. Transitional Period (68); Transitional Arrangements for Developing Countries and Technical Cooperation (73); Transitional Arrangements (74)

1A PARTIES shall take all necessary steps to ensure the conformity of their laws, regulations and practice with the provisions of this Annex within a period of not more than [-] years following its entry into force. The Committee on Trade Related Intellectual Property Rights may decide, upon duly motivated request, that developing countries which face special problems in the preparation and implementation of intellectual property laws, dispose of an additional period not exceeding [-] years, with the exception of points 6, 7 and 8 of Part II, in respect of which this additional period shall not apply. Furthermore, the Committee may, upon duly motivated request, extend this additional period by a further period not exceeding [-] years in respect of least developed countries. (68)

1B.1 Developing Countries (73)

(i) With a view to achieve full and successful adjustment and compliance with levels of protection and enforcement set forth in Parts III and IV above, and provided

⁵ This is because many legal systems in developing countries or LDCs do not have a comparable tradition of IP protection.

⁶ Such agreement was only expressed in the Dunkel Draft of December 1991 (see below).

⁷ For this purpose, the draft articles that later became two independent TRIPS provisions (i.e., Articles 65 and 66.1) will be discussed together.

⁸ See composite text of 23 July 1990, circulated by the Chairman (Lars E. R. Anell) of the TRIPS Negotiating Group, document MTN.GNG/NG11/W/76.

that existing levels of protection and enforcement are not reduced, developing PARTIES may not apply such standards for a period of a total of [X] years beginning with the date of acceptance or accession of such PARTY, but not later than the year [Z]. (73)

(ii) Delay in implementation of obligations under Parts III and IV above may be extended upon duly motivated request for a further period not exceeding [X] years by the Committee established under point 1B of Part VIII below. Such decision shall take into account the level of technological and commercial development of the requesting PARTY. (73)

(iii) Non-application of levels of protection set forth in Parts III and IV above after final expiration of the transitional period agreed shall entitle other PARTIES, without prejudice to other rights under the General Agreement, to suspend the application points 7 and 8 of Part II above and grant protection of intellectual property rights on the basis of reciprocity. (73)

1B.2 Least-Developed Countries (73)

(i) With a view to achieve full and successful adjustment and compliance with levels of protection and enforcement set forth in Parts III and IV above, least developed PARTIES are not expected to apply such standards for a period of a total of [X + Y] years. (73)

(ii) Delay of implementation of obligations may be further extended upon request by the Committee established under point 1B of Part VIII below. (73)”

The above proposals differ considerably from each other and from the final version of Articles 65 and 66.1. Compared to TRIPS, the proposal under 1A imposed tighter requirements on both developing countries and LDCs with respect to an initial period of transition and also a possible extension thereof.

As to developing countries, the proposal under 1A made an initial transition period subject to two conditions: first, the given developing country had to “face special problems in the preparation and implementation of intellectual property laws”; and second, the same country was supposed to submit a “duly motivated request” to the Committee on Trade Related Intellectual Property Rights (i.e., the body that later became the Council for TRIPS).⁹ Once this request was submitted, it was entirely in the discretionary power of the Committee to allow or to reject the request. There was no possibility of further extending a transitional period in favour of a developing country.¹⁰

With respect to LDCs, the “A” draft provided a specific, longer transitional period, which was added to the period available for developing countries. But as opposed to the current Article 66.1 (which accords an unconditional right), this required a duly motivated request and, like in the case of developing countries,

⁹ By contrast, Article 65.2 TRIPS accords developing countries an unconditional right of transition of four years (see Section 3, below).

¹⁰ Under TRIPS, in general, there is no such possibility, either. However, Article 65.4 authorizes such an additional period with respect to product patent protection in areas of technology not so protectable in the territory of the respective developing country Member on the general date of application of the TRIPS Agreement (see Section 3, below). Also, an extension of a transition period may be granted as a waiver of a WTO obligation pursuant to Article IX.3 of the WTO Agreement.

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depended on the Committee's discretion. Also, the "A" proposal did not provide for a possibility to extend this LDC-specific period.¹¹

Compared to the "A" proposal, the proposal under 1B contained an unconditional right for developing countries to benefit from an initial transition period (see 1B.1(i)), like under Article 65.2. Also, there was a general possibility to further extend this initial period in favour of developing countries (see 1B.1(ii)), unlike under TRIPS.

With respect to LDCs, the "B" proposal contained a specific (longer) period, which was to be enjoyed unconditionally (see 1B.2(i)), as under Article 66.1. Also, provision was made of a possibility to extend this LDC-specific period (see 1B.2(ii)), again as under Article 66.1.

Finally, the third paragraph under 1B.1 is worth noting. It addressed the situation of non-compliance with substantive IPR obligations after the expiry of the transitional periods. The proposed remedies for non-compliance included the suspension of the most-favoured nation (MFN) obligation¹² and the reciprocal withdrawal of IP protection with respect to nationals of the country found in non-compliance. On the other hand, there was no express reference to any dispute settlement procedures to bring the respective national law or practice into conformity with the relevant substantive IP standard.

2.2.2 The Brussels Draft¹³

As late as the Brussels meeting in December 1990, the Chairman of the TRIPS Negotiating Group circulated a report stating that there were differences in substance, among other things, in the transition period to be provided for developing countries and LDCs. Developing countries were interested in a transition period of at least 10 years. The USA, on the other hand, favoured the idea of "pipeline protection" which went in the opposite direction.¹⁴ Another reason for the deadlock in the negotiations was the fact that the issue of agriculture and textiles still remained unresolved. For developing countries, there was a link between what happened in the negotiations on the Agriculture and Textiles Agreements on the one hand and TRIPS on the other.¹⁵ At Brussels itself, there was consequently no breakthrough with respect to the determination of actual time frames.

¹¹ By contrast, such possibility exists under TRIPS Article 66.1, second sentence (Section 3, below).

¹² Points 7 and 8 in the quoted proposal above referred to the MFN principle and certain exceptions; now under Articles 4 and 5 of TRIPS.

¹³ Document MTN.TNC/W/35/Rev. 1 of 3 December 1990.

¹⁴ The U.S. position can be found in the patent section 7 of the Anell Draft. "Pipeline protection" refers to a method of protection that would deny any transition periods by obligating countries to protect foreign patents from the date they were granted in the country of origin. For more details, see Chapter 36 (Transitional provisions).

¹⁵ This position was based on the developing countries' hope to gain in the field of textiles and agriculture what they feared to lose in the new areas such as TRIPS and Services. Indeed, there was a negotiating linkage between the expiry of the transitional period of the Textiles Agreement and the expiry of the transitional period for providing product patent protection for pharmaceuticals, i.e., both periods expire on 1 January, 2005. Note, however, the more favourable situation for LDCs in the pharmaceutical sector, where those countries have until 2016 to implement the TRIPS disciplines on patents and undisclosed information. See in detail under Section 6.2, below.

In the following, the pertinent provisions of the Brussels Draft will be analysed. The immediate antecedent to Article 65 TRIPS provided:

“1. Subject to the provisions of paragraphs 2 and 3 below, PARTIES shall not be obliged to apply the provisions of this Agreement before the expiry of a period of [...] years following the date of entry into force of this Agreement for that PARTY.

2. A developing country PARTY may delay for a period of [...] years the date of application, as defined in paragraph 1, of the provisions of this Agreement other than Articles 3, 4 and 5 [, insofar as compliance with those provisions requires the amendment of domestic laws, regulations or practice.]

3. Any other PARTY which is undertaking structural reform of its intellectual property system and faces special problems in the preparation and implementation of intellectual property laws, may also benefit from a period of delay as foreseen in paragraph 2 above.

4. *No provision*

[5.] Any PARTY availing itself of a transitional period under paragraphs 1, 2 or 3 shall ensure that any changes in its domestic laws, regulations and practice made during that period do not result in a lesser degree of consistency with the provisions of this Agreement.

5. Any PARTY availing itself of a transitional period in accordance with paragraph 2 or 3 above shall provide, on accession, a schedule setting out its timetable for application of the provisions of this Agreement. [This timetable shall be without commitment.] [The Committee established under Part VII below may authorise, upon duly motivated request, departures, consistent with provisions of paragraphs 2 or 3 above, from the timetable.]”

Paragraphs 1 and 2 of the above draft were essentially similar to TRIPS Article 65.1 and 2. However, paragraph 1 determined as the base for the computing of the transitional period the date on which the Agreement entered into force *for the respective Party*. This differs from Article 65.1, according to which the decisive date is the general entry into force of the WTO Agreement. This difference has important consequences for countries acceding to the WTO at a later point in time (see Section 3 below).

Draft paragraph 3 was construed wider than its current counterpart. It applied to “any” country undertaking structural reforms of its IP system, whereas Article 65.3 is limited to transition economies. An important difference exists with respect to paragraph 4: the specific transition period for product patent protection in certain areas of technology (see Section 3 below) was not yet contained in the Brussels Draft. This appeared only in the Dunkel Draft text of 1991 (see below). Finally, paragraph 5 appeared twice in the Brussels Draft (see above). The text containing a bracketed numbering ([5]) is what later became the final version of paragraph 5. It states that any changes in domestic laws, regulations or practice made during a transitional period shall not result in a lesser degree of consistency with the provisions of the agreement.

The second text numbered as draft paragraph 5 represented an idea that was eventually dropped. According to this proposal, each country taking advantage of a transitional period was supposed to submit to the other Parties a timetable

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indicating as of when it would fully apply the substantive IPR disciplines. The purpose of this provision was to increase transparency. Since the end of a country's transition period was to be computed on an individual basis (i.e., on the respective date of entry into force of the Agreement in the country in question, see draft paragraph 1, above), the dates of full applicability of the Agreement could have varied from country to country, depending on the length of domestic ratification procedures. Under such circumstances, countries could not be expected to be aware of the multitude of different dates of application of the Agreement in other countries. However, with the abandonment of individual time frames and the introduction of a commonly applicable base for the computing of the transitional periods (i.e., the date of entry into force of the WTO Agreement, see below), the above provision was no longer necessary and therefore did not reappear in the final text of TRIPS.

Finally, the Brussels Draft contained an extra provision on least-developed countries (the provision that later became Article 66.1), which provided:

"1. In view of their special needs and requirements, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, least-developed country PARTIES shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 [and 5, insofar as compliance with those provisions requires the amendment of domestic laws, regulations or practices for a period of [...] years from the date of application as defined under paragraph 1 of Article [65] above. The Committee shall, upon duly motivated request by a least-developed country PARTY, accord extensions of this period.] The requirement of paragraph 5 of Article [65] above shall not apply to least-developed country PARTIES."¹⁶

This draft paragraph is quite similar to Article 66.1. The time frame for the transition period was still bracketed. So was the possibility of extending the initial period upon duly motivated request. The last sentence of the above paragraph appears to refer to the non-bracketed draft paragraph 5 regarding submission of timetables since (a) it is likewise non-bracketed, and (b) it appears in any case to be more consistent with the first sentence that refers also to paragraph 5 in a context apparently related to fixing a transition period. This last sentence reappeared neither in the Dunkel Draft nor in the final version of TRIPS.¹⁷

2.2.3 The Dunkel Draft¹⁸

The issue of transitional periods in TRIPS was essentially settled in 1991. The final time frames were agreed upon and reflected in the Dunkel Draft of December 1991, which contained the same provisions on transition periods that we find today in TRIPS. In particular, and in contrast to the Brussels Draft (see above), paragraph 1 of draft Article 65 referred to the date of the entry into force of "this Agreement",

¹⁶ Paragraph 2 of this draft provision was essentially the same as Article 66.2, which is not the subject of this chapter (see Chapter 34).

¹⁷ As to the treatment of LDCs in this respect under the current version of TRIPS, see below, Section 3.

¹⁸ Document MTN.TNC/W/FA of 20 December 1991.

and thereby introduced a common basis for the computing of the transitional periods, irrespective of the date on which the Agreement becomes binding for an individual country (TRIPS maintains this objective approach, referring to the “WTO Agreement” instead of to TRIPS alone).

The Dunkel Draft Article 65 contained an important additional paragraph 4, providing:

“4. To the extent that a developing country Party is obliged by this Agreement to extend product patent protection to areas of technology not protectable in its territory on the general date of application of this Agreement for that Party, as defined in paragraph 2 above, it may delay the application of Section 5 of Part II of this Agreement to such areas of technology for an additional period of five years.”

The reason for the inclusion of this paragraph was the fact that many developing countries, at the time of the Uruguay Round, did not provide patent protection in the areas of agricultural and pharmaceutical products. In fact, for most developing countries the issue of product patent protection in these sensitive areas was the most problematic feature of TRIPS. Paragraph 4 was therefore introduced to address such concerns. However, the extra transitional period was made subject to the mailbox provision under Article 70.8 and the obligation to provide exclusive marketing rights (EMRs) under Article 70.9 (see Section 3 below).¹⁹

3. Possible interpretations

Article 65 contains the transition period available for developed (para. 1), developing (para. 2) and economies in transition countries (para. 3). Article 66.1 contains the transition period for LDCs. These transition periods are effective automatically and do not have to be specifically requested or reserved.

3.1 Article 65.1

1. Subject to the provisions of paragraphs 2, 3 and 4, no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the WTO Agreement.

This provision lays down a general transition period that applies to all WTO Members, irrespective of their status. Accordingly, no Member was obligated to fully apply the provisions of TRIPS until one year after the entry into force of the Agreement (1 January 1995), i.e., until 1 January 1996. Note that this general transition period is made subject to the provisions of paragraphs 2, 3 and 4 of Article 65.

¹⁹ In brief, the mailbox rule obliges Members benefiting from a transition period to register incoming patent applications for later examination, thus preserving priority and novelty of the relevant inventions. An exclusive marketing right (EMR) has to be granted *in lieu* of a patent during the transition period, provided that certain important preconditions are met. Note that the obligation to provide EMRs does not apply to LDCs, see below, Section 6.2. For more details on the mailbox rule and on the notion of EMRs, see Chapter 36 (Transitional Provisions).

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On the one hand, those paragraphs further extend the general transition period in favour of developing countries and economies in transition. On the other hand, the general extension in paragraph 2 does not relieve Members of their obligations with respect to the national treatment and MFN disciplines (see below).

3.2 Article 65.2

2. A developing country Member is entitled to delay for a further period of four years the date of application, as defined in paragraph 1, of the provisions of this Agreement other than Articles 3, 4 and 5.

This paragraph deals with the transition period specifically available for developing countries. It extends the general transition period of paragraph 1 by four years. Thus, for developing countries the transition period generally available was five years from the date of the entry into force of TRIPS, i.e., 1 January 2000.

There is a very important exception to this rule. The additional transition period under paragraph 2 does not apply to Members' obligations under Articles 3, 4 and 5 (National Treatment, MFN and Multilateral Agreements on Acquisition or Maintenance of IPRs). These disciplines fall therefore under the first paragraph of Article 65 and have to be implemented by developing countries from 1 January 1996.²⁰

The reason for singling out national treatment and MFN for immediate implementation by all WTO Members is based on the perceived overall importance of those rules for the functioning of TRIPS.²¹ From a developed country perspective, immediate implementation of national treatment and MFN secures a level playing field in developing countries for IP holders with respect to domestic firms and third country foreigners. As a general rule, developing country governments may no longer treat foreigners less favourably than domestic IP holders, e.g., with a view to promoting the economic development of domestic infant industries.²² With respect to MFN, developed country governments may now be sure that in developing countries, the nationals of other developed countries are not treated more favourably than their own nationals with respect to the protection of IPRs.²³

²⁰ The same applies to economies in transition and LDCs, based on Articles 65.3 and 66.1, see below.

²¹ The WTO Appellate Body has qualified the national treatment and MFN obligations as "cornerstones" of the world trading system, including the TRIPS Agreement (see WTO Appellate Body, *United States – Section 211 Omnibus Appropriations Act of 1998*, WT/DS176/AB/R, 2 January 2002 (*U.S. – Havana Club*), at para. 297). For more details on the national treatment and MFN disciplines, see Part 1 of this Resource Book (Chapter 4).

²² See the relevant part of Article 3 TRIPS: "Each Member shall accord to the national of other Members *treatment no less favourable* than that it accords to its own nationals with regard to the protection [footnote omitted] of intellectual property, [...]" (emphasis added).

²³ See the relevant part of Article 4: "With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members." Note that prior to the establishment of TRIPS, there was growing concern among trade negotiators that due to bilateral pressure, some developing countries were granting certain IPR privileges to foreigners from selected countries only, to the detriment of both their own nationals and the

3.3 Article 65.3

3. Any other Member which is in the process of transformation from a centrally-planned into a market, free-enterprise economy and which is undertaking structural reform of its intellectual property system and facing special problems in the preparation and implementation of intellectual property laws and regulations, may also benefit from a period of delay as foreseen in paragraph 2.

The same period of five years available for developing countries (para. 2) applies to countries in transition. Contrary to paragraph 2, paragraph 3 does not automatically accord a transitional period, but makes this dependent on further conditions. The Member in question must undertake structural reforms of its intellectual property system and must face problems in implementing IP laws and regulations. There is no specification as to what are “special problems” in the preparation and implementation of intellectual property laws and regulations. It may be assumed, however, that the transition from a centrally-planned economy to a system of free markets constitutes *per se* a major challenge, not only in economic respects. The establishment of an IP system that is tailored to free market requirements would therefore appear to provide a strong *prima facie* case of “special problems” in the above sense. The reference to paragraph 2 makes clear that transition economies like developing countries had to comply with national treatment and MFN obligations as early as 1 January 1996.

3.4 Article 65.4

4. To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.

This is an important additional transition period on top of the five years generally provided to developing countries. As opposed to the general transitional periods in paragraphs 1 through 3, which apply to all types of IPRs, this additional period is limited to the obligation to extend product patent protection to areas of technology not so protectable in a Member’s territory on the date of application of TRIPS (i.e., 1 January 2000). It applies to areas such as, for instance, pharmaceutical or agricultural chemical products where many developing countries did not grant patent protection at the time of entry into force of TRIPS. However, this provision

nationals of third countries. Such practices do not constitute an infringement of the national treatment obligation. Hence, the call for an incorporation of the MFN principle into the TRIPS Agreement. (For details, see Chapter 4.)

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should be read in conjunction with Article 70.8 and 9, which obligates developing countries invoking Article 65.4 to provide, during the transition period, for a means of registering applications for the above patents as well as for exclusive marketing rights.²⁴

3.5 Article 65.5

5. A Member availing itself of a transitional period under paragraphs 1, 2, 3 or 4 shall ensure that any changes in its laws, regulations and practice made during that period do not result in a lesser degree of consistency with the provisions of this Agreement.

This is essentially a provision which prevents WTO Members from “rolling back” during the transition period, i.e., from providing a reduced degree of IP protection in their domestic laws. On the other hand, this provision also makes sure that, if under a bilateral arrangement some developing countries choose to go “TRIPS-plus”, the Agreement does not prevent them from rolling back to the common TRIPS standards. This issue would exclusively be governed by the respective bilateral agreement.

In this context, the question arises whether paragraph 5 also applies to LDCs. The reference in paragraph 5 is only to the transitional periods under Article 65, but not to the special LDC period under Article 66.1. In Article 66.1, there is no mention of any prohibition comparable to the one under Article 65.4, nor is there any reference to this provision. The obligation under Article 70.2 to protect existing subject matter does not apply to LDCs for the time indicated in Article 66.1 (see below). For these reasons, LDCs are not bound by Article 65.5 and may actually “roll back” on their IPR laws during the 10-year transition period. This obviously does not alter the fact that once their TRIPS obligations do begin, LDCs have to make sure that their IP laws are fully TRIPS-consistent.

3.6 Article 66.1

1. In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.

This provision pertains to LDC Members. It may be noted that only one LDC at the time, i.e., Tanzania, participated actively in the TRIPS negotiations. The provision in Article 66 acknowledges that there are special needs and requirements of LDC

²⁴ For details, see Chapter 36 (Transitional provisions).

Members²⁵ and allows them ten years to implement TRIPS, except the national treatment and most-favoured nation obligations (Articles 3–5). This means that LDCs will, in general, have to comply with TRIPS obligations as of 1 January 2006. Until then, Article 70.8 and 9 obliges them, like developing countries, to provide for a system of registration (mailbox) of patent applications for pharmaceutical and agricultural chemical products and for exclusive marketing rights (EMRs). However, LDCs have been exempted through a WTO waiver from the obligation to grant EMRs for pharmaceutical products until 2016.²⁶ Article 66.1 also provides that a duly motivated request for further extension of the transition period can be made by an LDC Member in the TRIPS Council and that the latter shall follow the request. In this regard, attention may be drawn to the Decision of the TRIPS Council to implement paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health, according to which LDCs shall be free to disregard the TRIPS disciplines on patents and undisclosed information with respect to pharmaceutical products until 2016.²⁷ The above-mentioned waiver from the obligation to grant EMRs has to be seen in conjunction with this extension of the transition period. Such extension would be of little use if LDCs nevertheless had to provide for EMRs, which presumptively give their holder the right to exclude others from the marketing of pharmaceutical products.²⁸

Finally, it should be noted that all of the above provisions for the computing of the time frame refer to paragraphs 1 or 2 of Article 65 (i.e., the date of the entry into force of the WTO Agreement). This means that with respect to countries acceding to the WTO at a later point in time, the same deadlines will apply. For instance, developing countries joining the WTO after 1 January 2005 will not be authorized to claim any transitional period with respect to product patents. LDCs acceding after 1 January 2006 will not automatically be granted a general transitional period comparable to the one available to LDCs under Article 66.1. Note that the situation would have been different under the Brussels Draft, according to which newly acceding Members would have been accorded the same time frames as original Members.²⁹

²⁵ Note that the TRIPS Preamble equally recognizes the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base.

²⁶ The waiver was approved by the WTO General Council on 8 July 2002. For more details, see below, Section 6.2.

²⁷ See the Decision of the Council for TRIPS on the *Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, IP/C/25 of 27 June 2002. For details on this Decision and the Doha Declaration, see below, Section 6.2.

²⁸ Note that under TRIPS, there is no definition of EMRs. Even though Members therefore have some flexibility as to the national design of EMRs, it follows from the term as such that there has to be some degree of exclusivity at least with respect to the marketing of the covered products. For more details on EMRs, in particular their distinction from patent rights, see Chapter 36.

²⁹ See above, Section 2.2, paragraph 1 of the draft Article that later became Article 65 TRIPS. This draft provision for the computing of transitional periods relied on the respective date of the entry into force of the Agreement for each individual country, and not on the general date of the entry into force of the WTO Agreement.

6. New developments

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4. WTO jurisprudence

4.1 EC – Protection of Trademarks and GIs

Following separate requests by Australia³⁰ and the USA,³¹ the WTO Dispute Settlement Body (DSB) at its meeting on 2 October 2003 established a single panel³² to examine complaints with respect to EC Council Regulation (EEC) No. 2081/92 of 14 July 1992³³ on the protection of geographical indications and designations of origin for agricultural products and foodstuffs. The complaints are based, *inter alia*, on alleged violations of Article 65.³⁴ The complainants contend that since the above EC Regulation is not in conformity with certain substantive TRIPS provisions (in particular those on national treatment, MFN treatment, trademarks and geographical indications),³⁵ the EC does not respect its obligation under Article 65.1 to apply TRIPS as of 1 January 1996.

5. Relationship with other international instruments

5.1 WTO Agreements

5.2 Other international instruments

The transitional periods contained in Articles 65, 66.1 refer only to TRIPS obligations. An LDC Member by benefiting from Article 66.1 or from paragraph 7 of the Doha Declaration on TRIPS and Public Health does not infringe the Agreement, but could, at the same time and through the same action, infringe non-TRIPS obligations such as the patent disciplines of the Paris Convention (provided it is a Party to this Convention).³⁶ However, such non-WTO agreements are not enforceable through trade sanctions, due to the lack of a dispute settlement system comparable to the DSU of the WTO.

6. New developments

6.1 National laws

6.2 International instruments

6.2.1 The Doha Declaration

6.2.1.1 The extension in paragraph 7. The Doha Ministerial Conference agreed to extend until 2016 the transition period for LDC Members to implement their

³⁰ WT/DS290/18 of 19 August 2003.

³¹ WT/DS174/20 of 19 August 2003.

³² *European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs* [hereinafter *EC – Protection of Trademarks and GIs*], WT/DS174/21 and WT/DS290/19 of 24 February 2004, Constitution of the Panel Established at the Requests of the United States and Australia.

³³ See above, Section 2.1.

³⁴ See the above requests by Australia and the USA for the establishment of a panel.

³⁵ See Chapters 4, 14 and 15. The complaints are principally based on those provisions.

³⁶ For a list of the Parties to the Paris Convention, among which there is a considerable number of LDCs, see <<http://www.wipo.org/treaties/documents/english/pdf/d-paris.pdf>>.

obligations in the areas of patents and undisclosed information with respect to pharmaceutical products. The relevant part of paragraph 7 of the Declaration reads as follows:

“[...] We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.”³⁷

Even though the legal character of this Declaration is controversial,³⁸ it clearly indicates Members' will to extend the transitional period contained in Article 66.1 beyond 1 January 2006, i.e., until 1 January 2016. Consequently, LDC Members may, until that date, disregard substantive TRIPS provisions on patents and undisclosed information with respect to pharmaceutical products.

LDC Members may equally engage in exports and imports of generic drugs among themselves.³⁹ Finally, as far as the importation into LDC Members of drugs from non-LDC Members is concerned, two situations need to be distinguished.⁴⁰ If a drug is off-patent in the non-LDC exporting Member (either because the patent there has expired or because the exporting Member is a developing country that does not have to honour patent rights until 2005, in line with Article 65.4), importation of low-priced medicines into the respective LDC Member will be possible. On the other hand, if the drug is on-patent in the exporting country (in particular after 1 January 2005, when developing country Members like India have to introduce patent protection for pharmaceutical products), generic producers there will no longer be permitted to the same extent as before to supply LDCs with low-priced copies of patented drugs. The fact that as of 1 January 2005, major developing country exporters of pharmaceuticals have to provide for product patent protection does not mean that from that date, the production of any generics will be prohibited. Patent protection will apply only to those pharmaceuticals for which

³⁷ See the Declaration on the TRIPS Agreement and Public Health, WTO document WT/MIN(01)/DEC/W/2, under para. 7.

³⁸ See F. Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting A Dark Corner at the WTO*, in: *Journal of International Economic Law* (2002), 469–505 [hereinafter Abbott, *Doha Declaration*]. As opposed to the position taken by the authors of this book, it could be argued that the Doha Declaration is not legally binding, because it was not adopted pursuant to the formalities laid down for authoritative interpretations in Article IX:1 of the WTO Agreement, i.e., not based on a recommendation by the TRIPS Council. This interpretation would be too formalistic, though, and would not only disregard the clear language of the Declaration (especially in the quoted para. 7), but also the rule of treaty interpretation in Article 31 of the Vienna Convention on the Law of Treaties, which considers the language of an agreement (in the context of its object and purpose) to be the essential criterion of interpretation.

³⁹ See Abbott, *Doha Declaration*, p. 503.

⁴⁰ *Ibid.*

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a patent application was filed after 1 January 1995,⁴¹ and which actually meet the national patentability criteria. Other drugs will not benefit from patent protection and may thus be further available as low-priced generics. Those drugs on-patent after 1 January 2005 may nevertheless be exported to qualifying importing Members at low prices under a compulsory license, according to the 2003 Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.⁴²

6.2.1.2 Paragraph 7 and the mailbox obligation. Apart from the above, there are further aspects limiting the benefits LDC Members can draw from paragraph 7 of the Doha Declaration. In particular, it has been observed that paragraph 7 does not expressly refer to the obligations under Article 70.8 and 9 of Part VII.⁴³ Therefore, a strict interpretation of paragraph 7 would lead to the conclusion that this paragraph does not relieve LDC Members from the obligation to provide for mailbox protection and to grant EMRs before 2016.⁴⁴ While the issue of EMRs has been settled through a 2002 WTO General Council waiver (see below), there has been no clarification on the part of the TRIPS Council concerning the mailbox obligation. According to Article 31.1 of the Vienna Convention on the Law of Treaties, a treaty is to be interpreted in accordance with the ordinary meaning of the terms of the treaty in their context and in the light and the objective of the treaty's object and purpose. The terms of paragraph 7 do not refer to Part VII of TRIPS. However, the purpose of paragraph 7 is to prevent the TRIPS patent rules to become an obstacle to Members' efforts to protect public health. On these lines, it could be argued that the extension of the transitional period only makes sense if LDC Members are not at the same time obliged to provide for mailbox protection. It is true that such obligation would not affect the LDC Members' right as such to disregard patents for pharmaceutical products until 2016. But it would require them to install and maintain mechanisms that permit the receipt and retention of pharmaceutical patent applications for the purpose of later examination (i.e., from 2016). This implies considerable financial and administrative efforts that will place an additional burden on a given country's health budget. More importantly, the mailbox obligation entails a considerable problem for the affordability of low-priced drugs after the expiry of the transition period in 2016. Provided they

⁴¹ See Article 70.8 ("mailbox"), and Chapter 36 for details. See also *Implementing the paragraph 6 decision and Doha Declaration: Solving practical problems to make the system work*, Report of a seminar organised by the Quaker United Nations Office 21–23 May 2004, Jongny-sur-vevey, Switzerland, Section I.

⁴² For details, see Chapter 25. In essence, this Decision of 30 August 2003 (WTO documents IP/C/W/405 or WT/L/540 as adopted by the General Council) authorizes WTO Members with drug manufacturing capacities to make and export pharmaceutical products to countries with public health needs, despite the requirement in Article 31(f) that products made under compulsory licences shall be predominantly for the domestic market of the country of production. For a critical analysis of this "paragraph 6 solution", see C. Correa, *Recent International Developments in the Area of Intellectual Property Rights*, paper submitted to the Second ICTSD-UNCTAD Bellagio Series on Development and Intellectual Property, 18–21 September 2003, available at <http://www.iprsonline.org/unctadictsd/bellagio/docs/Correa_Bellagio2.pdf>.

⁴³ Abbott, *Doha Declaration*, p. 502.

⁴⁴ *Ibid.*

meet the patentability requirements, the patent applications received during the transition period will turn into enforceable patents after 1 January 2016. Without a mailbox system in place, by contrast, the novelty of inventions made before 2016 will not be preserved for the time after 1 January 2016, with the result that after that date, a patent may not be issued and drugs remain available as generics.⁴⁵

From the above point of view, paragraph 7 of the Doha Declaration could therefore be interpreted as also relieving LDC Members from the mailbox obligation. However, it is by no means certain that a WTO panel or the Appellate Body would endorse the interpretation offered above. It could be argued that such interpretation would be contrary to the clear language of paragraph 7, which does not refer to Article 70. In addition, the free availability of generics would only be affected *after* the expiry of the transitional period. These effects could therefore be considered as falling outside the intended scope of protection of paragraph 7. Finally, the fact that the waiver issued by the General Council (see below) refers expressly only to EMRs, but not to the mailbox obligation, is very likely to be read as a sign that the mailbox obligation was intended to be maintained.

6.2.1.3 Paragraph 7 and pharmaceutical process patents. Another interpretative uncertainty persisted with respect to the question whether paragraph 7 extends to pharmaceutical process patents. The language directly refers to pharmaceutical “products”.⁴⁶ But this does not necessarily exclude process patents. It has been observed that paragraph 7 could be interpreted as covering those process patents that have been issued with respect to pharmaceutical products.⁴⁷ This would include processes employed for the production of a pharmaceutical product.

The TRIPS Council Decision of 30 August 2003 (WT/L/540) on the implementation of paragraph 6 of the Doha Declaration on TRIPS and Public Health contains a definition of “pharmaceutical product”, providing that:

“1. For the purposes of this Decision:

- (a) “pharmaceutical product” means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. [...].”

This definition does not completely clarify the interpretive issue highlighted above. It includes process patents to the extent they are necessary to produce a covered product. In any case, the definition was adopted in the particular context of paragraph 6 and does not necessarily apply to paragraph 7.

⁴⁵ Abbott, *Doha Declaration*, p. 502/503.

⁴⁶ “[...] We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement [...]” (see above).

⁴⁷ Abbott, *Doha Declaration*, p. 504, footnote 102, referring to TRIPS Article 28.1(b) as covering process patents that are arguably related to the subject matter of “pharmaceutical products” within the meaning of paragraph 7 of the Doha Declaration.

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6.2.1.4 Implementing paragraph 7 on the domestic level. It is important to note that paragraph 7 concerns only obligations Members have toward other WTO Members. Thus, one Member will not be able to successfully challenge an LDC Member for not implementing, applying or enforcing patent rights in its territory before 2016. However, if an LDC Member does not take advantage of its right under paragraph 7 and provides in its domestic law for product patent protection before 2016, a patent holder may invoke his patent right under local law and sue generic producers for infringement of this right.⁴⁸

Therefore, in case a domestic law of an LDC Member already provides for patent protection, one way of giving effect to the paragraph 7 extension would be to modify such law by internal legislation before authorizing third parties with the production of generic drugs. As noted above (Section 3), LDC Members are not prevented under TRIPS to adopt during the transition period new laws showing a lesser degree of TRIPS-consistency. Instead of modifying domestic law, LDC Member governments could alternatively take steps to allow their enforcement authorities, whether those are administrative authorities or courts, to reject requests for patent right enforcement. In fact, such authority need not be granted until the time it is exercised, and may even be granted “after the fact”. As in most legal matters, however, by acting in advance the government can save itself and its procurement authorities from the potential delay and expense involved in legal battles with IPR holders, and potential political pressure from the home governments of IPR holders.

Because the political and constitutional arrangement in each country is somewhat different, it is difficult to offer general guidance regarding the specific steps LDC governments should take to pave the way for avoiding IPR-based obstacles to procuring generic medicines and supplies. If the executive and parliament (or legislature) cooperate in adopting a grant of authority for the procurement authority to disapply IPRs in order to promote and protect public health, this should in most or all LDCs be adequate to accomplish the objective. Other procedures are certainly possible and acceptable.⁴⁹ The government should, however, avoid discriminating among IPR holders of different nationalities so as to comply with the TRIPS requirements of national treatment and MFN treatment.

6.2.2 The TRIPS Council Decision implementing the extension

On 27 June 2002, the TRIPS Council adopted a decision implementing paragraph 7 of the Doha Declaration on TRIPS and Public Health, as instructed by the

⁴⁸ This is independent of the question whether in the respective country WTO law may be directly relied upon by individuals before local courts. The local patent right at issue would not derive directly from WTO law, but from local law, which may usually be invoked directly.

⁴⁹ Action by the executive or parliament alone may well be adequate (depending on the constitutional arrangement), and the courts might have authority to act on their own to disapply patent protection taking into account TRIPS Agreement principles. Among all possible ways, the most reliable one appears to be the actual modification of the law that the courts then apply (see above). The downside of this solution, on the other hand, is that this process might be time consuming. In addition, legislation would have to be amended again at the end of the transition period, provoking the risk of delayed implementation of TRIPS rules.

Fourth Ministerial Conference in the same paragraph (see above). This decision provides:

“Having regard to paragraph 1 of Article 66 of the TRIPS Agreement;

Having regard to the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 7 of the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the “Declaration”);

Considering that paragraph 7 of the Declaration constitutes a duly motivated request by the least-developed country Members for an extension of the period under paragraph 1 of Article 66 of the TRIPS Agreement;

Decides as follows:

1. Least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016.
2. This decision is made without prejudice to the right of least-developed country Members to seek other extensions of the period provided for in paragraph 1 of Article 66 of the TRIPS Agreement.”⁵⁰

Paragraphs 1 and 2 of the decision essentially repeat the language employed in paragraph 7 of the Doha Declaration on TRIPS and Public Health. There is no clarification with respect to the interpretive uncertainties left by paragraph 7 (as discussed above).⁵¹ The third introductory clause of the decision (“Considering that . . .”) confirms that the extension of the transition period under paragraph 7 is based on Article 66.1, second sentence.

6.2.3 The waiver of the obligation to provide EMRs

On 8 July 2002, the WTO General Council approved a draft waiver submitted by the TRIPS Council concerning the obligation of LDC Members to provide exclusive marketing rights during the extended transitional period.⁵² The waiver provides:

“The General Council,

Having regard to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization (the “WTO Agreement”);

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

Noting the decision of the Council for TRIPS on the Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with respect to Pharmaceutical Products

⁵⁰ Decision of the Council for TRIPS on the *Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, WTO document IP/C/25 of 27 June 2002.

⁵¹ Note, however, that the issue of EMRs has been settled through a waiver adopted by the General Council. See below.

⁵² The draft waiver was adopted by the TRIPS Council on 27 June 2002. The text of the waiver is available at <http://www.wto.org/english/news_e/pres02_e/pr301_e.htm>.

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(IP/C/25) (the “Decision”), adopted by the Council for TRIPS at its meeting of 25–27 June 2002 pursuant to the instructions of the Ministerial Conference contained in paragraph 7 of the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the “Declaration”);

Considering that obligations under paragraph 9 of Article 70 of the TRIPS Agreement, where applicable, should not prevent attainment of the objectives of paragraph 7 of the Declaration;

Noting that, in light of the foregoing, exceptional circumstances exist justifying a waiver from paragraph 9 of Article 70 of the TRIPS Agreement with respect to pharmaceutical products in respect of least-developed country Members;

Decides as follows:

1. The obligations of least-developed country Members under paragraph 9 of Article 70 of the TRIPS Agreement shall be waived with respect to pharmaceutical products until 1 January 2016.
2. This waiver shall be reviewed by the Ministerial Conference not later than one year after it is granted, and thereafter annually until the waiver terminates, in accordance with the provisions of paragraph 4 of Article IX of the WTO Agreement.”

This waiver fulfils an important complementary function with respect to paragraph 7 of the Doha Declaration. As noted before, paragraph 7 leaves some interpretive uncertainty as to its precise extent, in particular with respect to EMRs and mailbox application systems. The waiver makes clear that the obligation of LDC Members with respect to EMRs in the area of pharmaceutical products shall be waived until 2016 (subject to annual review).

This considerably enhances the practical value of the extension of the transitional period under paragraph 7. If LDC Members had to honour EMRs, the availability of less costly generic copies of a drug would be seriously put into question. Depending on local law, the patent applicant might not be able to invoke EMRs against the making or the importation of the covered drugs. But the patent applicant would presumptively have the right to prevent the marketing of the less costly copies throughout the respective LDC Member.⁵³

On the other hand, the language employed in the waiver refers expressly to Article 70.9, thus arguably indicating that the waiver is not intended to cover the obligation of LDC Members to provide for mailbox application systems (Article 70.8) during the extended transitional period.

6.3 Regional and bilateral contexts

6.4 Proposals for review

There is no formal review of the transitional periods contained in Article 65 and 66.1.

⁵³ Abbott, *Doha Declaration*, p. 502, footnote 99, noting also that absent any clarification in the domestic law, EMRs might not be subject to the same limitations as patents (such as the general exception clause under Article 30, or the compulsory licensing provision in Article 31 TRIPS) and therefore be even more burdensome to a public health policy that seeks to promote the availability of low-priced medicines. Note, however, that India in its domestic law has subjected EMRs to compulsory licenses.

7. Comments, including economic and social implications

Considering the enormous adaptation efforts that need to be made in order to implement the TRIPS obligations in developing and least-developed countries, transitional periods are of vital importance to those Members. If a transition period of five years in the case of developing countries or even 10 or 20 years (for pharmaceuticals) in the case of LDCs seems long at first sight, it needs to be noted that these countries very often do not have a culture of IP protection like their industrialized country counterparts. The examples of the Republic of Korea⁵⁴ and Japan have shown that, in order for a country to develop an IPR-based industry that could engage in innovation and inventive activity it is essential for that country to have the human resources, the entrepreneurial capacity, the institutions and policies that are at the centre of a sound and viable technological base. It is only at that point that strong IP protection becomes relevant. If, on the other hand, a strong IP protection system prevents the domestic industry from engaging in legitimate imitation and innovation, developing countries will depend on the willingness of foreign right holders to share their knowledge. In that sense, transitional periods constitute an important tool for developing countries to set up that sound and viable base and thus develop their own IP-based industries.

⁵⁴ For a detailed analysis of the Korean experience with IPRs and their impact on technology transfer, see Linsu Kim, *Technology Transfer and Intellectual Property Rights: Lessons from Korea's Experience*, UNCTAD-ICTSD, Geneva 2003 (available at <<http://www.iprsonline.org/unctadictsd/docs/Kim2002.pdf>>.)

34: International and Technical Cooperation and Transfer of Technology

Article 69 International Cooperation

Members agree to cooperate with each other with a view to eliminating international trade in goods infringing intellectual property rights. For this purpose, they shall establish and notify contact points in their administrations and be ready to exchange information on trade in infringing goods. They shall, in particular, promote the exchange of information and cooperation between customs authorities with regard to trade in counterfeit trademark goods and pirated copyright goods.

Article 67 Technical Cooperation

In order to facilitate the implementation of this Agreement, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country Members. Such cooperation shall include assistance in the preparation of laws and regulations on the protection and enforcement of intellectual property rights as well as on the prevention of their abuse, and shall include support regarding the establishment or reinforcement of domestic offices and agencies relevant to these matters, including the training of personnel.

Article 66 Least-Developed Country Members

1. [...]
2. Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.

1. Introduction: terminology, definition and scope

The above-cited provisions of TRIPS create the basis for an international regime between its Members concerning international cooperation, technical cooperation and incentives for technology transfer. These three elements differ from each other and therefore need to be clearly distinguished.

International cooperation (Article 69) has the purpose of eliminating international trade in IPR-infringing goods. The provision makes explicit reference to trade in counterfeit trademark goods and pirated copyright goods and thus responds to the main concern voiced by industrialized countries prior to the Uruguay Round negotiations. According to Article 69, trade in IPR-infringing goods is to be eliminated through international cooperation. This is to be achieved by way of the establishment of contact points within Members' administrations, which will be notified to the other Members, and whose purpose is to exchange information on trade in infringing goods. In particular, the Members shall promote the exchange of information and cooperation between customs authorities with regard to trade in counterfeit trademark goods and pirated copyright goods. This provision applies to all Members regardless of their level of development. It aims to tighten up international procedures for cooperation in this field.⁵⁵

By contrast, the other provisions that contribute to this regime of cooperation are addressed specifically to developed country Members and aim to remedy particular problems experienced by developing and least-developed country Members. Two policy strands are covered: technical cooperation (Article 67) and the encouragement of technology transfer (Article 66.2). Under Article 67, developed country Members are obliged, under certain conditions,⁵⁶ to provide for technical and financial cooperation in favour of both developing country and least-developed country Members. Despite this obligation, the overall purpose of technical cooperation under Article 67 corresponds to developed countries' interests in that technical cooperation is to be provided "in order to facilitate the implementation of this Agreement".

The second policy strand applies only to the LDC Members, as expressed by Article 66.2. As opposed to the above provisions on international and technical cooperation, this provision promotes the interests of the LDCs. By obliging developed country Members to provide for incentives for the promotion and the encouragement of technology transfer to LDCs, this provision takes account of concerns that the benefits of TRIPS might bypass the world's poorest nations.

Transfer of technology may be realized through formal as well as informal means. Informal technology transfer is carried out by imitation, and is typically not based on any monetary transaction or legal agreement.⁵⁷ Formal technology

⁵⁵ Note that the rather general terms of this provision are complemented by detailed minimum requirements with respect to the enforcement, acquisition and maintenance of intellectual property rights (Articles 41–62; Article 51 referring to border measures concerning counterfeit trademark and pirated copyright goods.). For details, see Chapter 30 of this Resource Book.

⁵⁶ These conditions will be examined in detail below, Section 3.

⁵⁷ See UNCTAD-ICTSD, *Intellectual Property Rights: Implications for Development*, Policy Discussion Paper, Geneva 2003, chapter 5 [hereinafter UNCTAD-ICTSD Policy Discussion Paper].

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transfer is a commercial operation, based on a legal arrangement that involves monetary transaction. It includes foreign direct investment (FDI), joint ventures, whollyowned subsidiaries, licensing, technical-service arrangements, joint research and development (R&D) arrangements, training, information exchanges, sales contracts and management contracts.⁵⁸

2. History of the provisions

2.1 Situation pre-TRIPS

Prior to the adoption of TRIPS, the prevailing concern as regards IPR regimes in developing countries was the perceived lack of adequate protection. In particular, developed countries with advanced IPR protection, and the transnational corporations (TNCs) headquartered in such countries, expressed worries about the adverse effects on trade and investment stemming from inadequate IPR protection and enforcement in developing countries leading to the extensive copying of goods protected by such rights in their home countries. These copies could then be traded with ease across borders, thereby undermining the protection afforded to its owner by the IPR in question. Stronger cooperation in the elimination of such trade was therefore a major objective for the advocates of TRIPS.

On the other hand, while developing countries were perceived as having weak IPR regimes, they were also perceived as having very real problems obtaining technology that would be useful to their development. In response to such concerns, the Draft UN Code on the Transfer of Technology contained *inter alia* provisions that exhorted developed countries to implement policies aimed at encouraging technology transfer to such countries.⁵⁹ Equally, the OECD Guidelines for Multinational Enterprises, concluded in 1976, contained a chapter on “Science and Technology” which exhorted TNCs to co-operate in the science and technology policies of the countries in which they operated.⁶⁰ Furthermore, at the national level, special technology transfer regimes were adopted by many developing, and some developed, countries to regulate the terms and conditions of inward technology transfer transactions.⁶¹ Thus, prior to TRIPS, there was wide recognition of the special problems of developing countries in relation to technology transfer in both national laws and international deliberations.

2.2 Negotiating history

The negotiating history of these provisions suggests that the Agreement did not undergo any major changes. The most significant differences are outlined below.

⁵⁸ See also Keith Maskus, *Encouraging International Technology Transfer*, UNCTAD-ICTSD, Geneva 2004, available at <<http://www.iprsonline.org/unctadictsd/projectoutputs.htm#casestudies>>. [hereinafter Maskus, 2004]

⁵⁹ See S. Patel/P. Roffe/A. Yusuf, *International Technology Transfer. The Origins and Aftermath of the United Nations Negotiations on A Draft Code of Conduct*, Kluwer Law International, The Hague, 2001 [hereinafter Patel/Roffe/Yusuf]. See also UNCTAD, *International Investment Agreements: A Compendium* (New York and Geneva 1996, United Nations) Vols. I–III (See in particular chapters 2, 6 and 7 of Vol. I. at pp. 184–6, 195–8) [hereinafter UNCTAD, Compendium (IIAS)].

⁶⁰ UNCTAD, Compendium (IIAS), Vol. II. at p. 192.

⁶¹ See Michael Blakeney, *Legal Aspects of the Transfer of Technology to Developing Countries* (Oxford 1989, ESC Publishing).

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2.2.1 Article 69

2.2.1.1 The Anell Draft⁶²

“4. International Cooperation (68)

PARTIES agree to cooperate with each other with a view to eliminating international trade in goods infringing intellectual property rights. For this purpose they shall establish and notify contact points in their national administrations, and shall be ready to exchange information on trade in infringing goods. They shall, in particular, promote the exchange of information and cooperation between customs authorities with regard to trade in counterfeit goods. (68) (See also point [-] of Part IX below.)”⁶³

2.2.1.2 The Brussels Draft⁶⁴

“PARTIES agree to cooperate with each other with a view to eliminating international trade in goods infringing intellectual property rights. For this purpose, they shall establish and notify contact points in their administrations and be ready to exchange information on trade in infringing goods. They shall, in particular, promote the exchange of information and cooperation between customs authorities with regard to trade in counterfeit goods.”

As regards Article 69 the main change involves an extension of the types of illicit trade in IPRs that are to be covered by the duty of cooperation and exchange of information introduced by this provision. Thus, while the Anell Draft and the Brussels Draft specified only “trade in counterfeit goods”, the final version refers to trade in “counterfeit trademark goods and pirated copyright goods”.

2.2.2 Article 67

2.2.2.1 The Anell Draft

“2. Technical Assistance (68); Technical Cooperation (73); International Cooperation, Technical Assistance (74)

2A Developed PARTIES shall, if requested, advise developing PARTIES on the preparation and implementation of domestic legislation on the protection and enforcement of intellectual property rights covered by this Annex as well as the prevention of their abuse, and shall grant them technical assistance on mutually agreed terms and conditions, regarding the establishment of domestic offices and agencies relevant to the implementation of their intellectual property legislation, including the training of officials employed in their respective governments. (68)

2B PARTIES to this Agreement shall provide for technical cooperation to developing and least-developed PARTIES upon co-ordination by the Committee

⁶² Document MTN.GNG/NG11/W/76, of 23 July 1990.

⁶³ Note that the referenced section of Part IX provided: “*Desirous* of providing for adequate procedures and remedies to discourage international trade in counterfeit and pirated goods while ensuring an unimpeded flow of trade in legitimate goods;”

⁶⁴ Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Revision, Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, MTN.TNC/W/35/Rev. 1, 3 Dec. 1990.

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established under point 1B of Part VIII below in collaboration with the World Intellectual Property Organization, and other international organizations, as appropriate. Upon request, such cooperation includes support and advice as to training of personnel, the introduction, amendment and implementation of national laws, regulations and practices, and assistance by the Committee for settlement of disputes. (73)”

2.2.2.2 The Brussels Draft. This draft was essentially identical to the final version of Article 67.

Two main changes can be noted between the Anell Draft and the final version of Article 67. The first change involves the scope of the duty to provide technical assistance in the preparation of IPR laws and regulations. The Anell Draft used the term “shall grant them technical assistance . . .” (proposal 2A, above), suggesting a degree of compulsion in the discharge of this obligation. The final version has dropped the word “grant” and simply states that “[s]uch cooperation shall include assistance . . .”. This suggests a less directed approach to the carrying out of the assistance obligation, implying that assistance in this area may be part of a wider policy adopted by the developed country Member and may, in fact, be granted as a matter of discretion and judgment, as opposed to mandatory obligation. The second change involves the omission, from the final draft, of a proposed second paragraph to Article 67 (above, proposal 2B). This provision outlined an institutional process through which cooperation under this provision would take place. It involved the co-ordination of technical cooperation with developing and least-developed Parties through a Committee set up for this purpose in collaboration with the World Intellectual Property Organization. This draft paragraph had been dropped by the time of the Brussels Draft.

2.2.3 Article 66.2

Article 66.2 was not envisaged in the Anell Draft. It appears in the Brussels Draft in a form essentially identical to that of the final version of the provision. Like the final version of Article 66.2 TRIPS, the Brussels draft provision was addressed exclusively to LDCs.

3. Possible interpretations

3.1 Article 69

According to this provision (“Members agree to co-operate . . .”), WTO Members are committed to cooperate. The language suggests a compulsory method of cooperation through the contact points in the Members’ national administrations. The existence of these contact points must be notified to the other Members. They must also be “ready to exchange information . . .”. Thus there is no positive duty to volunteer information to other Members, but relevant information must be made available upon request.

Finally, promotion and cooperation between customs authorities is specified in relation to trade in counterfeit trademark goods and pirated copyright goods.

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3.2 Article 67

There are no mandatory rules or methods of cooperation imposed on developed country Members under this provision. However, the duty on developed countries to cooperate is activated upon the receipt of a request for cooperation by a developed country member from a developing or least developed country Member, followed by the conclusion of mutually agreed terms and conditions that will govern the cooperation process.

The nature of the cooperation is described as “technical and financial”. In view of the freedom to request cooperation on the part of the developing or least-developed country Member, and the concomitant freedom of the developed country Member to whom the request is made, to determine by mutual agreement the nature and scope of the cooperation so requested, that cooperation could involve technical and/or financial cooperation. The parties are free to determine this in the course of their negotiations.

The remaining parts of Article 67 add three further possible avenues of cooperation that shall be considered by the developed and developing or least-developed cooperating Members:

- assistance in the preparation of laws and regulations on the protection and enforcement of IPRs;
- assistance in the prevention of the abuse of laws and regulations on the protection and enforcement of IPRs (a matter related to the more general aims of Article 69);
- support regarding the establishment or reinforcement of domestic offices and agencies relevant to these matters, including the training of personnel.

3.3 Article 66.2

This provision places a duty on developed country Members to provide incentives to enterprises and institutions in their territory for the purpose of promoting and encouraging technology transfer to least-developed country Members with the aim of creating a sound and viable technological base.

The precise scope and nature of that duty is not defined in any detail. Thus there would appear to be considerable discretion on the part of the developed country Member on how to discharge this duty.⁶⁵ However, it is clear that the duty exists and must be discharged. This reading is consistent with the general objectives of TRIPS, as laid out in Articles 7 and 8, where the protection of IPRs is seen as having to contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers

⁶⁵ Note, however, that some precision has been added to this provision through the decision by the Council for TRIPS concerning the implementation of Article 66.2 of the TRIPS Agreement. For details, see below, Section 6.2.3.

5. Relationship with other international instruments

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and users of technological knowledge and in a manner conducive to social and economic welfare, and to the balance of rights and obligations. Moreover, the Doha Ministerial Declaration expressly reaffirmed the mandatory nature of the provisions under Article 66.2.⁶⁶

Finally, the obligation to encourage technology transfer includes proprietary technology and not only technology in the public domain.⁶⁷ The latter is more easily accessible, whereas the transfer of the former is in the exclusive discretion of the holder of the respective right.

3.4 The combined effect of these provisions

Thus, these provisions together create a model of cooperation between TRIPS Members, especially developed and developing or least-developed country Members which aims to:

- control international trade in counterfeit goods (Article 69);
- establish an effective legal and administrative regime for the protection of IPRs in developing and least-developed countries (Articles 69 and 67);
- encourage enterprises and institutions in developed country Members to transfer technology to least developed country Members to help in the development of a sound and viable technological base (Article 66.2).

In the light of these provisions, the Council for TRIPS regularly receives numerous notifications from developed countries of their technical cooperation programmes.

4. WTO jurisprudence

To date no dispute concerning these provisions has been brought before the dispute settlement body of the WTO.

5. Relationship with other international instruments

5.1 WTO Agreements

The WTO agreements specify, in numerous provisions,⁶⁸ the need to offer technical assistance to developing and LDC Members.⁶⁹ Each of those provisions relates specifically to the particular subject matter of the respective agreement.

⁶⁶ For details, see below, Section 6.2.2.

⁶⁷ See C. Correa, *Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?* Draft of March 2003, submitted to a Conference at Duke University [hereinafter Correa, Draft].

⁶⁸ For a detailed overview of these provisions, see UNCTAD (2001), *Compendium of International Arrangements on Transfer of Technology. Selected Instruments*, New York and Geneva, p. 52 et seq. [hereinafter Compendium (TOT)].

⁶⁹ A generally flexible approach to the obligations of, in particular, the least-developed country Members is advocated by the terms of the Decision on Measures in Favour of Least Developed Countries appended to the Final Act of the Uruguay Round of 1994.

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In particular, reference can be made to Articles 11, 12 TBT Agreement; Article IV GATS; Article 9 of the Agreement on the Application of Sanitary and Phytosanitary Measures; and Article 20.3 of the Agreement on Implementation of Article VII of the GATT 1994 (Customs Valuation Agreement).

5.2 Other international instruments

Other multilateral instruments contain provisions offering an opportunity to negotiate commitments for home country measures beneficial to developing countries.⁷⁰

6. New developments

6.1 National laws

6.2 International instruments

6.2.1 The WIPO-WTO agreement on technical cooperation

In 1996 the WTO and the World Intellectual Property Organization (WIPO) entered into a technical cooperation agreement. Of particular relevance to the provisions under discussion is Article 4 of that Agreement, which deals with "Legal-Technical Assistance and Technical Cooperation":

"(1) [*Availability of Legal-Technical Assistance and Technical Cooperation*] The International Bureau shall make available to developing country WTO Members which are not Member States of WIPO the same legal-technical assistance relating to the TRIPS Agreement as it makes available to Member States of WIPO which are developing countries. The WTO Secretariat shall make available to Member States of WIPO which are developing countries and are not WTO Members the same technical cooperation relating to the TRIPS Agreement as it makes available to developing country WTO Members.

(2) [*Cooperation Between the International Bureau and the WTO Secretariat*] The International Bureau and the WTO Secretariat shall enhance cooperation in their legal-technical assistance and technical cooperation activities relating to the TRIPS Agreement for developing countries, so as to maximize the usefulness of those activities and ensure their mutually supportive nature.

(3) [*Exchange of Information*] For the purposes of paragraphs (1) and (2), the International Bureau and the WTO Secretariat shall keep in regular contact and exchange non-confidential information."

Thus the secretariats of both organisations will offer the same technical and legal assistance to developing countries so long as those belong to at least one of the two organisations.

⁷⁰ Due to the great number of relevant agreements, a discussion of these would go beyond the scope of this book. For an overview of international instruments on technology transfer, see the Compendium (TOT). For a detailed analysis of home country measures for the promotion of foreign direct investment (FDI) and technology transfer to developing countries in international agreements see UNCTAD, *Home Country Measures: Facilitating the Transfer of Technology to Developing Countries*. UNCTAD Series on issues in international investment agreements, New York and Geneva (forthcoming, 2005).

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In addition, reference should be made to the WTO-WIPO joint initiative of 14 June 2001 to provide technical assistance to the least-developed countries aimed at helping those countries to comply with their obligations under TRIPS. The joint initiative builds on existing cooperation between WIPO and WTO⁷¹ and on each organization's own technical assistance programmes. It is also similar to a joint WIPO-WTO project⁷² launched in 1998 to help all developing countries, particularly those that are not least developed, which had to comply with TRIPS by 2000.⁷³ Least-developed countries have until 1 January 2006 to comply with TRIPS. They have to bring their laws on copyright, patents, trademarks and other areas of intellectual property into line with TRIPS.⁷⁴ They also have to provide ways of enforcing the laws effectively in order to deal with various forms of intellectual property infringement. To help these countries meet their obligations, the technical assistance available under the joint initiative includes cooperation with preparing legislation, training, institution-building, modernizing intellectual property systems and enforcement.⁷⁵ All LDCs can participate in the technical assistance offered. They do not need to be WIPO or WTO Members.⁷⁶

Technical cooperation is an important instrument to facilitate developing countries' adequate integration into the multilateral trading system. It should also be a vehicle for exploring the flexibilities inherent in TRIPS as highlighted throughout this book.

6.2.2 The Doha mandate on Article 66.2 TRIPS

At the WTO Ministerial Conference at Doha in November 2001, Members agreed, *inter alia*, on a Decision concerning implementation-related issues and concerns.⁷⁷ This Decision addresses several developing Members' preoccupations about the implementation of the WTO agreements into their domestic laws.⁷⁸ As to TRIPS, paragraph 11.2 of the Decision provides that:

⁷¹ Agreement between the World Intellectual Property Organization and the World Trade Organization, see at <<http://www.wto.org/english/tratop.e/trips.e/intel3.e.htm>>.

⁷² See the WTO press release of 21 July 1998, at <http://www.wto.org/english/news_e/pres98_e/pr108_e.htm>.

⁷³ Note that under Article 65.4 of TRIPS, this deadline is extended until 1 January 2005 concerning the obligation to provide product patents in areas not so protectable in a developing country Member on the general date of application of TRIPS (i.e., 1 January 1996).

⁷⁴ Note that on certain conditions, this deadline is extended under para. 7 of the Doha Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/W/2): Members agreed that "least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply" the TRIPS disciplines on patent rights and on the protection of undisclosed information until 1 January 2016 (independently of their right to seek further extension of transition periods as provided under Article 66.1 TRIPS). For details, see Chapter 33.

⁷⁵ Of the 50 countries defined by the UN as least developed, 31 are Members of the WTO (another nine are negotiating WTO membership). See <http://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm>.

⁷⁶ World Intellectual Property Organisation (WIPO)/World Trade Organisation (WTO) *Press Release* (Press/231) 14 June 2001 *WIPO and WTO launch new initiative to help world's poorest countries*.

⁷⁷ Decision on Implementation-Related Issues and Concerns, WTO document WT/MIN(01)/17 of 20 November 2001.

⁷⁸ See the third consideration of the Decision, reading as follows: "Determined to take concrete action to address issues and concerns that have been raised by many developing-country Members regarding the implementation of some WTO Agreements and Decisions, including the difficulties

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“Reaffirming that the provisions of Article 66.2 of the TRIPS Agreement are mandatory, it is agreed that the TRIPS Council shall put in place a mechanism for ensuring the monitoring and full implementation of the obligations in question. To this end, developed-country Members shall submit prior to the end of 2002 detailed reports on the functioning in practice of the incentives provided to their enterprises for the transfer of technology in pursuance of their commitments under Article 66.2. These submissions shall be subject to a review in the TRIPS Council and information shall be updated by Members annually.”

According to the second sentence of the Decision, developed country Members shall report on the “functioning in practice” of their respective incentive regimes for the transfer of technology. It has been suggested that this language could be interpreted as committing developed country Members to establish an incentives regime that actually promotes successful technology transfer.⁷⁹

6.2.3 Recent developments in the Council for TRIPS

Pursuant to the Doha Decision on Implementation-Related Issues and Concerns, the WTO Council for TRIPS adopted, on 19 February 2003, a Decision concerning the implementation of Article 66.2.⁸⁰ In essence, it lays down an obligation for developed country Members to submit reports on actions taken or envisaged (including any specific legislative, policy and regulatory framework) to provide incentives to enterprises and institutions in their territories for the promotion of technology transfer to LDC Members. Such reports are to be updated annually, and new detailed reports have to be submitted every third year. The reports are to be reviewed by the Council for TRIPS at its end of year meeting with a view to providing other Members with the opportunity to pose questions and request additional information. Developed country Members are obliged to disclose certain information concerning their incentive regimes, particularly on the functioning in practice of these incentives.⁸¹ Finally, the arrangements contained in this Decision are subject to a review after three years by the Council with a view to improving them.

This Decision constitutes an important step forward in the attempt to operationalize Article 66.2. It considerably reduces developed Members’ discretion as to their implementation of it.

and resource constraints that have been encountered in the implementation of obligations in various areas;”

⁷⁹ See Correa, Draft.

⁸⁰ See WTO document IP/C/28.

⁸¹ According to paragraph 3(d) of the Decision such information includes:

- statistical and/or other information on the use of the incentives in question by the eligible enterprises and institutions;
- the type of technology that has been transferred by these enterprises and institutions and the terms on which it has been transferred;
- the mode of technology transfer;
- least-developed countries to which these enterprises and institutions have transferred technology and the extent to which the incentives are specific to least-developed countries; and
- any additional information available that would help assess the effects of the measures in promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.”

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6.2.4 The WTO Working Group on Trade and Technology Transfer

In paragraph 37 of the Doha Ministerial Declaration, Members agreed to establish a Working Group on Trade and Technology Transfer. Its mandate is as follows:

“37. We agree to an examination, in a Working Group under the auspices of the General Council, of the relationship between trade and transfer of technology, and of any possible recommendations on steps that might be taken within the mandate of the WTO to increase flows of technology to developing countries. The General Council shall report to the Fifth Session of the Ministerial Conference on progress in the examination.”

6.2.5 The Conference of the Parties to the Convention on Biological Diversity

At its seventh meeting in February 2004, the Conference of the Parties (COP) to the Convention on Biological Diversity (CBD) decided to invite the Secretariat of the CBD, WIPO, UNCTAD and other relevant organizations to prepare:

“technical studies that further explore and analyse the role of intellectual property rights in technology transfer in the context of the Convention on Biological Diversity and identify potential options to increase synergy and overcome barriers to technology transfer and cooperation, consistent with paragraph 44 of the Johannesburg Plan of Implementation. The benefits as well as the costs of intellectual property rights should be fully taken into account.”⁸²

6.3 Regional and bilateral contexts

6.3.1 Regional context

6.3.1.1 Agreements between developed and developing country Members. The 2000 Cotonou Agreement⁸³ is intended to encourage developing country parties to integrate more fully into the global economy. To this end, cooperation between the EC and developing contracting parties in the field of economic sector development includes the development of scientific, technological and research infrastructure and services, including the enhancement, transfer and absorption of new technologies (see Article 23(j) of the Agreement).

Of particular relevance is the commitment of all parties, in Article 46, to ensuring an adequate and effective level of protection of IPRs and other rights covered by TRIPS. This includes, *inter alia*, an agreement to strengthen cooperation on the preparation and enforcement of laws and regulations in this field, the setting up of administrative offices and the training of personnel.

⁸² See UNEP/CBD/COP/7/L.20 of 19 February 2004, page 11.

⁸³ European Commission (EC) (2000), *Partnership Agreement between the Members of the African, Caribbean and Pacific Group of States of the one part, and the European Community and its Member States, of the other part, signed in Cotonou, Benin on 23 June 2000*. (See <<http://www.acpsec.org/gb/cotonou/accord1e.htm>>.)

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In a similar vein, agreements concluded between the EC and Latin American economic integration groups contain a commitment to economic cooperation that includes the encouragement of technology transfer.⁸⁴

6.3.1.2 Agreements between developing country Members. Certain intra-regional economic integration agreements among developing and least-developed country Members contain provisions encouraging the development and transfer of technology by enterprises operating within the region. These may be divided into two main groups: general provisions stressing cooperation in areas relevant to the development and transfer of technology within the region, and specialized provisions establishing regional multinational enterprises, which, in turn, serve the purpose of developing technology and transferring it across the region.⁸⁵

6.3.2 Bilateral context

Although almost all bilateral investment treaties (BITs) are silent on the question of technology transfer, it should be noted that the Dutch model agreement of 1997 states, in its Preamble, that “agreement upon the treatment to be accorded to investments [by the nationals of one Contracting Party in the territory of the other Contracting Party] will stimulate the flow of capital and technology and the economic development of the Contracting Parties”.⁸⁶ Thus the Dutch model agreement makes a clear connection between the promotion and protection of investors and their investments (arguably including IPRs) and the stimulation of technology transfer. However, it is far from certain that enhanced IPR protection will automatically result in more transfer of technology (see the discussion under Section 7 below).

7. Comments, including economic and social implications

7.1 Technical cooperation

Considering the lack of experience and expertise in IP issues prevailing in many developing and least-developed country Members, the need for technical assistance for those countries is obvious. It is of crucial importance in this respect that

⁸⁴ See Framework Agreement for Cooperation Between the EC and the Cartagena Agreement and its Member Countries, 1993, Article 3 (UNCTAD, *International Investment Agreements: A Compendium* (New York and Geneva, 2000) [hereinafter UNCTAD, 2000], Vol. V, p. 187); and EC-MERCOSUL/R Interregional Framework Cooperation Agreement, 1993, Articles 11(2) and 16(2)(b) (UNCTAD, World Investment Report 2001, pp. 162–164).

⁸⁵ For the general provisions, see, e.g., the Treaty Establishing the African Economic Community of 1991 that calls upon the Community to harmonize national policies on science and technology and to promote technical cooperation and the exchange of experience in the field of industrial technology and implement technical training programmes among member States (Articles 4(2)(e) and 49(h), in UNCTAD 2000, Vols. IV–V, in Vol. V, pp. 16–18). A similar commitment can be found in Article 26 (3)(i) of the Revised Treaty of the Economic Community of West African States (ECOWAS) of 1993 (UNCTAD, 2000a, Vol. V, p. 40), and in Articles 100 (d) and 103 (2) of the Treaty Establishing the Common Market for Eastern and Southern Africa (COMESA) of 1993 (UNCTAD Compendium (IIAS), Vol. III, p. 102). For the specialized provisions, see, e.g., Article 101 (2) (iv) of the COMESA Treaty (UNCTAD Compendium (IIAS), Vol. III, p. 103).

⁸⁶ UNCTAD, 2000, Vol. V, p. 333.

7. Comments, including economic and social implications

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policy makers and providers of technical cooperation are fully aware of the TRIPS-inherent flexibilities that may be used for the realization of development goals. Concerns have been voiced in this respect as to the appropriateness and nature of the technical assistance offered to developing countries.⁸⁷ In particular, any organization or institution involved in technical IP assistance should take account of the different levels of development of their target countries, and those countries' different needs with respect to IP implementation.

Another important aspect of technical assistance is the facilitation of active participation of developing countries in the ongoing negotiations in Geneva and their ability to be represented by experts to international meetings on IPRs. Here, two lines of assistance have been identified:⁸⁸ first, the expansion of funding schemes of international organizations to cover the related costs; second, the improvement of the quality of developing country participation through permanent advice in the area of intellectual property rights.

7.2 Technology transfer

Given the increasing dependence of a country's wealth and competitiveness on its ability to produce high technology products for the world market, the technological gap between developed and developing countries has become one of the main obstacles to a successful integration of developing nations into the globalized economy.⁸⁹ Considering that most developing countries are net importers of new technologies, incoming technology transfer is a critical source of technical change.⁹⁰ Article 66.2 takes account of this by obliging Members to provide incentives for the promotion and encouragement of technology transfer to least-developed country Members.

However, the effect of Article 66.2 on the encouragement of technology transfer to the LDCs, and on the development of a sound technological base in those

⁸⁷ Such criticism comes not only from many NGOs, but has also been expressed by the IPR Commission (see p. 158 of the Report): "We recognise that WIPO has a role to play in promoting IPRs. However, we believe that it needs to do so in a much more nuanced way that is fully consistent with the economic and social goals to which the UN, and the international community are committed. A more balanced approach to the analysis of IPRs, and, in consequence WIPO programmes, would be beneficial to both the organisation and the developing world, which forms the majority of its membership." See also p. 161 of the Report: "There is also evidence that, in cases where WIPO's assistance has been acknowledged, the result has not incorporated all TRIPS flexibilities. For instance, the revised Bangui Agreement for the OAPI countries, where WIPO's assistance is acknowledged, has been criticised in various quarters for going further than TRIPS. It obliges LDC members (the majority of OAPI members) who ratify it to apply TRIPS in advance of need; it restricts the issuance of compulsory licences to a greater extent than required by TRIPS; it does not explicitly allow parallel imports; it incorporates the elements of UPOV 1991 in the agreement and it provides for a copyright term of 70 years after the death of the author." See also S. Musungu/G. Dutfield, *Multilateral agreements and a TRIPS-plus world: The World Intellectual Property Organisation (WIPO)*, TRIPS Issue Paper 3, Quaker United Nations Office, Geneva 2003 (available at <[http://www.geneva.quino.info/pdf/WIPO\(A4\)final0304.pdf](http://www.geneva.quino.info/pdf/WIPO(A4)final0304.pdf)>).

⁸⁸ *Ibid.*, p. 165.

⁸⁹ The importance of this gap may be illustrated by the following figures from 2000: only 10 developed countries accounted for 84% of global R&D annually, received 91% of global cross-border technology licence fees and royalties, and took out 94% of the patents granted in the USA between 1977 and 2000. Figures from Correa Draft, Table 1.

⁹⁰ See Policy Discussion Paper, chapter 5, and Maskus, 2004.

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countries, has been very limited.⁹¹ This raises concerns as to the appropriateness not only of Article 66.2, but of TRIPS in general to foster effective transfer of technology.⁹² The decisive issue is whether enhanced IPR protection in developing countries and LDCs, as promoted by TRIPS, will actually result in increased technology transfer to these countries. Opinions differ widely in this respect, and the available empirical evidence is inconclusive.⁹³

⁹¹ See Keith Maskus, *Intellectual Property Rights in the Global Economy* (Washington DC, Institute for International Economics, 2000), p. 225. See also the IPR Commission, p. 26.

⁹² See IPR Commission, p. 26. See also Correa, Draft, in his conclusions: "The TRIPS Agreement was essentially conceived as a means of strengthening the control by titleholders over the protected technologies, and not with the objective of increasing the transfer and use of technology globally. The transfer of technology was not, in fact, a concern of TRIPS proponents, and the possible effects of the new protectionist standards on such transfer were never seriously considered during the negotiations."

⁹³ See Policy Discussion Paper, Chapter 5, and Maskus, 2004.

35: Council for TRIPS

Article 68 Council for Trade-Related Aspects of Intellectual Property Rights

The Council for TRIPS shall monitor the operation of this Agreement and, in particular, Members' compliance with their obligations hereunder, and shall afford Members the opportunity of consulting on matters relating to the trade-related aspects of intellectual property rights. It shall carry out such other responsibilities as assigned to it by the Members, and it shall, in particular, provide any assistance requested by them in the context of dispute settlement procedures. In carrying out its functions, the Council for TRIPS may consult with and seek information from any source it deems appropriate. In consultation with WIPO, the Council shall seek to establish, within one year of its first meeting, appropriate arrangements for cooperation with bodies of that Organization.

1. Introduction: terminology, definition and scope

The Council for TRIPS is charged with the monitoring of WTO Members' compliance with their obligations under TRIPS.⁹⁴ The legal base for its establishment is Article IV:5 of the WTO Agreement, which stipulates that the Council "shall oversee the functioning" of TRIPS. With a view of understanding the role of the Council within the general institutional structure of the WTO, a brief account is presented below.

- a) The Ministerial Conference is the main body of the WTO, being composed of the representatives of all WTO Members at a ministerial level meeting at least once every two years. According to Article IV:1 of the WTO Agreement, the Ministerial Conference "shall have the authority to take decisions on all matters under any of the Multilateral Trade Agreements" including TRIPS. It is the Ministerial Conference that has the exclusive authority to adopt generally binding interpretations of the Multilateral Trade Agreements (Article IX:2 of the WTO Agreement).
- b) The General Council is composed of representatives of all WTO Members who are generally Geneva-based ambassadors accredited to the WTO, meeting as appropriate (Article IV:2 of the WTO Agreement). According to the same provision,

⁹⁴ For more details on the functions of the Council, see below, under Section 3.

the General Council shall conduct the functions of the Conference in the intervals between the meetings of the ministers. In other words, the decision-making authority of the Conference is most of the time delegated to the General Council. In addition to this, the General Council has two other functions: it also meets, under different rules, as the Dispute Settlement Body (as such responsible for the adoption of reports by dispute settlement panels and the Appellate Body) and as the Trade Policy Review Body (see Article IV:3 and 4 of the WTO Agreement).

c) The Council for TRIPS, the Council for Trade in Goods and the Council for Trade in Services operate “under the general guidance of the General Council” (Article IV:5 of the WTO Agreement). According to the same provision, membership in these Councils shall be open to the representatives of all WTO Members.

2. History of the provision

2.1 Situation pre-TRIPS

As explained elsewhere in this book, the trade-related aspects of intellectual property rights are a new and complex subject in the new structure of GATT-WTO and it was thus considered necessary to establish a new organ responsible to deal with the operation and implementation of the new Agreement.

2.2 Negotiating history

The negotiating history of Article 68 was intertwined with the substantive aspects of the negotiations. Since the idea of substantive standards in TRIPS itself was not commonly accepted until the mid-term review of the Uruguay Round in April 1989, not much consideration was given to what kind of body would supervise the operation of an agreement in this area. Adding to this complication was the debate on what exactly the successor organization to the GATT would be.

Developing countries, in general, insisted for a long time after the Uruguay Round was launched that both TRIPS and the Services Agreement should be on separate tracks and not on a par with negotiations in the goods area. Their idea was to make these two subjects non-justiciable under any possible dispute settlement rules. While this did not happen, it constituted the main reason for the developing countries' entertaining the idea of a separate organ for supervision of TRIPS.

2.2.1 The Anell Draft

This draft provided:⁹⁵

“Committee on Trade-Related Intellectual Property Rights (68); The Committee on Trade-Related Aspects of Intellectual Property Law (73); The TRIPS Committee (74)

1A PARTIES shall establish a Committee on Trade Related Intellectual Property Rights composed of representatives from each PARTY. The Committee shall elect its own chairman, establish its own rules of procedures and shall meet not less

⁹⁵ See composite text of 23 July 1990, circulated by the Chairman (Lars E. R. Anell) of the TRIPS Negotiating Group, document MTN.GNG/NG11/W/76.

2. History of the provision

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than once a year and otherwise upon request of any PARTY. The Committee shall monitor the operation of this Annex and, in particular, PARTIES' compliance with their obligations hereunder, and shall afford PARTIES the opportunity of consulting on matters relating to trade related intellectual property rights. It shall carry out such other responsibilities as assigned to it by the CONTRACTING PARTIES, and it shall, in particular, provide any assistance requested by them in the context of procedures under Articles XXII and XXIII of the General Agreement. In carrying out its functions, the Committee may consult with and seek information from any source they deem appropriate. (68)

1B (i) All PARTIES shall be represented in the Committee on Trade-Related Aspects of Intellectual Property Rights (hereinafter the Committee). It shall elect its Chairman annually and meet as necessary, but not less than once a year. It shall carry out its responsibilities as assigned to it under this PART or by the PARTIES. It may establish working groups. (73)

(ii) The Committee shall monitor the implementation and operation of this PART, taking into account the objectives thereof. It shall examine periodical country reports prepared by the GATT Secretariat on laws, regulations, practices and international agreements related to, and affecting, the protection of intellectual property rights. It shall make recommendations, as appropriate, to the PARTIES concerned. (73)

(iii) The Committee shall periodically agree upon a schedule of country reports. It shall adopt a work programme and coordinate activities of PARTIES in the field of technical cooperation. (73)

(iv) The Committee shall annually report to the CONTRACTING PARTIES. It may submit recommendations. (73)

(v) The Committee is entitled to elaborate and adopt guidelines for the interpretation, in particular of Parts III and IV above. It shall take into account relevant findings of adopted panel reports. (73)

1C The TRIPS Committee composed of representatives of the PARTIES shall be established. The TRIPS Committee shall carry out functions under this Agreement or otherwise assigned to it by the PARTIES. (74)

Joint Expert Group (68), Joint Group of Experts (73)

2A In order to promote co-operation between the Committee on Trade Related Intellectual Property Rights and bodies under the World Intellectual Property Organization, the latter shall be invited by the Committee to serve together with the GATT Secretariat as Secretariat for a joint Expert Group which shall consist of representatives of the CONTRACTING PARTIES and of the Member States of the Paris and Berne Unions. The Expert Group shall, when requested to do so by the Committee, advise the Committee on technical matters under consideration. (68)

2B In order to promote co-operation between the Committee and bodies under the World Intellectual Property Organization, the Committee may establish, as appropriate, Joint Groups of Experts consisting of representatives of the PARTIES and of the Member States of the Unions created by the Paris Convention (1967) and the Berne Convention (1971), respectively. Upon request of the Committee, the Joint Groups of Experts shall give advice on technical matters under consideration. (73)"

Both proposals “A” and “B” had a broader coverage than the final version of Article 68. The latter is limited to the substantive functions of the Council for TRIPS, whereas the proposals under the Anell Draft additionally contained some provisions on the organizational structure of this body (in particular with respect to its composition, its chairperson and its rules of procedure). Such organizational rules were subsequently removed from the specific TRIPS context and incorporated into the WTO Agreement (see Article IV:5 and 6). Contrary to the Anell Draft, however, the WTO Agreement does not expressly refer to the election of the Chairperson. As to the actual functions of the “Committee” (i.e., the body that later became the Council for TRIPS), the final version is closer to proposal “A” than to proposal “B”. The latter contained more details than the former. In the context of the Committee’s monitoring function, it referred expressly to the objectives of the Agreement that should be taken into account. These objectives at the time of the Anell Draft were contained in a provision that later became Article 7. This draft provision provided:

“1B PARTIES recognize that intellectual property rights are granted not only in acknowledgement of the contributions of inventors and creators, but also to assist in the diffusion of technological knowledge and its dissemination to those who could benefit from it in a manner conducive to social and economic welfare and agree that this balance of rights and obligations inherent in all systems of intellectual property rights should be observed.

2B PARTIES agree that the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and enhance the international transfer of technology to the mutual advantage of producers and users of technological knowledge.”⁹⁶

The reference to these objectives in the context of the Committee’s monitoring task highlights the concerns of some developing countries relating to the loss of flexibility in handling IP issues. A comparable reference is missing under the current Article 68.

Finally, both draft proposals contained, in a separate provision, reference to cooperation with WIPO. The “A” and the “B” proposal did not differ much from each other, in particular with their reference to the advice that the Committee should receive from the joint GATT-WIPO group of experts. In this respect, both draft proposals were more detailed than the final version of Article 68, which only makes a general reference to establishing “appropriate arrangements for cooperation” with WIPO bodies (see below, Section 3).

2.2.2 The Brussels Draft

Once the agreement of all countries to negotiate on substantive IPRs standards was secured in April 1989, discussions began on the institutional arrangements

⁹⁶ Note that the final version of Article 7 is closer to the second of the quoted paragraphs.

2. History of the provision

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and by the time the meeting took place in 1990 in Brussels, the draft⁹⁷ contained the following provision:

“PARTIES shall establish a Committee on Trade Related Intellectual Property Rights composed of representatives from each PARTY. The Committee shall elect its own chairperson, establish its own rules of procedures and shall meet not less than once a year and otherwise upon request of any PARTY. The Committee shall monitor the operation of this Agreement and, in particular, PARTIES’ compliance with their obligations hereunder, and shall afford PARTIES the opportunity of consulting on matters relating to the trade-related aspects of intellectual property rights. It shall carry out such other responsibilities as assigned to it by the PARTIES, and it shall, in particular, provide any assistance requested by them in the context of dispute settlement procedures. In carrying out its functions, the Committee may consult with and seek information from any source they deem appropriate. In consultation with the World Intellectual Property Organization, the Committee shall seek to establish, within one year of its first meeting, appropriate arrangements for co-operation with bodies of that Organization.^a”

Note: (a) This provision depends on the decision to be taken regarding the institutional arrangements for the international implementation of this Agreement.”

This draft Article was in essence quite similar to today’s Article 68. There are three minor differences. First, the draft Article in its two first sentences contained a reference to the organizational structure of the Committee (which is now to be found in Article IV:5 and 6 of the WTO Agreement). Second, the terminology used in the draft differed slightly in employing the terms “Committee” (instead of “Council for TRIPS”) and “Parties” instead of “Members”. The latter may be explained by the fact that the GATT 1947 lacked legal personality, as it was not an international organization but only an agreement. Consequently, it did not have “Members”, but only “Contracting Parties”. Likewise, “Committee” reflected the usage in the GATT and its various agreements. Third, the note at the end of the draft provision was not maintained in Article 68. The Cooperation Agreement with WIPO was subsequently established in 1995 (see Section 3 below).

2.2.3 The Dunkel Draft

When the Dunkel Draft⁹⁸ was submitted by December 1991, the term “Council” was used rather than “Committee”. This was because intensive negotiations had taken place prior to the issuance of the Dunkel Draft on institutional matters. Apart from this, Article 68 of the Dunkel Draft was essentially identical to the current TRIPS provision.

Briefly, it was during this period that the following issues were settled: first, that the results of the Uruguay Round were a single undertaking, i.e., either a country could accept all the agreements or none at all; second, that there was to be an international organization called MTO (Multilateral Trade Organization, later

⁹⁷ Document MTN.TNC/W/35/Rev. 1 of 3 December 1990.

⁹⁸ Document MTN.TNC/W/FA of 20 December 1991.

changed to World Trade Organization) which would be the successor to the GATT; and third, that there would be an integrated dispute settlement mechanism, i.e., binding dispute settlement rules would apply across the board.⁹⁹ Finally, there was to be a General Council at the apex and there would be three Councils directly under it (Goods Council, Services Council and TRIPS Council).

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3.1 The functions of the Council

The Council for TRIPS shall monitor the operation of this Agreement and, in particular, Members' compliance with their obligations hereunder, [...]

The monitoring of Members' compliance with their obligations is the predominant task of the Council. In order to facilitate such action, Article 63.2 lays down Members' obligation to notify to the Council their TRIPS-related laws and regulations.¹⁰⁰ This is a way of reducing the necessity for Members to have recourse to the dispute settlement procedures for breaches of the Agreement.¹⁰¹ The reference in the first sentence of Article 68 to the term "in particular" indicates that this monitoring does not exclusively consist of the review of Members' compliance with their TRIPS obligations. In more general terms, the Council is supposed to monitor the "operation" of the Agreement, a term that refers to the overall objective of ensuring a smooth functioning of the Agreement, including its objectives and principles. Besides the compliance monitoring, the Council also fulfils other functions, as indicated below.

[...] and shall afford Members the opportunity of consulting on matters relating to the trade-related aspects of intellectual property rights. [...]

The Council equally provides a forum for consultations on IPR-related matters. This is an important contribution to the building of mutual trust and cooperation, which ideally prevents Members from having recourse to dispute settlement proceedings.

[...] It shall carry out such other responsibilities as assigned to it by the Members, and it shall, in particular, provide any assistance requested by them in the context of dispute settlement procedures. [...]

⁹⁹ This implies the possibility of cross-retaliation (for a definition of that notion, see Chapter 30).

¹⁰⁰ For more details, see Chapter 31.

¹⁰¹ Note, however, that the obligation to notify TRIPS-related domestic rules applies only after their entry into force (see Chapter 31).

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In case there is no room for a settlement of a dispute between the parties, it is an important responsibility of the Council to provide assistance in dispute settlement procedures before a WTO panel or the Appellate Body.

[...] In carrying out its functions, the Council for TRIPS may consult with and seek information from any source it deems appropriate. [...]

The Council has considerable discretion as to the procurement of relevant information necessary to carry out its main functions properly.

In consultation with WIPO, the Council shall seek to establish, within one year of its first meeting, appropriate arrangements for co-operation with bodies of that Organization.

The cooperation agreement between the WTO and WIPO was established in 1995 and entered into force on 1 January 1996.¹⁰² In essence, it concerns three different areas of cooperation. First, WIPO agrees to make available to WTO Members, WTO Member nationals, the WTO Secretariat and the Council laws and regulations contained in the WIPO database and to provide to the same parties access to computerized databases of the International Bureau containing laws and regulations. Second, both organizations agree on the procedures regarding the implementation of Article 6*ter* of the Paris Convention for the purposes of TRIPS. This concerns the communication from WTO Members to the International Bureau of state emblems that shall not be used as trademarks.¹⁰³ Third, and most importantly for developing country and LDC Members that are Members of the WTO or of WIPO but not of both, the organizations agree to make available to these countries the legal-technical assistance/technical cooperation relating to TRIPS that Members are entitled to even if it is the other organization that they belong to. Likewise, the organizations agree to enhance cooperation in their technical assistance activities with a view to maximizing the usefulness of those activities.

Apart from the functions expressly provided for in Article 68, the Council is equally entrusted with other tasks that are referred to in other TRIPS provisions:¹⁰⁴

- Various exceptions provided for in different parts of the TRIPS Agreement have to be notified to the Council, in particular the ones in Articles 1.3, 3.1, 4(d), and 63.2.¹⁰⁵

¹⁰² The text of this agreement is available at <http://www.wto.org/english/tratop_e/trips_e/wtowip_e.htm>.

¹⁰³ Article 6*ter* of the Paris Convention prohibits, *inter alia*, the registration of trademarks consisting of, or incorporating, state emblems.

¹⁰⁴ For more detailed information on these provisions, see the respective chapters in this book.

¹⁰⁵ Detailed technical information on the notification procedures can be found in the Technical Cooperation Handbook on Notification Requirements, WTO document WT/TC/NOTIF/TRIPS/1, which is available in the documents online section of the WTO Website (<<http://www.wto.org>>).

- Under Article 23.4, the Council shall undertake negotiations concerning the establishment of a multilateral system of notification and registration of geographical indications for wines and spirits.¹⁰⁶
- Under Article 24.2, the Council is given the authority to review the application of the provisions on geographical indications.
- Under Article 63.2, the Council shall receive notifications from WTO Members concerning their TRIPS-related legislation.
- Article 66.1 authorizes the Council to accord, upon motivated request by an LDC Member, an extension of the transition period after the expiry of which the TRIPS disciplines become fully binding on LDC Members.
- Under Article 71, the Council is charged with the review of the implementation of the TRIPS Agreement at two-year-intervals.

3.2 The Council in actual practice

3.2.1 The meetings

According to Article IV:5 of the WTO Agreement, the Council “shall meet as necessary” to carry out its functions. The Council has followed this suggestion in practice. The number of meetings is decided upon by the Chairman in consultation with Members and is based on the workload that is expected in the year which lies ahead. In other words, the TRIPS Council meets as appropriate. Four to five formal meetings have been the norm in the recent past. The main purpose of these meetings is to monitor the operation of TRIPS. In addition, the Council for TRIPS also meets in “special sessions” for the negotiations on a multilateral system for the registration and the notification of geographical indications for wines and spirits under Article 23.4 (see above).

3.2.2 The decision-making process

In accordance with Article IV:5 of the WTO Agreement, the Council has established its own rules of procedures, which have been approved by the General Council. The rules of procedure for the Council are essentially the same as for the General Council, with adjustments.

As in other WTO bodies, the decisions in the Council are always taken by consensus. In case of no agreement, the Council will refer the matter to the General Council, which will then take the decision. This means that when decisions are adopted by the Council, no Member present at the meeting should formally object. In theory, this means that any country not agreeing to a proposed decision has the right to block it. In practice, of course, there would be a need to justify such a position and the country doing so can be expected to come under pressure from other Members wanting to move forward. Negotiations in the WTO

See also the WTO's IP gateway page at <<http://www.wto.org/english/tratop.e/trips.e/trips.e.htm>> (“Notifications under the TRIPS Agreement”).

¹⁰⁶ Note that according to para. 18 of the Doha Ministerial Declaration (WTO document WT/MIN(01)/DEC/1 of 20 November 2001), Members agreed to negotiate such multilateral system “by the Fifth Session of the Ministerial Conference”. However, by the time of the fifth Ministerial Conference, which took place from 10–14 September 2003 in Cancun, Mexico, no agreement was reached on the multilateral register (for details, see Chapter 15).

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follow the same pattern in the various bodies. When a delegation raises an issue it considers important, it usually convenes an informal meeting (which could be outside the ambit of the TRIPS Council) among what it believes are like-minded delegations who are likely to support the issue. Once a certain critical mass is reached, the delegation could approach the Chairperson and request the matter be included on the agenda of the next formal TRIPS Council meeting. If the issue is straightforward, the Chairperson might do so without further consultations. On the other hand, if the issue is likely to be a contentious one, then the Chairperson is likely to call what are known as small group informal meetings to seek an agreed compromise.

3.2.3 The compliance review

The Council in actual practice has devoted a lot of time to this task. Those notifications that Members are obliged to make to the Council according to Article 63.2 constitute the basis for reviews of the implementing legislation.¹⁰⁷ Obviously, the precondition of this exercise is that a Member's obligation to implement the TRIPS Agreement has already commenced.¹⁰⁸ Thus, the Council one year after the entry into force of the Agreement started the review of the legislation of the developed countries whose transitional period ended on 1 January 1996. This exercise has now been completed. At present, the TRIPS Council is involved in reviewing the national legislation of the vast majority of developing countries.¹⁰⁹ Concerning LDC Members, the review has not yet begun, taking into account the fact that their obligations to implement the Agreement are yet to be activated (in general, as of 1 January 2006, see Article 66.1).

As far as the review exercise itself is concerned, it is carried out as follows. The Member notifies the laws and regulations, preferably in full but if not, even in part.¹¹⁰ Then, an opportunity is given to other interested WTO Members to ask questions in writing; after that the concerned WTO Member whose legislation is being reviewed answers in writing, preferably ahead of the meeting of the Council. Often, there are further questions on the answers provided by the Member and these would have to be answered at a subsequent meeting of the Council. In order for the answers to be of satisfying substance, the Member whose legislation is being reviewed should bring in its experts and officials from its capital.

It may be observed that the time period and deadlines provided for the questions and answers are quite flexible. This is the reason why the reviews could spread over two or more meetings lasting from six to nine months. Another reason for the length of this procedure is the fact that some developing countries and LDC Members do not have the resources to bring all the experts they have for all the meetings.

¹⁰⁷ Article 63.2 states in relevant part: "Members shall notify the laws and regulations referred to in paragraph 1 to the Council for TRIPS in order to assist that Council in its review of the operation of this Agreement. [...]" See in detail under Chapter 31.

¹⁰⁸ See the transition periods as laid down in Articles 65 and 66. For more details, see Chapter 33.

¹⁰⁹ For a list of those countries whose legislation is currently under review, see the WTO's IP gateway page at <<http://www.wto.org/english/tratop.e/trips.e/trips.e.htm>> ("Review of members' implementing legislation").

¹¹⁰ This was designed to motivate Members to notify relevant legislation even if the latter has only been partly elaborated.

Finally, it should be stressed that the review exercise is without prejudice to the rights and obligations of the WTO Member whose legislation is being reviewed. Such Member remains free to maintain the relevant legislation, even if another Member expresses doubts about the WTO compatibility of these provisions. The only way of possibly forcing a Member to modify its domestic laws is through the remedies available under the DSU (in particular, the suspension of concessions). But this may only be authorized after the adoption of a panel or Appellate Body dispute settlement report. This procedure is entirely independent of the review exercise in the Council for TRIPS. The opinion expressed by a WTO Member in the context of this review about another Member's domestic law does not anticipate the conclusion of a relevant examination conducted by a panel or the Appellate Body.

4. WTO jurisprudence

Article 68 does not contain any substantive obligations and thus far has not been the specific object of a dispute before the WTO. However, panels or the Appellate Body, while reviewing the TRIPS-compliance of a Member's legislation, might draw on the comments provided by Members during the review procedure before the Council.

5. Relationship with other international instruments

5.1 WTO Agreements

The Council has specifically been set up for the purpose of monitoring the operation of TRIPS. There is no other WTO organ that could take over this function, except for the General Council in the specific case when a decision needs to be taken and the Members of the Council have not been in a position of reaching such decision.

When compared, for example, to the GATS Council, it can be noted that the powers conferred to the Council for TRIPS are considerably greater. Contrary to Article 68, Article XXIV GATS does not authorize the GATS Council to monitor Members' compliance with their GATS obligations. This difference in the attribution of powers is due to the fact that under TRIPS there are common (minimum) standards that have to be respected by every Member. The extent of GATS obligations, by contrast, depends on each Member's schedule of specific commitments and thus varies from Member to Member. From a practical point of view, a monitoring of such commitments appears much more complicated than the review of the common standards under TRIPS.

5.2 Other international instruments

6. New Developments

6.1 National laws

6.2 International instruments

The Chairperson's Statement accompanying the 2003 General Council Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement

7. Comments, including economic and social implications

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and Public Health contained several references to the work and competencies of the Council for TRIPS:

“[...] Third, it is important that Members seek to resolve any issues arising from the use and implementation of the Decision expeditiously and amicably:

- To promote transparency and avoid controversy, notifications under paragraph 2(a)(ii) of the Decision would include information on how the Member in question had established, in accordance with the Annex, that it has insufficient or no manufacturing capacities in the pharmaceutical sector.
- In accordance with the normal practice of the TRIPS Council, notifications made under the system shall be brought to the attention of its next meeting.
- Any Member may bring any matter related to the interpretation or implementation of the Decision, including issues related to diversion, to the TRIPS Council for expeditious review, with a view to taking appropriate action.
- If any Member has concerns that the terms of the Decision have not been fully complied with, the Member may also utilise the good offices of the Director General or Chair of the TRIPS Council, with a view to finding a mutually acceptable solution.

Fourth, all information gathered on the implementation of the Decision shall be brought to the attention of the TRIPS Council in its annual review as set out in paragraph 8 of the Decision.

[...]”¹¹¹

6.3 Regional and bilateral contexts

6.4 Proposals for review

There are no proposals to modify the functions of the Council.

7. Comments, including economic and social implications

For delegates from developing and least-developed countries, formal and informal participation in Council meetings presents an opportunity to better familiarize themselves with the review exercise. Thus, when their turn comes, they will be able to cooperate more efficiently with the Council and its Members. In this context, it should be stressed again that the review of national IP laws does not constitute a pre-stage of dispute settlement proceedings (see above, under Section 3). To the contrary, this exercise should be understood as a means of avoiding recourse to the DSU through cooperation and dialogue between Members. With respect to the review exercise the written records of those reviews provide for a source of highly valuable information.¹¹²

The issue of the proper participation of developing countries in a highly technical body such as the Council for TRIPS deserves further consideration. It is

¹¹¹ Reproduced in the minutes of the General Council, WT/GC/M/82.

¹¹² The records of the introductory statements made by delegations, the questions put to them and the responses given are made public, six months after their circulation, in the WTO on-line database (at <<http://www.wto.org>>). In this context, see also the WTO's IP gateway page at <http://www.wto.org/english/tratop_e/trips_e/trips_e.htm> (“Review of members’ implementing legislation”).

not always the case that the Council is attended by experts on TRIPS matters but by trade diplomats that normally cover a wide variety of subjects. This is not the case of developed countries that participate, in general, with technical support from capitals. This issue deserves the attention of not just policy-decision makers in developing and least-developed countries, but also of international organizations and NGOs. In order to improve the situation, the first step to be taken is to create awareness among the aforementioned institutions of the importance of informed and efficient participation of developing and least-developed countries in the Council deliberations. It should be noted, however, that in recent years a number of activities are being organized back to back to the Council's meetings to precisely support developing countries' proper participation in those discussions.

36: Transitional Provisions

Article 70 Protection of Existing Subject Matter

1. This Agreement does not give rise to obligations in respect of acts which occurred before the date of application of the Agreement for the Member in question.
2. Except as otherwise provided for in this Agreement, this Agreement gives rise to obligations in respect of all subject matter existing at the date of application of this Agreement for the Member in question, and which is protected in that Member on the said date, or which meets or comes subsequently to meet the criteria for protection under the terms of this Agreement. In respect of this paragraph and paragraphs 3 and 4, copyright obligations with respect to existing works shall be solely determined under Article 18 of the Berne Convention (1971), and obligations with respect to the rights of producers of phonograms and performers in existing phonograms shall be determined solely under Article 18 of the Berne Convention (1971) as made applicable under paragraph 6 of Article 14 of this Agreement.
3. There shall be no obligation to restore protection to subject matter which on the date of application of this Agreement for the Member in question has fallen into the public domain.
4. In respect of any acts in respect of specific objects embodying protected subject matter which become infringing under the terms of legislation in conformity with this Agreement, and which were commenced, or in respect of which a significant investment was made, before the date of acceptance of the WTO Agreement by that Member, any Member may provide for a limitation of the remedies available to the right holder as to the continued performance of such acts after the date of application of this Agreement for that Member. In such cases the Member shall, however, at least provide for the payment of equitable remuneration.
5. A Member is not obliged to apply the provisions of Article 11 and of paragraph 4 of Article 14 with respect to originals or copies purchased prior to the date of application of this Agreement for that Member.
6. Members shall not be required to apply Article 31, or the requirement in paragraph 1 of Article 27 that patent rights shall be enjoyable without discrimination

as to the field of technology, to use without the authorization of the right holder where authorization for such use was granted by the government before the date this Agreement became known.

7. In the case of intellectual property rights for which protection is conditional upon registration, applications for protection which are pending on the date of application of this Agreement for the Member in question shall be permitted to be amended to claim any enhanced protection provided under the provisions of this Agreement. Such amendments shall not include new matter.

8. Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:

(a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;

(b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and

(c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).

9. Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member.

1. Introduction: terminology, definition and scope

TRIPS significantly alters the rights and obligations of states regarding the treatment of intellectual property. One major issue in determining the extent of change was how the new agreement would affect subject matter existing when it entered into force, or that would come into being during relevant transition periods. Because TRIPS has been in force since 1995, it might appear that most of the questions likely to arise in connection with the protection of existing subject matter have already been asked and answered. However, since the duration of some forms of protection is lengthy, and since some transition arrangements have not expired (and some have been extended), it is important to address the implications of Article 70.

2. History of the provision

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Because TRIPS negotiations were promoted by developed country parties to GATT 1947 that were seeking to oblige other parties to the new WTO to enhance protection of IP, it would logically follow that *demandeur* countries would seek to maximize the extent to which existing subject matter came under the protective umbrella of the new TRIPS Agreement. By the same logic, developing countries would seek to preserve the *status quo ante* with respect to existing subject matter. The greater the extent of existing subject matter that came under the new regime, the higher would be the static rent payments flowing to the preponderant new IP holders.

2. History of the provision

2.1 Situation pre-TRIPS

Article 70 concerns the protection of IP subject matter existing when TRIPS entered into force, or that will come into being during transition periods. Its provisions are therefore unique to the agreement, and the product of particularized negotiation. This does not mean that prior treaties addressing IP failed to include provisions regarding pre-existing subject matter. They typically did. So, for example, the Berne Convention provides:

“Article 18:

[*Works Existing on Convention's Entry Into Force*: 1. Protectable where protection not yet expired in country of origin; 2. Non-protectable where protection already expired in country where it is claimed; 3. Application of these principles; 4. Special cases]

(1) This Convention shall apply to all works which, at the moment of its coming into force, have not yet fallen into the public domain in the country of origin through the expiry of the term of protection.

(2) If, however, through the expiry of the term of protection which was previously granted, a work has fallen into the public domain of the country where protection is claimed, that work shall not be protected anew.

(3) The application of this principle shall be subject to any provisions contained in special conventions to that effect existing or to be concluded between countries of the Union. In the absence of such provisions, the respective countries shall determine, each in so far as it is concerned, the conditions of application of this principle.

(4) The preceding provisions shall also apply in the case of new accessions to the Union and to cases in which protection is extended by the application of Article 7 or by the abandonment of reservations.”

The Berne Convention formula requires state parties to extend protection to works that are not in the public domain in the “country of origin” (a term of art in the Convention) through “expiration of the term of protection” when the Convention enters into force. Berne countries may, however, exclude protection for the same works to the extent they are in the public domain within their territory, also by virtue of expiration of the term of protection. Note these provisions apply to new accessions. So, for example, when the United States acceded to the Berne

Convention in 1989, it was required to grant copyright protection to foreign works whose copyright term had not expired in their countries of origin, unless those works had previously been protected by copyright in the United States (and had lost protection by expiration of the copyright term).

The Paris Convention makes limited reference to the protection of existing subject matter. This is not surprising considering that the Convention does not define the subject matter of protection for patents and trademarks. Article 4*bis* provides with regard to its rule of independence of patents that:

“(3) The provision shall apply to all patents existing at the time when it comes into effect.

(4) Similarly, it shall apply, in the case of the accession of new countries, to patents in existence on either side at the time of accession.”

A panel and the WTO Appellate Body have interpreted Article 70 as it relates to pre-existing patents.¹¹³ There is no discussion in those reports of the Paris Convention treatment of pre-existing subject matter.¹¹⁴

2.2 Negotiating history

2.2.1 The Anell Draft

The Anell Draft included the following on the subject of existing subject matter (“A” developed and “B” developing country proposals):¹¹⁵

“SECTION 1: COPYRIGHT AND RELATED RIGHTS

9. Protection of Works Existing at Time of Entry into Force

9A A PARTY shall provide protection, consistent with this agreement, for all works not yet in the public domain in its territory at the time of entry into force of this agreement. In addition, a PARTY that has afforded no effective copyright protection to works or any class of works of other PARTIES prior to its entry into force in its territory shall provide protection, consistent with this agreement, for all works of other PARTIES that are not in the public domain in their country of origin at the time of entry into force of this agreement in its territory.

SECTION 5: PATENTS

7. Transitional Protection

7A.1 PARTIES shall provide transitional protection for products embodying subject matter deemed to be unpatentable under its patent law prior to its acceptance of this Agreement, where the following conditions are satisfied:

(a) the subject matter to which the product relates will become patentable after acceptance of this Agreement;

(b) a patent has been issued for the product by another PARTY prior to the entry into force of this Agreement; and

¹¹³ See Section 4, below.

¹¹⁴ There is a reference in the Appellate Body report to the terms of the Paris Convention, but in another context. *Canada, Term of Patent Protection*, Report of the Appellate Body, AB-2000-7 WT/DS170/AB/R, 18 Sept. 2000, at para. 40.

¹¹⁵ MTN.GNG/NG11/W/76, 23 July 1990.

2. History of the provision

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the product has not been marketed in the territory of the PARTY providing such transitional protection.

7A.2 The owner of a patent for a product satisfying the conditions set forth above shall have the right to submit a copy of the patent to the PARTY providing transitional protection. Such PARTY shall limit the right to make, use, or sell the product in its territory to such owner for a term to expire with that of the patent submitted.”

The developed country “A” proposal regarding copyright would have effectively required each Member to extend copyright protection consistent with the agreement for all works already under protection within their territory (that is, works not yet in the public domain). This is similar to the result achieved in Article 70.2 through incorporation of Article 18 of the Berne Convention, although it lacks explicit reference to expiration of the copyright term. The proposal would have required that countries which had not provided effective copyright protection to foreign works provide such protection “consistent with this agreement” for works that were not in the public domain in their country of origin.¹¹⁶

The developed country “A” proposal regarding patent is directed to providing protection to subject matter previously unpatentable based on existing patents in other Members. This is a form of so-called “pipeline protection” under which a country that has not provided patent protection undertakes to give effect to patents and/or patent applications from another country(s), notwithstanding circumstances that might otherwise have precluded late-patenting within the former country’s territory. This is a substantially more ambitious proposal from the developed country side than was ultimately adopted because it would effectively have required all Members to extend protection to existing patents granted in other Members (with some limitation). Article 70 as adopted did not require Members to grant patents based on those previously granted in other Members. Its effect is prospective.

2.2.2 The Brussels Draft

The Brussels Ministerial Text of December 1990 provided:¹¹⁷

“Article 15: Protection of Works Existing at Time of Entry into Force

The provisions of the Berne Convention (1971) concerning the protection of works existing at the time of entry into force shall apply in respect of the rights secured under that Convention.

Article 16: Protection of Performers, Producers of Phonograms (Sound Recordings) and Broadcasts

Any PARTY to this Agreement may, in relation to the rights conferred under paragraphs 1–3 above, provide for conditions, limitations, exceptions and reservations

¹¹⁶ Article 7(8) of the Berne Convention provides that regarding the term of copyright where protection is claimed, “unless the legislation of that country otherwise provides, the term shall not exceed the term fixed in the country of origin of the work.” It is not clear whether the proposal in the Anell text was intended to modify this rule.

¹¹⁷ MTN.TNC/W/35/Rev.1, 3 Dec. 1990.

to the extent permitted by the Rome Convention. However, the provisions of Article 15 of this Section shall also apply *mutatis mutandis* to the rights of performers and producers of phonograms in phonograms.

Article 73: Protection of Existing Intellectual Property

1. PARTIES shall apply the provisions of Articles 3, 4 and 5 of Part I, of Sections 2, 3, 7 and 8 of Part II, of Part III and of Part IV to subject matter under protection in a PARTY on the date of application of the provisions of this Agreement for that PARTY as defined in Part VI above.
2. PARTIES are not obliged to apply the provisions of Sections 1, 4, 5 and 6 of Part II to subject matter under protection in a PARTY on the date of application of the provisions of this Agreement for that PARTY, subject to the provisions of Articles 15 and 16.6. Subject matter in respect of which the procedures for the acquisition of rights have been initiated as of that date for which, however, the intellectual property title has not yet been granted shall not benefit from the provisions of this Agreement. Nothing in this Agreement shall affect other subject matter covered by these Sections which is already in existence and not under protection in a PARTY on the date of application of the provisions of this Agreement for that PARTY, subject to the provisions of Articles 15 and 16.6.
3. The application of Articles 2 and 6 of this Agreement to existing intellectual property shall be governed by paragraphs 1 and 2 of this Article, as appropriate to the intellectual property right in question."

In respect to copyright, the Brussels Text began to approximate the final Article 70 text by shifting focus for protection of traditional copyright subject matter to the Berne Convention. Since the Berne Convention does not cover producers of phonograms and performers, it was necessary to address this subject matter separately, although by cross reference to Berne. Article 73.1 of the Brussels Text would have extended protection to existing subject matter in the areas of trademark, geographical indications, undisclosed information and competition law, while Article 73.2 would have exempted layout-designs of integrated circuit, industrial designs and patents. Article 73.3 would have subjected rules on application of other IP treaties and exhaustion to the provisions of Article 73.1-2. With respect to the sensitive subject of patents, negotiators had not yet agreed in Article 68 of the Brussels Text on a general approach to the implementation of patent protection, and this accounts for the absence of special treatment such as later appears in Article 70.8-9 of TRIPS for pharmaceutical and agricultural chemical products. The commentary by the Chair of the TRIPS Negotiating Group to the Brussels Ministerial reflects that transition arrangements remained a major point of contention.

Article 73 of the Brussels Text was largely abandoned in favour of a new Article 70 appearing in the Dunkel Draft. There are no material differences between the Dunkel Draft text and the final TRIPS text, with the exception of subparagraph 9, which adds the phrase "notwithstanding the provisions of Part VI". Part VI addresses "Transitional Arrangements", and appears directed to clarifying that exclusive marketing rights (EMRs) are to be granted in respect of mailbox applications (and when relevant criteria are met) notwithstanding the absence of an obligation to provide patent protection as to relevant subject matter. By broadly

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referring to Part VI, the clarification appears to extend to least developed Members enjoying a transitional exemption. Note, however, that least developed countries were granted a waiver as to compliance with Article 70.9 EMR rules by action taken pursuant to Paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health (discussed below).

3. Possible interpretations

3.1 Article 70.1

1. This Agreement does not give rise to obligations in respect of acts which occurred before the date of application of the Agreement for the Member in question.

“obligations”

Article 70.1 provides that the Agreement does not give rise to *obligations* [emphasis added] with respect to certain acts. This raises the threshold question of what parties might have obligations under the agreement. From a dispute settlement standpoint, only Members are the subject of disputes, so it may appear that only Members have obligations. Yet TRIPS is unique among WTO agreements in stating that IPRs are private rights. If TRIPS at least indirectly creates private rights, it might also indirectly create “private obligations”. This suggests at least two possible interpretations of “obligations” in Article 70.1. A first interpretation is that Members as government entities are not liable for acts which they may have taken before TRIPS became applicable to them. A second interpretation is that private parties within Members are not liable for acts they may have undertaken before TRIPS became applicable within the subject territory.

This threshold question of interpretation is important because it may affect the extent to which Members are (or were) required to provide remedies with respect to conduct that occurred before the agreement became applicable. If Article 70.1 only addresses the obligations of Members, it might not address the question whether conduct by private parties taking place before application of the agreement should be subject to potential liability. If Article 70.1 is more broadly interpreted to encompass both public and private obligations, then remedies for conduct preceding TRIPS need not be provided. The latter view appears to be more consistent with the “private rights” character of the agreement. That is, TRIPS did not directly or indirectly establish private obligations predating its application in a Member.

“acts”

The term “act” is defined as a noun by the New Shorter Oxford English Dictionary as “a thing done; a deed”. In its common meaning, Article 70.1 excludes from obligation things that were done by a party prior to application of the agreement.

In the *Canada – Patent Term* case, Canada argued that the term “act” extended to the granting of a patent prior to the application of TRIPS. Canada argued that when Article 33 extended the term of patents to 20 years from the date of grant, this did not affect Canada’s “act” of granting a patent prior to TRIPS, and did not oblige Canada to extend the term of patents previously granted.

The Appellate Body disagreed, finding that the term “acts” referred to things that had already been completed or ended. It said that if “acts” were interpreted to apply to the continuing results of “acts” (that is, rights that had been created by “acts”), this would effectively negate the extension by Article 70.2 of protection to subject matter existing when TRIPS became applicable.

“date of application of the Agreement”

Article 65.1 draws a distinction between the date of application of TRIPS for a Member and the date of entry into force of the Agreement. Various transition periods establish different dates of application.¹¹⁸ Article 70.1 is most logically interpreted not to impose obligations prior to the date of application of relevant provisions for a Member. Otherwise, a Member would incur responsibility for acts occurring during a transition period, and this would be contrary to the spirit of affording such transition periods.

On the whole, Article 70.1 appears most reasonably interpreted to exclude a Member from obligation (that is, from taking steps to provide a remedy) for acts by that Member or by private parties taking place within its territory prior to the date of application of the relevant TRIPS provisions in that Member.

3.2 Article 70.2

2. Except as otherwise provided for in this Agreement, this Agreement gives rise to obligations in respect of all subject matter existing at the date of application of this Agreement for the Member in question, and which is protected in that Member on the said date, or which meets or comes subsequently to meet the criteria for protection under the terms of this Agreement. In respect of this paragraph and paragraphs 3 and 4, copyright obligations with respect to existing works shall be solely determined under Article 18 of the Berne Convention (1971), and obligations with respect to the rights of producers of phonograms and performers in existing phonograms shall be determined solely under Article 18 of the Berne Convention (1971) as made applicable under paragraph 6 of Article 14 of this Agreement.

The introductory clause indicates that the general rule stated in Article 70.2 may be varied by other terms of TRIPS. This may, of course, give rise to the interpretive question of whether a particular other provision is intended to vary the general rule, but it is difficult to approach this question in the abstract, that is, without identifying a particular provision.

¹¹⁸ For more details on the TRIPS transitional periods, see Chapter 33.

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“all subject matter existing”

As TRIPS is concerned with “intellectual property”, it is reasonable to assume that the “subject matter” referenced by this second clause is intangible subject matter protectable by intellectual property. Thus, an invention meeting applicable patentability criteria would be subject to the grant of a patent, following appropriate review of an application, from the date the relevant patent provisions of TRIPS become applicable in the Member in question. However, this rule must be understood in the context of the criteria for IPR protection. For example, an invention that has been disclosed to the public and therefore is no longer novel¹¹⁹ is not patentable subject matter in the sense of meeting the criteria for patentability recognized by Article 27.1. So TRIPS does not retroactively protect subject matter that may have been protectable at some stage but was no longer protectable IPR subject matter when the TRIPS provisions became applicable. (Article 70.8 addresses the situation of subject matter that might otherwise have become non-patentable as a result of the operation of the patent transition period and mailbox rules.)

“and which is protected in that Member on the said date,”

The third clause indicates that if subject matter is already protected in a Member when TRIPS provisions take effect, then the rules of TRIPS apply to that subject matter. Of course, the application of these new rules may have significant consequences. And, this was the issue raised by Canada in its challenge to application of Article 33 (20-year patent term) to previously granted patents. Canada argued that the intent of Article 70.2 was not to extend previously granted rights, but only to cause them to be recognized. The Appellate Body disagreed, saying that the intent of Article 70.2 was to apply new rules to existing patented subject matter, thereby effectively extending the term of patents in many cases.

“or which meets or comes subsequently to meet the criteria for protection under the terms of this Agreement.”

The fourth clause provides that when subject matter existing in a Member becomes eligible for protection, that subject matter will be accorded the benefits of TRIPS Agreement rules. So, for example, an invention reduced to practice following the date TRIPS provisions become applicable will be subject to patent rules that are TRIPS-consistent.

“In respect of this paragraph and paragraphs 3 and 4, copyright obligations with respect to existing works shall be solely determined under Article 18 of the Berne Convention (1971), and obligations with respect to the rights of producers of phonograms and performers in existing phonograms shall be determined solely under Article 18 of the Berne Convention (1971) as made applicable under paragraph 6 of Article 14 of this Agreement.”

¹¹⁹ Subject to certain exceptions, such as the one-year grace period in the United States.

Article 70.3 refers to subject matter that has already fallen into the public domain. Article 70.4 refers to the limitation of remedies regarding pre-existing situations that become infringing. These paragraphs, as well as Article 70.2, are governed by Article 18 of the Berne Convention with respect to copyright subject matter, including the rights of phonogram producers and performers “in existing phonograms”.

Article 18.1 of the Berne Convention provides that works that have not entered the public domain in the country of origin through the expiry of the term of protection will become protectable at the moment the Convention enters into force. There is a proviso in Article 18.2 that a country in which a copyright on the subject matter has already expired does not need to restore protection. Article 18.3 subjects the general principle to special conventions on this subject that might be concluded by the Berne Union, and further provides: “In the absence of such provisions, the respective countries shall determine, each in so far as it is concerned, the conditions of application of this principle.” Article 18.4 subjects new adherents to the Convention to these rules. It should be noted that Article 7.8 of the Berne Convention limits the duration of copyright term to that prescribed in the country of origin, unless a country has otherwise provided.

The foregoing provisions were the subject of a dispute between the United States (and later the European Community) on one side, and Japan on the other.¹²⁰ The United States asserted that Japan was obliged to provide protection to sound recordings made in the United States before 1972 that were in the public domain in the United States not as a result of expiration of the term of copyright, but because of an absence of copyright protection. U.S. federal copyright protection for sound recordings was initiated only in 1972. Japan had initiated protection for sound recordings as of 1971. The USA argued that Japan was obliged to provide a minimum 50-year term for sound recordings of U.S. origin from 1946 since those recordings were not in the public domain as a result of expiration of the copyright term, even though U.S. legislation only granted protection for the same recordings from 1972. (The term of protection would commence from the fixation of the work in the United States.)

Japan argued that Article 18.3 of the Berne Convention allowed it flexibility with respect to the manner in which it implemented Articles 18.1 and 18.2. It argued that granting protection for works back to 1971 was a good faith application of the retroactivity rule. It seemed anomalous that the result of applying Article 18 of the Berne Convention would be that Japan would grant copyright protection to U.S. sound recordings more extensive than that provided by the United States. Yet, Japan agreed to adopt the measures proposed by the United States, and the complaints against Japan were withdrawn.¹²¹

¹²⁰ *Japan-Measures Concerning Sound Recordings*, Request for Consultations by the United States, WT/DS28/1, 14 Feb. 1996; *Japan-Measures Concerning Sound Recordings*, Request for Consultations from the European Communities, WT/DS42/1, 28 Feb. 1996. See Stephen Obenski, *Retroactive Protection and shame Diplomacy in the US-Japan Sound Recordings Dispute, or, How Japan Got Berne-d*, 4 Minn. Intell. Prop. Rev. 183 (2002).

¹²¹ See notifications of mutually agreed solutions, WT/DS28/41, 24 Jan. 1997; WT/DS42/4 (17 Nov. 1997).

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3.3 Article 70.3

3. There shall be no obligation to restore protection to subject matter which on the date of application of this Agreement for the Member in question has fallen into the public domain.

When an intangible is in the public domain, this means that it is the common property of the people, with the consequence that it may not be appropriated to the exclusive control of any person or people. Typically, intellectual property that has lost its legal effect in the sense of conferring a right to exclude others from use, commonly at the end of the term of protection, falls into the public domain. Generally speaking, once an intangible has fallen into the public domain, it remains open to use by any person. However, as noted in respect to Japan's decision to retroactively provide copyright protection to sound recordings that were already in the public domain, it is possible that intangibles within the public domain may be restored to private ownership.

Intangibles do not enter the public domain only as a consequence of the expiration of a term of IPR protection. For intangibles to qualify as "intellectual property" they must meet the criteria of protection. If they do not, they do not benefit from exclusive rights as intellectual property and may be part of the public domain.¹²² Also, IPRs may be lost other than through the expiration of the term of protection. For example, trademark holders may lose their exclusive rights through non-use of the mark, and the sign that constituted the mark may fall into the public domain.

Article 70.3 uses the term "restore", which means to return something to a position it previously held. This implies that the option not to provide IPR protection to otherwise qualifying subject matter applies only to subject matter which at some point *was* protected as intellectual property, but for some reason lost that protection.¹²³

It is important to note that Article 70.2 and Article 18 of the Berne Convention draw an express distinction between subject matter that has fallen into the public domain as a consequence of the expiration of a term of protection, and subject matter that has fallen into the public domain for other reasons. This clearly implies that, outside the specific context of copyright protection covered in Article 70.2, the Article 70.3 option *not* to provide protection for subject matter that has fallen into the public domain applies equally to subject matter which fell into the public domain for reasons other than expiration of a term of protection (as well as by reason of expiration of a term of protection).

It is also important to note that Article 70.3 provides Members with the option to not restore protection. It is not mandatory, and Members may decide to grant

¹²² Whether an intangible that is not "intellectual property" may also fall outside the public domain is an important theoretical question that cannot be adequately addressed here. Consider, for example, the situation of databases that are not "intellectual property" in the generally accepted sense, but may be protected by *sui generis* rights in data (e.g., in the European Union). Is the data in the database in the public domain?

¹²³ This interpretation is consistent with Article 70.2 which says that subject matter qualifying for protection on the date of application of TRIPS provisions shall be protected.

protection to subject matter that fell into the public domain for whatever reason. This is not to suggest that such a decision would be good public policy.

3.4 Article 70.4

4. In respect of any acts in respect of specific objects embodying protected subject matter which become infringing under the terms of legislation in conformity with this Agreement, and which were commenced, or in respect of which a significant investment was made, before the date of acceptance of the WTO Agreement by that Member, any Member may provide for a limitation of the remedies available to the right holder as to the continued performance of such acts after the date of application of this Agreement for that Member. In such cases the Member shall, however, at least provide for the payment of equitable remuneration.

Article 70.4 uses the “date of acceptance of the WTO Agreement by that Member” as the point at which the exceptional treatment it provides may be based. For original Members of the WTO, this date is 1 January 1995.¹²⁴ For later acceding Members it will differ.

Article 70.4 effectively allows for the establishment of a “prior user’s right” as to all forms of IPRs protected by the Agreement. In other words, if a third party was making use of subject matter prior to its becoming subject to protection (per the terms of Article 70.2), the law of a Member does not need to allow the new IPR holder to exclude the third party user from the market. However, it must provide for the payment of “equitable remuneration”. TRIPS does not define “equitable remuneration”. The term is used in Article 14.4 with respect to phonogram rentals. The term differs from that used in connection with Article 31(h) (compulsory licensing) providing for “adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization”.

To benefit from an exception, the third party user should have “commenced” otherwise infringing acts regarding the specific object of protection, or made a significant investment regarding the specific object of protection, before the date the WTO Agreement was accepted. The date of commencement of IPR-contravening acts may not be so easily determined because this requires a clear delimitation of the scope of an IPR, as well as an evidentiary determination regarding the date of an occurrence. There is interpretive flexibility in the term “made a significant investment”, *inter alia*, because what is “significant” will vary in relation to the financial situation of the investor, the country that investor is investing in, and the industry in which the investment is being undertaken. In sum, rule makers and enforcement authorities have some discretion in developing and applying the Article 70.4 prior user’s right rule.

¹²⁴ Although an argument could be made that a Member “accepted” the WTO Agreement on the date it conveyed its acceptance to the WTO Director General, and not the date of entry into force for the Member, it seems unlikely that negotiators intended to draw such a fine distinction. Instead, this appears as discussed above as a means to distinguish between Members accepting the WTO Agreement as original Members, and Members that subsequently acceded to the WTO.

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3.5 Article 70.5

5. A Member is not obliged to apply the provisions of Article 11 and of paragraph 4 of Article 14 with respect to originals or copies purchased prior to the date of application of this Agreement for that Member.

Article 11 establishes rental rights with respect to computer programs and cinematographic works (i.e., videos). Paragraph 4 of Article 14 extends equivalent rights to producers of and other right holders in phonograms. The qualifications and conditions associated with these rights are discussed in Chapters 10 and 13 of this book.

Article 70.5 provides Members with the option not to provide rental rights as against those who purchased the subject works prior to the date of application of this Agreement for that Member. Recall from discussion of Article 70.1 that the date of application refers to the date when the provisions regarding the subject matter became effective, and are subject to the transition provisions of the Agreement.

A Member that decides not to grant rental rights regarding purchasers of originals or copies is effectively providing that the copyright holder's right is exhausted at the point of first sale. The former holder does not have the right to control the buyer's decision to rent out the object of the purchase. Articles 11 and paragraph 4 of Article 14 are qualified in the extent to which they require the grant of rental rights. There are other circumstances in which Members may provide for the exhaustion of rights in computer programs, videos and phonograms (i.e., without providing a rental right).

A copyrighted work may be an original, or it may be a copy or reproduction of the original. Article 70.5 does not distinguish between authorized and unauthorized copies. If a work was protected by copyright prior to application of TRIPS, and a copy was made without the consent of the copyright holder, that copying would have violated local law. Generally, the sale of a counterfeit copy would not exhaust the copyright holder's right in the work. If, however, the object was not protected by copyright, then the initial sale would not have been unlawful. Thus, the absence of reference to authorization with respect to copying does not appear to affect the rights of the holder of a copy.¹²⁵

3.6 Article 70.6

6. Members shall not be required to apply Article 31, or the requirement in paragraph 1 of Article 27 that patent rights shall be enjoyable without discrimination as to the field of technology, to use without the authorization of the right holder where authorization for such use was granted by the government before the date this Agreement became known.

¹²⁵ Except perhaps in cases of good faith purchasers in due course without notice.

Article 70.6 adds yet another effective date, “the date this Agreement became known.” It is perhaps fair to attribute knowledge of TRIPS to any Member that was part of the Uruguay Round negotiations. Yet a Member could not have known of the Agreement in the sense of security as to its terms until the signing of the WTO Agreement by Ministers in Marrakesh on 15 April 1994. While an argument might be made in favour of relating the date of knowledge back to the approval of the texts (the Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations) on 15 December 1993,¹²⁶ at that stage the agreements still required the approval of the Ministers. No cases appear to have arisen in which a compulsory license was granted in the period between 15 December 1993 and 15 April 1994, and as to which controversy might arise concerning the date of knowledge of the Agreement. It is very doubtful that such a case might arise at this late stage, so there is little practical reason to explore this interpretive issue further. Suffice it to say that the drafters of Article 70.6 appear to have had in mind a date prior to the entry into force of the WTO Agreement (and TRIPS Agreement), or application of TRIPS in the subject Member.

Article 70.6 effectively provides that a Member must apply the provisions of Article 31 to any compulsory license that was granted after the Agreement became known. However, by virtue of Article 70.1 (providing that no obligations arise in respect to acts occurring prior to the date of application of the Agreement), this could only mean with prospective effect after the provisions become applicable. In other words, licenses granted after the Agreement became known and that did not comply with the Agreement (for example, by not including provision for adequate remuneration) would have to be brought into compliance, but only after Article 31 became applicable. For developing Members, Article 31 became applicable on 1 January 2000.

The second clause of Article 70.6 provides that the Article 27.1 rule that patent rights shall be enjoyable without discrimination as to the field of technology need not be applied to compulsory licenses granted before the Agreement became known. By logical implication, Members are required to apply Article 27.1 to compulsory licenses granted after the Agreement became known. The panel in the *Canada-Generic Pharmaceuticals* case interpreted Article 70.6 this way.¹²⁷

¹²⁶ GATT Doc. MTN/FA, 15 Dec. 1993.

¹²⁷ See *Canada – Patent Protection of Pharmaceutical Products*, Report of the Panel, WT/DS114/R of 17 March 2000. In the context of interpreting Article 30, the panel accepted the presumption of the EC and Canada that Article 31 is subject to the rule of non-discriminatory treatment of patents with respect to place of invention, field of technology and whether products are imported or locally produced. The panel concluded by implication that Article 27.1 also applies to Article 30, but this conclusion does not necessarily follow since Article 30 and Article 31 are drafted differently and directed to different purposes. As to the applicability of the non-discrimination requirement of Article 27.1 to compulsory licensing, it has been observed that the panel in the *Canada – Generic Pharmaceuticals* case may be interpreted as making a distinction between “discrimination” and “differentiation” for *bona fide* purposes (see Chapter 25). Moreover, the argument has been made that Article 27 deals with patentable subject matter and that Article 31 is a self-standing Article. To affirm that Article 31 is generally subject to Article 27 could limit its application in ways that were not intended either by the negotiators or indeed by the text. In fact, the *EC-Canada* case was not about compulsory licensing and the panel’s report cannot be considered as definite jurisprudence.

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This peculiar drafting of Article 70.6 almost certainly reflects specific concerns between the United States and Canada. The United States pressured Canada to amend its compulsory licensing legislation for pharmaceuticals in connection with negotiation of the NAFTA, concluded in 1993. Canada had issued a substantial number of compulsory licenses under its previous regime that, for example, treated pharmaceutical inventions differently from other fields of technology.¹²⁸ The United States was unable to persuade Canada to modify licenses that had been issued while its pre-NAFTA regime was in effect, but wanted to assure that Canada did not grant post-NAFTA licenses that did not comply with its new TRIPS obligations. Any such licenses that were granted would have to be brought into conformity with Article 31 upon the application of that Article on 1 January 1996. This is not to suggest that Article 70.6 will not affect other Members, but only to account for the obtuse drafting, and specifically to the reference concerning the date the Agreement became known.

3.7 Article 70.7

7. In the case of intellectual property rights for which protection is conditional upon registration, applications for protection which are pending on the date of application of this Agreement for the Member in question shall be permitted to be amended to claim any enhanced protection provided under the provisions of this Agreement. Such amendments shall not include new matter.

Article 70.7 concerns IPRs for which protection is conditional upon registration. Under the Berne Convention, protection of copyrighted works may not be conditioned on registration, and for that reason Article 70.7 would not generally be relevant to copyright subject matter. Patents are “granted” following a review of an application. The term “registration” is not ordinarily associated with the field of patents, and it is doubtful whether this Article 70.7 has relevance to patent applications. In most countries, trademark rights are conferred by registration, and registration is also a predicate to protection for industrial designs, geographical indications, plant varieties and layout-designs of integrated circuits, depending on the national system for conferring IPRs.

However, in some countries Article 70.7 was invoked by applicants that under pre-TRIPS law were denied the possibility of obtaining product patent protection for pharmaceuticals. The argument was that Article 70.7 would give a right to the “conversion” of applications relating to processes into product applications, to the extent (as was often the case) that the product had been described in the original application (and, therefore, would not constitute “new matter”). In the case of Argentina, several lower courts accepted this interpretation. Nevertheless, the Supreme Court¹²⁹ correctly dismissed it, arguing that accepting such a

¹²⁸ See Jerome H. Reichman and Catherine Hasenzahl, *Non-Voluntary Licenses of Patent Inventions: The Canadian Experience*, UNCTAD/ICTSD, Oct. 2002 (available at <http://www.iprsonline.org/unctadictsd/docs/reichman_hasenzahl.Canada.pdf>).

¹²⁹ *Pfizer Inc. c/ Instituto Nacional de la Propiedad Industrial s/ denegatoria de patente*, 21 May 2002.

theory would contradict the prospective character of the Agreement and, in particular, render meaningless Article 70.8, which established a special regime to recognize patent protection for pharmaceutical products, provided that applications were filed after January 1, 1995 (or January 1, 1994 if a priority right was invoked).

Article 70.7 allows for the amendment of applications pending at the date of application of the Agreement to claim any enhanced protection provided under the provisions of this Agreement, as qualified by the restriction that “Such amendments shall not include new matter.” In most cases, the protection accorded to a particular form of IPR will not be “claimed” in an application because the scope of protection is determined as a matter of national IP legislation, not by the applicant by virtue of a claim on an application form. In other words, when registration is granted, the applicant enjoys the rights conferred by national law. When that is combined with the restriction against including “new matter”, the scope of this provision is narrowed further.

TRIPS Agreement rules (Article 18) on trademarks, by way of illustration, require that the term of protection conferred by an initial application will be a minimum 7 years. If a Member, prior to application of the trademark rules, conferred only a five-year term and that term was referenced (i.e., “claimed”) in the form of application, then the application could be amended to claim an initial term of 7 years. TRIPS also established trademarks and service marks on the same footing from the standpoint of registration.¹³⁰ Whether a trademark application, as to the same mark, could be amended to claim service mark protection (in a Member that previously did not allow registration of service marks) is not clear, since service mark protection might be considered to cover “new matter”. That is, the provision of a service is different from the sale of goods, and a mark covering services might be said to claim “new matter” in comparison to a trademark. However, because the mark is unchanged, that might be construed not to involve a claim of new matter.

The question of applicability of Article 70.7 can be properly evaluated only in light of particular national legislation because the question whether rights are conditioned on registration will vary, and the types of claims asserted in an application will vary.

3.8 Article 70.8

8. Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:

(a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;

¹³⁰ Effectively modifying the rule of Article 6*sexies* of the Paris Convention. See Chapter 14.

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(b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and

(c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).

“Where a Member does not make available as of the date of entry into force of the WTO Agreement”

The WTO Agreement entered into force on 1 January 1995. The first clause of Article 70.8 makes that date its initial reference point.

“patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27,”

Article 27 requires that patents shall be available in all fields of technology, subject to exceptions otherwise allowed in Article 27.2 and 27.3.¹³¹ Article 27.1 states, *inter alia*,

“Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.” [italics added]

Since Article 65.4 allows a developing Member that did not previously grant product patent protection in an area of technology to delay its availability until 1 January 2005,¹³² and since that right is recognized in Article 27, it is a poor semantic choice to refer to that Member’s “obligations under Article 27”. Despite the poor choice of words, it seems clear that Article 70.8 refers to Members that did not provide patent protection for pharmaceutical and agricultural chemical products when the WTO Agreement entered into force (even if they did not have an “obligation” to do so at that time).

“(a) notwithstanding the provisions of Part VI,”

Part VI of TRIPS addresses Transitional Arrangements, and addresses both developing and least-developed Members. It relieves developing Members of an

¹³¹ In Chapter 17 the extent to which Article 27 mandates patent protection for pharmaceutical products is considered, including the extent to which Articles 27.2 and 27.3 might allow exceptions to such patentability. That discussion will not be repeated here.

¹³² Paragraph 65.4 provides, as discussed in Chapter 6.1:

“4. To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.”

obligation to provide pharmaceutical and agricultural chemical product patent protection until 1 January 2005 (where such protection was not earlier provided), and it relieves least-developed Members of any obligation to provide such protection until at least 1 January 2006 (which period was extended as to pharmaceutical products by action taken under the Doha Declaration until 1 January 2016).

“provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;”

As noted above, the date of entry into force of the WTO Agreement was 1 January 1995. The requirement to “provide” arose as of that date. The Member must provide a “means by which applications . . . can be filed”. This would suggest at least the designation of a receiving point for applications, such as a designated administrative authority within the government. The term “filed” implies that the application is recorded and stored in some manner. “Applications for patents” is a term of art that refers to a form on which the applicant for a patent sets out its claims and related specification or description, as well as prior art references where applicable, as a request for the grant of a patent. Article 70.8 does not refer to preliminary documents or statements of intent to file, but to “applications”. Therefore, a Member should allow for the filing of complete applications.

Because Article 70.8(a) requires that Members without patent coverage provide a means for filing applications, but not for granting patents, Article 70.8(a) applications have commonly been referred to as “mailbox” applications.

The term “patents for such inventions” appears to refer to patents for pharmaceutical and agricultural chemical products.¹³³ The definition of “pharmaceutical . . . products” and “agricultural chemical products” is subject to interpretation. This was much discussed in the context of more recent negotiations regarding implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.

The Oxford New Shorter English Dictionary defines “pharmaceutical” by cross reference to “medicinal drug”.¹³⁴ It defines “medicinal” as “1 Having healing or curative properties or attributes; therapeutic”¹³⁵ and “drug” as “1. Any substance that affects the physical or mental functioning of a living organism; *esp.* one used for the treatment or prevention of an ailment or disease”.¹³⁶ The term “pharmaceutical products” can be given a broader or narrower interpretation depending on the context.

“Agricultural chemical” may encompass chemical products with multiple uses, and it would appear that a Member might restrict applications to those claiming uses of chemicals specifically in the field of agriculture, so as to avoid the prospect

¹³³ It will be interesting to examine the practice of the pharmaceutical companies with respect to these applications. The Decision on Implementation of Paragraph 6 of the Doha Declaration refers to pharmaceutical products, and there may be interpretative issues with respect to the scope of coverage.

¹³⁴ “Pharmaceutical” is defined as an adjective, as “Pertaining to or engaged in pharmacy; pertaining to the preparation, use, or sale of medicinal drugs”. As a noun, it is defined as “A pharmaceutical preparation; a medicinal drug.” (at page 218 2)

¹³⁵ *Id.*, at page 1730.

¹³⁶ *Id.*, at page 756.

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of applicants attempting to extend the scope of Article 70.8 protection to “multiple uses” of the same chemicals outside the field of agriculture.

“(b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and”

The date of application of this Agreement for developing Members is up until 1 January 2005, at latest, in respect of newly covered areas of technology. If a developing Member elects to extend the scope of patent protection prior to 1 January 2005 (as most such countries have done) that date should logically be considered “the date of application of this Agreement” for the purposes of this provision.¹³⁷ There is no apparent reason why patent protection for pharmaceutical and agricultural chemical products cannot be extended by a developing Member at different times prior to 1 January 2005. For least-developed Members, the relevant end-point date for pharmaceutical products is 1 January 2016 (per paragraph 7 of the Doha Declaration), and for agricultural chemical products until 1 January 2006.¹³⁸

The phrase “apply to these applications, as of the date of application of this Agreement” is relevant to the question when applications filed under Article 70.8(a) should be processed. A patent application is typically processed by a patent office over a period of between 18 and 36 months from the filing date, depending on a variety of factors such as the volume of applications in the patent office, the complexity of an application, the exchange of correspondence with the applicant, and so forth. The first two clauses of Article 70.8(b) might be interpreted in two ways. First, it might be interpreted to require that when applications are taken out of the mailbox on the date of application of the Agreement (e.g., 1 January 2005), the applications should be processed in the customary manner (that is, subject to procedural and substantive review), with the determination as to the grant of a patent made in due course. Because the phrase is followed by an instruction as to patentability criteria (that is, to apply “the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member”), a natural interpretation is that the phrase is an instruction to the patent examiner regarding patentability standards to apply when the applications are ultimately processed. From this perspective, the phrase “apply to these

¹³⁷ A developing Member might argue that early extension of scope was “voluntary” because it might have taken advantage of further delay, and therefore it was not applying the TRIPS Agreement when it extended the scope. However, in light of the obligation in Article 65.5 that consistency with TRIPS should not be reduced during the transition period, it would be difficult to argue in favour of withdrawing an action that established such consistency. In this regard, the “date of application of this Agreement” is most reasonably understood as the date on which the developing Member extends patent protection to pharmaceutical or agricultural chemical products, respectively.

¹³⁸ Also, because least developed Members are not subject to Article 65.5, they may withdraw patent protection for agricultural chemical (and other) products until 1 January 2006, and for pharmaceutical products up until 1 January 2016. Thus, in theory, least developed Members might suspend the processing of applications under Article 70.8(b) after initiating their processing and until the date when protection is mandated.

applications, as of the date of application of this Agreement,” is an instruction to the Member that applications must be withdrawn from the mailbox and their processing initiated on a certain date.

A second interpretation would place greater emphasis on the phrase, “as of the date of application of this Agreement”, and oblige a Member to actually make a decision regarding patentability on that date, taking into account the rule regarding patentability criteria stated in the subsequent phrase. This interpretation is implausible and would be inconsistent with the general structure of Article 70.8 and patent law as it is customarily applied. Recall that Article 70.8(a) obliges a Member to provide a means to file a patent application. It does not obligate a Member to put in place a mechanism for the substantive review of patent applications, including corresponding with patent applicants, and so forth. There is good reason why patent offices do not grant patents immediately on the filing of applications. These are highly technical documents requiring research into prior art, evaluation of claims, correspondence with applicants, and so forth. Unless a Member were obliged to process and review applications prior to the date of application of the Agreement, it would simply be implausible (if not impossible) to grant patents as of that date. On the assumption that the negotiators of TRIPS did not intend an implausible or absurd result, the interpretation that applications must be reviewed and acted upon on the date of application of the Agreement should not prevail.

Article 27.1 lays down three traditional criteria of patentability, that inventions must be “new, involve an inventive step and are capable of industrial application”. Article 29 lays down a fourth criterion, “an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.”

Article 70.8 provides that the Member will apply the criteria of patentability “as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application”. When a patent application is first filed in a member country of the Paris Union (as made applicable also under TRIPS), the applicant thereby secures a priority date. From this priority date, a one-year period is counted during which that applicant may file in other countries of the Paris Union (Article 4, Paris Convention), and such applications “shall not be invalidated by any acts accomplished in the interval, in particular, another filing, the publication or exploitation of the invention, . . . and such acts cannot give rise to any third party right or any right of personal possession.”

The filing date and priority date for an application will typically be different (except in the country of first filing) with the priority date being earlier outside the country of first filing. A Member that has not provided pharmaceutical or agricultural product patent protection is likely to have initial filings only from its own nationals (if those),¹³⁹ with the preponderance of applications from inventors

¹³⁹ An inventor outside a country with no patent protection would have little reason to make its first filing in that country. An inventor within that country might have reason for filing an Article 70.8

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that first filed abroad. Most holders of applications under Article 70.8 will therefore be relying on the priority date as the date of application, since the earlier date cuts off claims of subsequent applicants.

Article 70.8 (b) refers to “where priority is available and claimed.” Unless a filing under Article 70.8(a) is within the priority period established by the Paris Convention (that is, within 12 months of the initial filing), the criteria for patentability will be based on the filing date, and not an earlier priority date. If a patent applicant neglects to file its application under Article 70.8(a) during its priority period, its invention might not be novel (by virtue of disclosure) when its filing is made.

Patent examination authorities in the Member that is reviewing applications under Article 70.8(b) are instructed to apply the criteria of patentability as of the earlier of the filing or priority date. This means that events or acts that occur after that date are not to be considered in the review of the application. Ordinarily, a patent application will be published approximately 18 months after the date of initial application, and the invention becomes known to the public at least as of that date (it may have been introduced and made public earlier).

When an application is filed in a country that provides patent protection, the application may not be substantively reviewed for a number of months (since patent offices are backlogged), but when the patent examiner does evaluate the application he or she considers circumstances as they existed as of the initial filing or priority date.¹⁴⁰ The inventor is held to a standard of knowledge at or before the date of application.

If an inventor does not file a patent application in a country prior to expiration of the priority period,¹⁴¹ the inventor is not protected against disclosures made in connection with publication of the application abroad or putting the invention on the market. In the ordinary case, failure to file a patent application during the priority period will make it impossible to obtain a patent later on since the invention will have been disclosed, and it will no longer be considered new or novel. (In some cases, countries have granted retroactive patent protection, or “pipeline protection”, to inventions that would not ordinarily meet novelty standards, but this is an exception from generally applicable patenting criteria.)

Article 70.8(b) addresses this situation. If a Member that does not provide patent protection for a particular subject matter, a patent application claiming such an invention would be rejected, and the inventor would not enjoy a right of priority. Publication of the patent application in a foreign country, or availability of the product on the market (at least in the subject country) would negate the novelty of the invention if patent protection subsequently became available. By requiring a preservation of priority even without the availability of patent protection, Article 70.8(b) guards against this result. By specifying that the determination as

application there because, for example, of domestic laws requiring national security review of patent applications.

¹⁴⁰ See, e.g., *Biogen v. Medeva*, U.K. House of Lords, [1997] RPC 1, 31 Oct. 1996.

¹⁴¹ The rule is modified by operation of the Patent Cooperation Treaty, which deems applications incorporating designated countries to be filed within the priority period, but that technical matter does not affect this discussion.

to criteria of patentability relates back to the priority (or filing) date, Article 70.8(b) avoids doubt as to whether the application would be subject to later acts or events, such as marketing of the product in the subject country. If an application is filed in 1996, it might not be reviewed until 2005, and there might be concerns about the preservation of patentability criteria for such an extended period. Since the drafters of the provision were dealing with a unique legal situation, there were reasonable grounds for specifying the intended result; that is, patentability will be evaluated as of the date of the filing or priority date, whichever is earlier.

“(c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).”

The first clause of subparagraph (c) requires the Member where Article 70.8 applications are processed to provide patent protection “as from the grant of the patent.” Recall from discussion under subparagraph (b) that the grant of the patent will be made following a substantive review of the application. Article 70.8(c) imposes no obligation on the Member granting the patent to relate protection back to a date earlier than the grant, or to provide provisional protection during the period following the filing date (but see Article 70.9 below).

Although criteria of patentability are evaluated as of the earlier of the filing or priority date, the term of the patent is expressly based on the filing date of the application. (Recall that unless the filing was within the priority period established by the Paris Convention, that is, within 12 months of the initial filing, the criteria for patentability will be based on the filing date, and not an earlier priority date.) Article 33 establishes a minimum patent term of 20 years “counted from the filing date”. The “remainder of the patent term” will therefore relate back to the filing date (under Article 70.8(a)) in the Member processing the application. This date may be as early as 1 January 1995 (the date of entry into force of the WTO Agreement). And, of course, patent protection will only be granted for those applications that meet the criteria of patentability applicable under Article 70.8(b).

Doha Concerns

When the TRIPS Council made its recommendations to the General Council concerning implementation of Paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health, concern was expressed by least-developed Members that the requirement to accept the filing of mailbox applications and subsequently to grant patents based upon them (for example, after 1 January 2016), would reduce the incentive for commencement of medicines production within their territories. While the TRIPS Council recommended, and the General Council waived, the obligation to provide exclusive marketing rights under Article 70.9 (see discussion below), it did not waive the obligation on least-developed Members to accept mailbox applications, or to grant patents based on such applications following the entry into force of patent protection.

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3.9 Article 70.9

"9. Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member."

"Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a),"

Article 70.9 applies only with respect to patent applications filed in a Member under Article 70.8(a). Article 70.8(a) is discussed in the preceding section. Recall that the definition or scope of "pharmaceutical product" and "agricultural chemical product" is not fixed, and there may be questions regarding the inventions which qualify for coverage under Article 70.8 and, by extension, Article 70.9.

"exclusive marketing rights shall be granted"

From the moment the term "exclusive marketing rights" was agreed upon in the TRIPS Negotiating Group there has been uncertainty concerning its meaning. The language was used to effectuate a compromise between the countries demanding early patent protection for pharmaceutical and agricultural chemical products, and countries demanding a full 10-year transition period for those products.¹⁴² The term was not known in intellectual property law generally, or patent law specifically. Its use permitted each side to the negotiations to give it the meaning that suited their immediate purpose of concluding the negotiations. While a mechanism for allowing TRIPS negotiations to be brought to a conclusion, those implementing the phrase are not guided by customary practices.

It may be useful to start with what exclusive marketing rights are *not*. They are not the equivalent of patent rights. Were that the intent of the negotiators, a reference to the rights ordinarily conferred by patent could readily have been used.

The Oxford New Shorter Dictionary defines "exclusive" as an adjective: "5. Of a right, privilege, quality, etc.: possessed or enjoyed by the individual(s) specified and no others; confined or restricted to." The term marketing is defined as a verb as "1 *b spec.* The action, business, or process of promoting and selling a product etc., including market research, choice of product, advertising, and distribution." The term "right" is defined as a noun as "5 A legal, equitable, or moral title or

¹⁴² The author bases this observation on conversations with TNG negotiators that took place shortly following agreement on the text, and in which he queried several negotiators regarding the intended meaning of the phrase. The reply can be paraphrased as "no one knows". India and the United States were said to be the principal parties at odds over this matter.

claim to the possession of property or authority, the enjoyment of privileges or immunities, etc.”

Article 28 gives the patent holder the right to prevent third parties without its consent from making, using, offering for sale, selling or importing the product covered by the patent. The term “marketing” does not appear to encompass the right to prevent others from “making” a product, or to prevent others from “using” a product except in the sense of promoting and selling the product. Based on the dictionary definition, the term “marketing” appears to apply to the acts a business enterprise undertakes in connection with selling products that are already manufactured; that is, acts associated with placing the products into sales channels. A reasonable interpretation of the term marketing in the context of pharmaceutical and agricultural chemical products is that the holder of the patent application may not prevent third parties from producing the product within the territory of the Member, but may prevent third parties from advertising, offering or selling the product to a person other than the patent applicant.

If the patent applicant is in a position to supply the market with a product, whether through local manufacturing or importation, an exclusive right to sell may have the effect of curtailing potentially competing local producers just as effectively as the grant of a patent, although it would not preclude such manufactures from exporting and selling the products in foreign countries where patent protection was not in force.

Questions also arise concerning how exceptions to the grant of exclusive marketing rights should be treated. Exclusive marketing rights are not patents, so they are not subject to the rules of Part II, Section 5, of TRIPS regarding patents. They are a *sui generis* creation of Article 70.9. As Members implement EMRs, they will need to consider the extent to which the public interest will require allowing use by third parties without the consent of the holder of the exclusive marketing rights. They may look to the exceptions allowed with respect to patents, including prior user rights, compulsory licensing and so forth, but are not restricted to these. Per Article 1.1, it will be up to Members to “determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice”.

“for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter,”

Before a pharmaceutical or agricultural chemical product is placed on the market within a country, its marketing must be approved by regulatory authorities. As noted by the panel in the *Canada-Generic Pharmaceuticals* case, the period for approval in the case of new pharmaceutical products is commonly over 6 years.

The substantive and procedural conditions to putting a pharmaceutical or agricultural chemical product on the market, and the terminology with respect thereto, vary among countries. Marketing approval should be understood to refer to the final action by regulatory authorities that allows the entry of a product into circulation and use within a Member.

Article 70.9 refers to the time when a product patent is granted or rejected in that Member. If marketing approval had been granted, and led to the grant of exclusive marketing rights, those rights would terminate on the date of rejection

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of the patent application. Such a rejection would typically take place by official action of the patent office. When a patent is granted, EMRs terminate and patent protection begins. The grant of a patent likewise typically takes place by official action of the patent office.

The maximum period of EMR protection is five years. If that period expires before the grant or rejection of a patent, EMR protection will end. IPR protection may subsequently be initiated upon the grant of a patent, considering that patentability criteria will have been preserved under Article 70.8(b).

“provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member.”

There is an important precondition to the grant of exclusive marketing rights. First, a patent application must have been filed and a patent granted for the subject product in another Member. This condition was to assure that a Member was not required to grant EMRs with respect to a product that would not ultimately be subject to patent protection. The condition refers not only to a patent grant, but to the filing of a patent application. A patent application contains the claims and description defining the scope of an invention and enabling its production. Article 29 requires an enabling disclosure as a condition to granting a patent. The requirement in Article 70.9 to file an application was presumably intended to prevent an applicant for EMRs to rely on a patent granted by a Member with inadequate patenting standards, although it is not clear that the mere requirement of an application would meet that objective.

Second, marketing approval must have been granted in that same “other Member”. Marketing approval for a pharmaceutical or agricultural chemical product is typically granted significantly later than a patent. Patents are applied for when a new molecule is created and may show promise in application. Approval for such molecule to be used by humans involves years of refinement and testing. A Member is not expected to grant exclusive marketing rights until a pharmaceutical or agricultural chemical product has completed its development and testing cycle and been approved for marketing. There are no express grounds for preventing a less scrupulous private enterprise from obtaining a patent in a country where minimal review is undertaken, and where marketing approval is not the subject of a rigorous review process. However, the Member country where EMRs are sought still controls the process because such rights need not be granted until it has internally approved the marketing of the product. Moreover, there is a general obligation of good faith in all legal systems, and a Member would not need to grant EMRs on the basis of a manifestly inadequate or “sham” foreign patent and marketing approval.¹⁴³

Doha Developments

Finally, the application of Article 70.9 to least-developed Members with respect to pharmaceutical products was waived by the General Council in connection with

¹⁴³ In this context, the question arises whether a patent that has been granted without examination should be considered a “patent” in terms of Article 70.9.

implementation of Paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health.¹⁴⁴ That waiver provides:

- “1. The obligations of least-developed country Members under paragraph 9 of Article 70 of the TRIPS Agreement shall be waived with respect to pharmaceutical products until 1 January 2016.
2. This waiver shall be reviewed by the Ministerial Conference not later than one year after it is granted, and thereafter annually until the waiver terminates, in accordance with the provisions of paragraph 4 of Article IX of the WTO Agreement.”

4. WTO jurisprudence

4.1 Canada – Term of Patent Protection (“Canada – Patent Term”)¹⁴⁵

In *Canada – Patent Term* the Appellate Body interpreted Articles 70.1 and 70.2 regarding subject matter existing prior to its application in a Member. This case involved a complaint by the United States against Canada for an alleged failure to apply the minimum 20-year patent term requirement of Article 33 to patents that were granted under pre-TRIPS patent legislation.

Canada argued that it was not required to extend the term of patents that had been granted under an act that applied to patents granted up until 1989 (and which patents remained in force when Article 33 became applicable), because Article 70.1 excluded application of TRIPS to “acts” which occurred before the date of application. In Canada’s view, the grant of a patent was an “act” that occurred before Article 33 became applicable. Canada argued that Article 70.2, which establishes obligations regarding “subject matter existing at the date of application . . . and which is protected in that Member on the said date” covered patents granted prior to application of the Agreement, but did not obligate it to extend the patent term, which was excluded under Article 70.1 as prior “acts”.

The decision of the panel and Appellate Body in this case focused on the plain meaning of Articles 70.1 and 70.2. Neither the panel nor the AB found Canada’s attempt to distinguish the act of setting out a patent term (as within Article 70.1), and the general “existing” nature of the patented invention under Article 70.2, persuasive. The Appellate Body found that Article 70.2 required the application of Article 33 to the term of existing patents based on the express language of the Agreement.

4.2 India – Patent Protection for Pharmaceutical and Agricultural Chemical Products (“India – Mailbox”)¹⁴⁶

The first case brought under TRIPS was a claim by the United States alleging that India had failed to implement its obligations to provide an adequate mailbox

¹⁴⁴ General Council, Decision of 8 July 2002, Least-Developed Country Members – Obligations Under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products, WT/L/478, 12 July 2002.

¹⁴⁵ *Canada – Term of Patent Protection*, WT/DS170/AB/R, 18 Sept. 2000 (*Canada – Patent Term*).

¹⁴⁶ *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, AB-1997-5, WT/DS50/AB/R, 19 Dec. 1997 (*India – Mailbox*).

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mechanism to receive and preserve applications pending the availability of patent protection for pharmaceutical and agricultural chemical products (Article 70.8, TRIPS Agreement), and that India had failed to establish a legal mechanism for the granting of exclusive marketing rights (Article 70.9, TRIPS Agreement). India argued that it met its mailbox obligations by virtue of administrative instructions given by the executive to the patent commissioner. The United States claimed that those instructions were inconsistent with express terms of the India Patents Act that required the patent commissioner to reject patent applications for pharmaceutical and agricultural chemical products, and that the Indian Constitution did not permit the executive to override the terms of the Patents Act in this manner. Regarding EMRs, India claimed that it had no obligation to establish a mechanism for granting them until the need arose. The United States said that the obligation was not contingent on future events, and that India had an explicit obligation to immediately establish a legal mechanism.

The panel and Appellate Body held that India had failed to act consistently with its obligations under Articles 70.8 and 70.9. However, the AB rejected a key element of the panel's legal approach (and also differed on a minor procedural issue). The panel held that India's approach to providing a legal means for implementing its mailbox obligation did not satisfy the "legitimate expectations" of the United States and private patent holders, and that India should have adopted a system that would allay reasonable doubts the parties might have concerning the security of patent mailbox applications.

The AB faulted the panel for what, in its view, was lack of sufficient attention to the express terms of TRIPS. The AB said that the concept of "legitimate expectations" derived from GATT 1947 jurisprudence on adverse treatment of imported products. It was typically applied to assess conditions of competition after finding of a *prima facie* violation of GATT rules, and in the context of a Member seeking to disprove nullification or impairment of benefits. In the AB's view, the panel had instead used the concept of "legitimate expectations" in the sense of a non-violation nullification or impairment cause of action alleging the undermining of benefits expected from negotiated concessions in the absence of a rule violation. Used in this sense, the panel had exceeded the scope of its authority because Article 64.2–3 precluded non-violation causes of action as of the date of the proceeding. Thus, to the extent that the panel had suggested that it should interpret TRIPS in light of the legitimate expectations of the United States or its patent holders, or had placed on India a burden to relieve them of "reasonable doubts", the panel was in error.

The AB emphasized that India's textual obligation under TRIPS was to provide a "means" to implement its mailbox obligations, and analogized this obligation to providing a "sound legal mechanism". India was under no further obligation. The AB concurred with the panel that India had not done this since it appeared from the evidence that the Indian Constitution did not permit the executive to override a statutory requirement in the manner alleged by India. The AB rejected India's assertion that it alone should decide on what means were adequate within its legal system, noting that legal rules could be treated as matters of fact by international judicial bodies, and referring to the fact that the United States had been subject

to just such an inquiry in the *U.S. – Section 337*¹⁴⁷ case under GATT 1947. The AB went on to hold that the plain language of TRIPS required India to provide a mechanism for granting EMRs from its entry into force. It said that Article 70.9 operates in tandem with Article 70.8(a), which clearly takes effect from the entry into force of the WTO Agreement, and that India's argument that its obligation was contingent on the need for granting an EMR was not supported by the text of the agreement.

In the *India – Mailbox* decision, the AB stressed the importance of adhering to the text of the TRIPS Agreement in the process of interpretation, and of avoiding the addition of new obligations based on broad concepts such as removing reasonable doubts. Such an approach can hardly be faulted, particularly since Members may have very different views regarding their expectations as to TRIPS.

4.3 Japan – Measures Concerning Sound Recordings¹⁴⁸

The United States and European Communities requests for consultations regarding Japan's alleged failure under Article 70.2 to provide retroactive protection for sound recordings in the public domain (but not by virtue of expiration of the term of copyright) is discussed above at Section 3.2.

5. Relationship with other international instruments

Article 70 is specifically directed to obligations surrounding its entry into force. Generally speaking, these obligations are not related to the provisions of other WTO agreements or other international instruments. However, because TRIPS, including Article 70, incorporates by reference provisions of the Paris, Berne and other IPR conventions, it necessarily bears a relationship to those instruments. As seen in the *Japan – Sound Recordings* request for consultations, interpretation of Article 70 may depend upon incorporated provisions of WIPO Conventions. This is not a feature unique to Article 70.

As with all other elements of TRIPS, interpretation of Article 70 must take into account the Doha Declaration on the TRIPS Agreement and Public Health, and the agreement by Members that TRIPS should be interpreted in a manner supportive of access to medicines for all.

6. New developments

6.1 National laws

Each Member of the WTO takes into account the provisions of Article 70 in the implementation of its TRIPS obligations, and we will not undertake to review that panoply of Member action. However, it may be useful to consider an example of

¹⁴⁷ United States – Section 337 of the Tariff Act of 1930 Panel Report, adopted 7 November 1989, BISD 36S/345 (*U.S. – Section 337*).

¹⁴⁸ *Japan-Measures Concerning Sound Recordings*, Request for Consultations by the United States, WT/DS28/1, 14 Feb. 1996; and *Japan-Measures Concerning Sound Recordings*, Request for Consultations from the European Communities, WT/DS42/1, 28 Feb. 1996.

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legislation adopted to establish an Article 70.8 patent application mailbox and an Article 70.9 mechanism for the grant of EMRs.

6.1.1 The India 1999 Patents Amendment Act

Following the decision of the Appellate Body in the *India – Mailbox* case, India amended its Patents Act in 1999 to add a mechanism for the filing of patent applications with respect to pharmaceutical products,¹⁴⁹ as well as a mechanism for the grant of exclusive marketing rights.¹⁵⁰ It added a new Chapter IVA to the Patents Act titled “Exclusive Marketing Rights”. That new Chapter provided that the Controller General of Patents would not refer an application regarding a medicine or drug to a patent examiner until December 31, 2004. However, if an application was made for the grant of EMRs, it would be referred to an examiner for the purposes of preparing a report as to whether it fell within the scope of claimed inventions otherwise excluded from patentability in India,¹⁵¹ such as the mere discovery of a scientific principle,¹⁵² or an invention claiming a new use for a known substance.¹⁵³ If the report does not conclude that the invention should be rejected as outside the subject matter scope of patenting (this report is *not* an examination as to whether the claimed invention satisfies the criteria of patentability), then the Controller may grant exclusive marketing rights under the specified conditions.¹⁵⁴ The 1999 Amendment Act enumerated the preconditions set out in Article 70.9 (i.e., that a patent was filed for and granted in a Paris Convention country on or after 1 January 1995, a patent had been granted in that country, and “the approval to sell or distribute the article or substance on the basis of appropriate tests conducted on or after the 1st day of January, 1995, in that country has been granted on or after the date of making a claim for a patent covered under [the provision referring to medicines or drugs].” If those conditions are met, and marketing approval for the medicine or drug has been granted in India,

“then, he shall have the exclusive right by himself, his agents or licensees to sell or distribute in India the article or substance on and from the date of approval granted by the Controller in this behalf till a period of five years or till the date of grant of patent or the date of rejection of application for grant of patent, whichever is earlier.”¹⁵⁵

The 1999 Amendment Act provides for a prior user’s right in the following terms:

¹⁴⁹ India’s Patents Act did not at that time exclude patenting of agricultural chemical products. Also, the Patents Act permitted the patenting of processes relating to pharmaceutical products. See Patents Act, 1970, Sec. 5, pre-amendment.

¹⁵⁰ The Patents (Amendment) Act, 1999 (No. 17 of 1999), 26th March, 1999, to amend the Patents Act, 1970 (India) (hereinafter “1999 Amendment Act”). Note that the India Patents Act has also been amended by the Patents (Amendment) Act, 2002, No. 38 of 2002, 25th June 2002. The mechanism excluded “intermediate” chemical substances used in the production of medicines. 1999 Amendment Act, sec. 2.

¹⁵¹ *Id.*, sec. 3, at 24A(1).

¹⁵² Patents Act, sec. 3(c).

¹⁵³ Patents Act, sec. 3(d).

¹⁵⁴ 1999 Amendments Act, sec. 3, 24A(3).

¹⁵⁵ *Id.*, sec. 24B(1).

“24B(2) Where, the specifications of an invention relating to an article or a substance covered under sub-section (2) of Section 5 [i.e., medicines and drugs] have been recorded in a document or the invention has been tried and used, or, the article or the substance has been sold, by a person, before a claim for a patent of that invention is made in India or in a convention country, then, the sale or distribution of the article or substance by such person, after the claim referred to above is made, shall not be deemed to be an infringement of exclusive right to sell or distribute under sub-section (1).” [emphasis added]

Thus, a third party that has sold a medicine prior to the earlier of the filing date in India or the priority date may continue to sell and distribute the product.¹⁵⁶ And, since exclusive marketing rights do not address the manufacture of pharmaceutical products, the prior user’s right effectively allows producers to make, sell and distribute medicines in India *provided that* they were producing and selling such products prior to the applicant’s filing or priority date. This right would not permit generic producers that commenced production *after* originators filed patent applications to continue their activities, and in that sense is not an extensive grant of rights. The prior user’s right is consistent with exceptions to patent rights customarily applied, for example, in Europe. The European Commission proposal for a Community Patent Regulation expressly incorporates a prior user’s right.¹⁵⁷

The Indian exclusive marketing rights legislation applies the compulsory licensing provisions of the Patents Act *mutatis mutandis* to those new rights, exchanging the rights under patent for “exclusive right to sell and distribute”. In addition, the legislation authorizes government use of medicines or drugs covered by exclusive marketing rights, as follows:

“24D(1) Without prejudice to the provisions of any other law for the time being in force, where, at any time after an exclusive marketing right to sell or distribute any article or substance has been granted under sub-section (1) of section 24B, the Central Government is satisfied that it is necessary or expedient in public interest to sell or distribute the article or substance by a person other than a person to whom exclusive right has been granted under sub-section (1) of section 24B, it may, by itself or through any person authorized in writing by it in this behalf, sell or distribute the article or substance.

¹⁵⁶ This is so because the patent in such cases lacks novelty: the third party has already sold the product before the priority date of the patent.

¹⁵⁷ *Article 12*

Right based on prior use of the invention

1. A Community patent may not be invoked against a person who, in good faith and for business purposes, had used the invention in the Community or had made effective and serious preparations for such use before the filing date or, where priority has been claimed, the priority date of the application on the basis of which the patent is granted (hereinafter referred to as “the prior user”); the prior user shall have the right, for business purposes, to continue the use in question or to use the invention as planned during the preparations.

2. The right of the prior user may not be transferred either during the user’s lifetime or following his death other than with the user’s undertaking or that part of the undertaking in which the use or the preparations for use took place.”

Proposal for a Council Regulation on the Community patent, Brussels, 1.8.2000, COM(2000) 412 final 2000/0177 (CNS).

7. Comments, including economic and social implications

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(2) The Central Government may, by notification in the Official Gazette and at any time after an exclusive right to sell or distribute an article or a substance has been granted, direct, in the public interest and for reasons to be stated, that the said article or substance shall be sold at a price determined by an authority specified by it in this behalf.”

The government use right is an especially important feature of the Indian approach to exclusive marketing rights because it will allow the government to manage the introduction of pharmaceutical patents in a manner that protects the public interest. Because, as discussed earlier, EMRs are not patents, and are not governed by the patent rules of TRIPS, India is entitled to provide for more extensive exception to such rights than might be permitted with respect to patents. For example, government use of exclusive marketing rights does not require payment of remuneration to the holder of the rights.

6.2 International instruments

Article 70 is a transitional mechanism under TRIPS. It has not been the subject of other international instruments.¹⁵⁸

6.3 Regional and bilateral contexts

6.3.1 Regional

6.4 Proposals for review

To the extent that Article 70.8-9 implicate the availability of pharmaceutical products, they are the subject of ongoing study. More generally, as a provision relating to subject matter existing upon entry into force of its provisions, Article 70.1-7 is not the subject of proposals for review.

7. Comments, including economic and social implications

The extension of intellectual property protection to subject matter existing in a Member as of the date of the application of TRIPS necessarily changes the balance between public access to ideas and expression, and the interests of private claimants to such ideas and expressions. Negotiators might have decided that TRIPS Agreement rules would apply only to subject matter arising after the date of its application, and this would have resulted in a less dramatic shift in the balance. At least in the short run, the decision to protect existing subject matter worked in favour of the preponderant creators of IPR subject matter, which are enterprises from OECD countries. However, this decision by now is largely in the category of “old business”, and the focus of attention for developing countries is whether the present TRIPS Agreement balance, in its many forms, is in their interests. And, if not, what changes should be sought.

Articles 70.8 and 70.9 continue to be important to those few developing Members that have yet to implement pharmaceutical product patent protection, and

¹⁵⁸ On the WTO waiver for least-developed country Members with respect to Article 70.9 see above, Section 3.9 (“Doha Developments”).

Article 70.8 remains important to least-developed Members. On 1 January 2005, India will initiate pharmaceutical product patent protection and should then begin the review of mailbox applications. The extent to which patents and/or EMRs granted on the basis of those applications impedes the manufacture and sale of generic medicines in India and for export markets may have dramatic consequences for public health in many developing countries. It will be important for the WHO and other multilateral organizations, including the WTO, to pay close attention to the impact of the end of the pharmaceutical product transition period on medicines pricing and availability.

37: Review and Amendment

Article 71 Review and Amendment

1. The Council for TRIPS shall review the implementation of this Agreement after the expiration of the transitional period referred to in paragraph 2 of Article 65. The Council shall, having regard to the experience gained in its implementation, review it two years after that date, and at identical intervals thereafter. The Council may also undertake reviews in the light of any relevant new developments which might warrant modification or amendment of this Agreement.

2. Amendments merely serving the purpose of adjusting to higher levels of protection of intellectual property rights achieved, and in force, in other multilateral agreements and accepted under those agreements by all Members of the WTO may be referred to the Ministerial Conference for action in accordance with paragraph 6 of Article X of the WTO Agreement on the basis of a consensus proposal from the Council for TRIPS.

1. Introduction: terminology, definition and scope

Article 71 deals with two distinctive issues: the review and the amendment of the Agreement. While paragraph 1 refers mainly to review, paragraph 2 provides a (simplified) procedure for amendments adjusting the TRIPS standards of IPRs to higher levels of protection. In general, a review does not necessarily have to result in an amendment of a given agreement; it may also confirm the agreement as it is. Despite this distinction of subject matter, it follows from paragraph 1 that review and amendment are closely interlinked: the purpose of a TRIPS review is not limited to an examination of Members' implementation efforts (see first sentence of para. 1); it may equally be undertaken with a view to accommodating relevant new developments warranting modification or amendment of the Agreement (see third sentence of para. 1).

1.1 Review

The purpose of the first paragraph of Article 71 is to monitor the operation of TRIPS in practice with a view to ensuring a successful realization of

its objectives.¹⁵⁹ To this end, paragraph 1 provides for three different review procedures:

- a) Its first sentence refers to the review of the implementation by Members of the TRIPS Agreement. This review is mandatory (“The Council for TRIPS shall . . .”) and must take place after the expiration of the transitional period referred to in Article 65.2, i.e., as of 1 January 2000.
- b) By contrast, the second sentence refers to the review of the provisions of the TRIPS Agreement itself. This review is also mandatory (“The Council shall . . .”) and must be commenced two years after the expiration of the transitional period under Article 65.2 (i.e., as of 1 January 2002) and every two years thereafter. In reviewing the TRIPS Agreement, the Council for TRIPS shall have “regard to the experience gained in its implementation”.
- c) Finally, the third sentence of paragraph 1 equally refers to a review of the TRIPS provisions. As opposed to the above review exercises, though, this review is optional (“The Council may . . .”) and may expressly result in a modification or an amendment of the TRIPS Agreement, in case such developments merit an amendment to the treaty. Unlike for the other two cases of review, there is no reference to any date as of when this review may be commenced (see Section 3 for details of all three kinds of review).

1.2 Amendment

Amendments are dealt with under Article 71 paragraph 1, third sentence (see above) as well as under paragraph 2. Contrary to a review, an amendment will necessarily result in the changing of the text of an agreement. It may be (but does not have to be) the consequence of a review, as illustrated by the third sentence of Article 71.1.

The latter provision refers to “modification or amendment” of TRIPS. Due to this language, it could be argued that amendment and modification of a treaty must be distinguished from one another. While an “amendment” seeks to change the treaty between *all* the parties to it, a “modification” operates *inter partes* between two or more parties to the treaty. It seeks to modify that treaty on the basis of an agreement authorized, or conversely not prohibited, by the treaty which neither affects the rights of third parties nor the objectives and purposes of the agreement.¹⁶⁰

2. History of the provision

2.1 Situation pre-TRIPS

Neither the review nor the amendment or modification of a treaty is specific to TRIPS. Amendment and modification of treaties have been traditional

¹⁵⁹ For the objectives of TRIPS and the rationales underlying its adoption see Section 7. For a detailed analysis, see Chapter 6 (in particular on Article 7) and Chapter 1 (on the preamble).

¹⁶⁰ See Article 41 of the Vienna Convention on the Law of Treaties. It is doubtful, however, if this provision is directly applicable to the TRIPS Agreement. In any case, in the TRIPS context, such modification could occur where a vote among WTO Members does not result in unanimity. In that case, the proposed modifications of the Agreement would apply only to those Members supporting it.

2. History of the provision

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instruments under public international law and are reflected in Part IV of the Vienna Convention on the Law of Treaties (Articles 39-41). Both revision and amendment are provided for in the most important pre-TRIPS conventions on IPR protection, namely the Paris and the Berne Conventions.

2.1.1 The Paris Convention

The Paris Convention for the Protection of Industrial Property in its Article 17 grants state parties the possibility to propose amendments to a number of organizational provisions. Article 18 of the same Convention constitutes the legal basis for revision conferences to be held successively in one of the countries of the Union. Such revisions concern, *inter alia*, the substantive provisions of the Paris Convention. Each revision has the stated purpose of introducing amendments “designed to improve the system of the Union” (Article 18.1). Accordingly, the Paris Convention has been revised at a series of conferences between its entry into force in 1883 and the latest revision in 1967.¹⁶¹

2.1.2 The Berne Convention

The Berne Convention for the Protection of Literary and Artistic Works follows the same approach as the Paris Convention. Its Article 26 accords any party the right to propose the amendment of certain organizational provisions.¹⁶² Article 27 provides for the possibility of holding successive revision conferences with a view to introducing “amendments designed to improve the system of the Union” (Article 27.1). These amendments concern, *inter alia*, the substantive provisions of the Berne Convention.¹⁶³

2.2 Negotiating history

2.2.1 The Anell Draft

This draft provided:¹⁶⁴

“7. Review and Amendment (68); Amendments (73)

7A PARTIES shall review the implementation of this Annex after the expiration of the transitional period referred to at point 1 of Part VII above. They shall, having regard to the experience gained in its implementation, review it [-] years after that date, and at identical intervals thereafter. The PARTIES shall also undertake reviews in the light of any relevant new developments which might warrant modification or amendment of this annex. (68)

7B (i) Amendments to this part shall take effect in accordance with the provisions on entry into force and on provisional application. (73)

¹⁶¹ The Paris Convention Revision Conferences were held in 1911 (Washington), 1925 (The Hague), 1934 (London), 1958 (Lisbon), and 1967 (Stockholm).

¹⁶² Accordingly, the Berne Convention was amended in 1979.

¹⁶³ The 1886 original text of the Berne Convention has undergone revisions or completions in 1896 (Paris), 1908 (Berlin), 1914 (Berne), 1928 (Rome), 1948 (Brussels), 1967 (Stockholm), and 1971 (Paris).

¹⁶⁴ See composite text of 23 July 1990, circulated by the Chairman (Lars E. R. Anell) of the TRIPS Negotiating Group, document MTN.GNG/NG11/W/76.

(ii) Amendments merely serving the purpose to adjust to higher levels of protection of intellectual property rights achieved, and in force, in other multilateral agreements and accepted by all PARTIES may be adopted by the Committee. (73)”

Comparing these proposals, there is a striking similarity between the proposal under “A” and the final version of Article 71.1. The proposal refers to the same kinds of review as mentioned earlier (see 1.1 above). The only substantive difference is that under the proposal, the Parties were *obliged* to undertake reviews in case of relevant new developments, whereas under Article 71.1, the TRIPS Council *may* do so. By contrast, this proposal did not contain a separate paragraph dealing with amendment as Article 71.2.

The “B” proposal differed from Article 71 in two important respects: first, it did not make any provision for the review of domestic implementation laws. Second, the “B” proposal did not contain a specific legal basis for “spontaneous” reviews of the Agreement in the light of relevant new developments. Finally, the “B” proposal with respect to the introduction of higher levels of IP protection was essentially similar to Article 71.2 TRIPS.

2.2.2 The Brussels Draft

This draft¹⁶⁵ came very close to the current Article 71. It provided:

“1. PARTIES shall review the implementation of this Agreement after the expiration of the transitional period referred to in paragraph 2 of Article [65]. They shall, having regard to the experience gained in its implementation, review it [-] years after that date, and at identical intervals thereafter. The PARTIES may undertake reviews in the light of any relevant new developments which might warrant modification or amendment of this Agreement.

2. Amendments merely serving the purpose of adjusting to higher levels of protection of intellectual property rights achieved, and in force, in other multilateral agreements and accepted by all PARTIES may be adopted by the Committee.”

The first paragraph derived from the “A” proposal under the Anell Draft and thus established the obligation of Members to have their domestic legislation reviewed by the TRIPS Council (referred to as the “Committee” in the Brussels draft).¹⁶⁶ The second paragraph was directly taken from the “B” proposal in the Anell Draft (see above).

3. Possible interpretations

3.1 Article 71.1

1. The Council for TRIPS shall review the implementation of this Agreement after the expiration of the transitional period referred to in paragraph 2 of Article 65. The Council shall, having regard to the experience gained in its implementation,

¹⁶⁵ Document MTN.TNC/W/35/Rev. 1 of 3 December 1990.

¹⁶⁶ For an historical overview of the Uruguay Round negotiations on the establishment of the Council for TRIPS, see Chapter 35.

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review it two years after that date, and at identical intervals thereafter. The Council may also undertake reviews in the light of any relevant new developments which might warrant modification or amendment of this Agreement.

As stated in the introduction, this provision establishes three distinct forms of review:

a) The first sentence refers to the *mandatory* review of WTO Members' domestic implementing legislation. It has to be read in conjunction with Articles 65.2 and 63.2. The former provides the basis for computing the actual date for the commencement of the review of the TRIPS implementation in the Council, which is at the same time the date of the expiration of the transitional period after which developing country Members are obliged to comply with TRIPS (i.e., 1 January 2000).¹⁶⁷ Article 63.2 obliges Members to notify the Council about their intellectual property-related laws and regulations for the purpose of assisting the Council in its review of the operation of the Agreement.¹⁶⁸ Such review is one of the core competencies of the Council for TRIPS, as stipulated under Article 68.¹⁶⁹ Seen from a larger perspective, necessity for the review exercise under Article 71.1 arises from each Member's obligation to ensure the conformity of its laws, regulations and administrative procedures with its obligations under the covered agreements (see Article XVI:4 of the WTO Agreement).¹⁷⁰

The five-year transitional period referred to in Article 65, paragraph 2, expired on 1 January 2000. Therefore, the first review of developing countries' TRIPS legislation started in 2000.¹⁷¹ As far as developed country Members are concerned, review of their implementing legislation by the Council started as early as 1996.¹⁷² This earlier date is not expressly referred to in Article 71.1. However, it may be inferred from that provision that the review of a Member's implementing legislation may start after the expiry of the transitional period applying to that Member. For developed country Members, that was 1 January 1996 (see Article 65.1).

Article 71 does not define "implementation". However, according to Article 63.2, Members shall notify to the Council their laws and regulations pertaining to the subject matter of TRIPS (i.e., the availability, scope, acquisition, enforcement and prevention of the abuse of IPRs) with a view to assisting the Council in its review of the operation of the Agreement. Thus, review of a Member's implementation encompasses domestic legislation passed by parliament as well as regulations adopted by the administration. On the other hand, the Article 71.1 review does not extend to a Member's final judicial decisions and administrative rulings of general application. This follows from Article 63.2 that refers only to laws and

¹⁶⁷ For details, see Chapter 33.

¹⁶⁸ For more details on Article 63 TRIPS, see Chapter 31.

¹⁶⁹ For more details on Article 68 TRIPS, see Chapter 35.

¹⁷⁰ Article XVI:4 of the Marrakesh Agreement establishing the World Trade Organization reads as follows: "Each Member shall ensure the conformity of its laws, regulations and administrative procedures with its obligations as provided in the annexed Agreements."

¹⁷¹ For a list of those developing country Members whose legislation is currently being reviewed, see the IP gateway page at <<http://www.wto.org/>>.

¹⁷² *Ibid*, with an overview of the reviewed IPR categories.

regulations as the objects of the review. As to judicial decisions, they are not subject to the review because of the division of powers, which makes the judiciary independent of a national government's control. Concerning "administrative rulings of general application", they need to be distinguished from "regulations" that according to Article 63.2 are subject to review by the Council. Both are instruments of the administration, and both are addressed to an undetermined number of people (as opposed to one single party). The difference is that regulations of any sort apply to a multitude of cases, whereas administrative rulings of general application, even though addressed to the public at large, concern only particular facts of one particular case. This follows from the term "ruling". Such ruling is of general application in the sense that it is not addressed to one single party only (like an administrative act), but to an undetermined number of addressees. This limitation to one particular case is the reason why such administrative rulings are not subject to the review by the Council under Articles 63.2 and 71.1. Contrary to laws or regulations that apply to an indefinite number of cases, a case-specific administrative ruling, even though addressed to the public at large, does not represent a generally valid application of the law and therefore cannot be considered as a Member's implementation of TRIPS for the purpose of Article 71.1.

In this context, it is important to stress that the review of domestic laws and regulations by the Council is neither related to, nor a first phase of, the WTO dispute settlement procedures. In case other Members during the review express doubts about the TRIPS compatibility of the legislation under review, this will not lead to an automatic establishment of a WTO panel. For this purpose, the Dispute Settlement Understanding (DSU) provides for a separate set of procedural rules to be followed.¹⁷³ A possible panel would have to assess the case before it independently of some views expressed in the Council during the review exercise. Thus, the review of domestic legislation should rather be considered as a means of multilateral consultations with a view to making the recourse to dispute settlement procedures unnecessary. This is confirmed by the title of Part V of TRIPS that refers to "Dispute Prevention and Settlement". Part V consists of only two Articles, 63 and 64. The latter is on "Dispute Settlement". Thus, the reference in the title to dispute prevention can only be to Article 63, which deals, *inter alia*, with the review by the Council of domestic laws.

b) The second sentence obliges the Council to review TRIPS itself ("review it"). This exercise is not to be commenced at the same time as the review of the national implementing legislation, but two years later (i.e., as of 1 January 2002). This time frame appears very ambitious considering that in actual practice, the Council so far has not started reviewing the provisions of TRIPS under the Article 71.1 mandate. This is due to the fact that the review of the domestic implementing legislations (see above) has not yet been concluded. As the Council when reviewing TRIPS shall have "regard to the experience gained in its implementation", it would be against the spirit of this provision to engage in a substantive TRIPS review before such experience has fully been acquired.

Article 71 contains a general mandate for the review of all TRIPS provisions. In particular cases, other TRIPS provisions that contain a more specific review

¹⁷³ For more details on WTO dispute settlement in the context of TRIPS, see Chapter 32.

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mandate concerning a particular provision will prevail over Article 71. For instance, as far as the review of the TRIPS rules on the protection of biological material is concerned, Article 27.3(b) represents a *lex specialis*, prevailing over Article 71.1.¹⁷⁴

With respect to the authorization of the Council to review TRIPS under Article 71, the question arises if such review would be limited to the formulation of non-binding recommendations (concerning the interpretation of certain TRIPS provisions), or if it would authorize the TRIPS Council to actually propose legally binding amendments to the Ministerial Conference according to Article X:1 of the WTO Agreement.¹⁷⁵ In this respect, the view has been expressed that Article 71.1 does not provide the TRIPS Council with a mandate to propose any amendments to TRIPS.¹⁷⁶ In this vein, it could be argued that such mandate would be referred to in express terms, like under Articles 23.4,¹⁷⁷ 64.3¹⁷⁸ and 71.2 (see below). On the other hand, Article X:1 expressly authorizes the GATT, GATS and TRIPS Councils to “submit to the Ministerial Conference proposals to amend the provisions of the corresponding Multilateral Trade Agreements . . . the functioning of which they oversee.” In addition, it should not be overlooked that according to the third sentence of Article 71.1, the Council may undertake reviews “in the light of any relevant new developments which might warrant modification or amendment” of TRIPS. This kind of review implies an authorization by the Council to propose amendments (or modifications) to the Ministerial Conference (see below). The purpose behind this provision is to ensure that TRIPS addresses in an efficient way current trends in actual IP practice. The same reasoning applies to the second sentence. By stating that the review of TRIPS shall be guided by the experience gained in its implementation, this provision shows Members’ intention to adapt the TRIPS provisions to actual needs and practices, including the amendment of provisions that have proven difficult to implement. Efficiency of TRIPS with respect to its objectives can only be ensured if its provisions may actually be amended in case they turn out to be contrary to what is practicable on the domestic level. Therefore, it appears logical to consider the mandate given to the Council under the second sentence of Article 71.1 as encompassing the possibility of proposing substantive amendments to the Ministerial Conference.¹⁷⁹ While the

¹⁷⁴ Note that the special review of the provisions under Article 27.3(b) should have commenced in 1999. Due to disagreement between Members concerning the scope of the review, this exercise was delayed. For more details on the Article 27.3(b) review, see Chapter 21.

¹⁷⁵ Pursuant to this provision, the TRIPS Council may propose amendments of the TRIPS Agreement to the Ministerial Conference. The final acceptance of any proposed amendment is up to the WTO Members.

¹⁷⁶ See Communication of Australia of 3 October 2000, WTO document IP/C/W/210, page 5.

¹⁷⁷ This provision obligates the TRIPS Council to undertake negotiations concerning the establishment of a multilateral register for geographical indications for wines.

¹⁷⁸ Article 64.3 obliges the TRIPS Council to submit to the Ministerial Conference recommendations with respect to the applicability of non-violation complaints in the context of TRIPS.

¹⁷⁹ Such proposals would then follow the procedure laid down in Article X:1 of the WTO Agreement: the Ministerial Conference would have to decide by consensus to submit the proposed amendment to the Members for acceptance.

review exercise as such is mandatory (“The Council shall [...] review it [...]”), the Council is free to actually make proposals for amendment.

c) The third sentence authorizes the Council to conduct reviews in the light of any relevant new development that might warrant amendment or modification of the Agreement. Contrary to the other forms of review (see above), this review is not mandatory and may be undertaken any time. As mentioned above, the TRIPS Council is expressly authorized, under the third sentence, to propose amendments of TRIPS to the Ministerial Conference.

Summing up, the sequential logic of actions to be taken by WTO Members under Articles 63.2 and 71.1 includes:

- notification of relevant laws and regulations by Members implementing TRIPS (Article 63.2);
- collective review of Members’ intellectual property systems (Article 71.1, first sentence);
- collective review of the provisions of the TRIPS Agreement (Article 71.1, second and third sentence);
- consideration of possible amendments and modifications in the light of the experience of implementation (second sentence) or relevant new developments (third sentence);
- possible formulation of proposals for modification or amendment to be submitted to the Ministerial Conference (second and third sentence).

3.2 Article 71.2

2. Amendments merely serving the purpose of adjusting to higher levels of protection of intellectual property rights achieved, and in force, in other multilateral agreements and accepted under those agreements by all Members of the WTO may be referred to the Ministerial Conference for action in accordance with paragraph 6 of Article X of the WTO Agreement on the basis of a consensus proposal from the Council for TRIPS.

Article X:6 of the WTO Agreement provides:

“Notwithstanding the other provisions of this Article, amendments to the Agreement on TRIPS meeting the requirements of paragraph 2 of Article 71 thereof may be adopted by the Ministerial Conference without further formal acceptance process.”

The purpose of Article 71.2 of TRIPS is to facilitate the adoption of certain amendments by exempting them from the lengthy acceptance process provided under Article X:1 of the WTO Agreement. Amendments falling under Article 71.2 may be adopted directly by the Ministerial Conference, and do not have to be submitted, by consensus, to the Members for acceptance.¹⁸⁰

¹⁸⁰ Acceptance through a Member usually means that the proposed amendment has to be approved by the respective national parliament, depending on constitutional requirements. This might take

4. WTO jurisprudence

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As to the multilateral agreements referred to in Article 71.2, there does not seem to be any of that kind in force at present. The WIPO-sponsored Copyright Treaty (WCT) and the Performers and Phonograms Treaty (WPPT) have some potential eventually to fall under this provision. However, Article 71.2 requires the acceptance by all WTO Members of the higher IPR standards under the respective agreements.

Finally, the case of amending TRIPS for the purpose of adjusting the Agreement to higher levels of IP protection has to be distinguished from the case where higher levels of IP protection are agreed upon in a separate treaty by a limited number of WTO Members and subsequently have to be extended to all other Members on the basis of the most-favoured-nation principle (MFN). MFN requires any Member granting higher IP protection to the nationals of any other country (not necessarily a WTO Member) to accord the same TRIPS-plus protection to the nationals of all other WTO Members (Article 4 TRIPS). But such obligation only applies to those Members that are parties to the relevant TRIPS-plus agreement. Non-party WTO Members are not obliged to grant the same level of TRIPS-plus protection, even though they are entitled to claim such protection for their nationals. By contrast, an amendment of TRIPS binds all WTO Members. The WCT and WPPT may serve to illustrate this point. Those WTO Members that are parties to these treaties have to accord any TRIPS-plus IP protection deriving from the WIPO treaties to all other WTO Members, even those that are not parties to the WIPO treaties.¹⁸¹ But those non-parties in their territories do not have to grant the same rights. If, by contrast, the higher levels of protection were agreed upon in an amendment to TRIPS, they would have to be complied with by all WTO Members.

4. WTO jurisprudence

So far, there have been no cases before a panel or the Appellate Body dealing specifically with Article 71.

5. Relationship with other international instruments

5.1 WTO Agreements

As mentioned above, Article X:6, WTO Agreement, refers to Article 71 in the context of simplified adoption procedures. Another WTO provision also dealing with

a considerable amount of time. In comparison, acceptance by the Ministerial Conference will be much speedier.

¹⁸¹ Note that according to Article 5, the MFN obligation does not apply in the case of the WIPO treaties on acquisition or maintenance of IPRs. These encompass the Madrid Agreement (and Protocol) Concerning the International Registration of Marks, the Hague Agreement Concerning the International Deposit of Industrial Designs, the Patent Cooperation Treaty, the Trademark Registration Treaty and the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, and certain provisions of the Lisbon Agreement for the Protection of Appellations of Origin and their International Registration. The list of such agreements is not fixed, and new multilateral acquisition and maintenance agreements adopted under WIPO auspices would also qualify for national and MFN treatment exemption under Article 5 of the TRIPS Agreement. For details, see Chapter 4.

amendments is Article XXX of the GATT 1994, but it is limited to the trade in goods sector.

5.2 Other international instruments

As indicated above (Section 2.1), provisions on review and amendment are not particular to TRIPS, but also exist, *inter alia*, under the Paris and Berne Conventions. Since these Conventions have to be respected by all WTO Members (see Articles 2.1 and 9.1), any amendments to their texts are automatically binding, even for those Members not parties to the respective Convention. This does not apply vice versa, in that TRIPS amendments will not be binding on countries that are Paris/Berne Convention parties, but not WTO Members.

6. New developments

6.1 National laws

6.2 International instruments

In February 2000 the WTO General Council agreed that mandated reviews should address the trade and development impact on developing countries of the agreement concerned.¹⁸² Even more importantly, at the 2001 Ministerial Conference at Doha, Members in the Ministerial Declaration referred to the Article 71.1 review as follows:

“We instruct the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 [...], to examine, *inter alia*, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by Members pursuant to Article 71.1. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension.”¹⁸³

By referring to the development dimension/impact, both of the above instruments make an important contribution to the clarification of the criteria according to

¹⁸² WT/GC/M/53, paragraph 39.

¹⁸³ See para. 19 of the Ministerial Declaration of 14 November 2001, WTO document WT/MIN(01)/DEC/W/1. Article 7 of the TRIPS Agreement reads:

“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 the balance of rights and obligations.”

Article 8 establishes the principles that underpin the TRIPS Agreement:

“1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.”

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which TRIPS reviews under Article 71 should be undertaken. In addition, the Doha Declaration as quoted above obliges the Council to take into account the public policy objectives in Articles 7 and 8, i.e., *inter alia*, technological innovation and the transfer and dissemination of technology, the protection of public health and nutrition, the promotion of the public interest in sectors of vital importance to socio-economic and technological development, and the control of IPR abuses and other restrictive behaviour. This means that when reviewing national implementing legislation, compliance with TRIPS minimum standards shall not be considered an objective in itself, but rather a means of promoting the non-IP policy goals referred to above (see Section 7 below).

The Doha Declaration as cited above also contains some concrete proposals for topics to be examined under the Articles 27.3(b) and 71.1 reviews (i.e., with respect to the Convention on Biological Diversity, traditional knowledge and folklore, and other relevant new developments). Even though these topics are not expressly assigned to one particular review, Article 27.3(b) is the *lex specialis* in the area of biodiversity, traditional knowledge and folklore, whereas the “other relevant new developments” are a reference to the review under the third sentence of Article 71.1.

6.3 Regional and bilateral contexts

6.3.1 Regional

6.4 Proposals for review

There have been no proposals to review Article 71 itself.

7. Comments, including economic and social implications

As observed above, Article 71 serves the purpose of ensuring that national implementing legislation is in conformity with TRIPS, and that the TRIPS provisions themselves correspond to the actual needs and trends in trade-related IPRs. Article 71 is supposed to ensure the efficiency of the Agreement with respect to the attainment of its objectives. These objectives set the criteria according to which the Council for TRIPS examines national implementing legislation as well as possible amendments to TRIPS. The assessment of the current state of domestic laws and of TRIPS provisions, and consequently the possible need for changes, will vary according to what is considered the main objective of the Agreement. Developed country Members tend to emphasize the private property nature of IPRs, whereas developing country Members put more emphasis on the public policy objectives of the Agreement. The former position is partly supported by the TRIPS preamble that refers to the promotion of “effective and adequate protection” of IPRs. In addition, the provisions on substantive and procedural IPRs standards as spelled out in TRIPS are very detailed, whereas the public policy objectives are held in very general terms. In this vein, it has been observed that

“The TRIPS Agreement was essentially conceived as a means of strengthening the control by titleholders over the protected technologies, and not with the objective of increasing the transfer and use of technology globally. The transfer of technology

was not, in fact, a concern of TRIPS proponents, and the possible effects of the new protectionist standards on such transfer were never seriously considered during the negotiations.”¹⁸⁴

TRIPS is actually the result of a political compromise. In order to make the Agreement more acceptable to developing countries, some rather broad provisions on technology transfer and other public policy objectives were included in the Agreement.¹⁸⁵

On the other hand, the broad formulation of these objectives provides Members with discretion as to the interpretation of the TRIPS disciplines. Also, the TRIPS objectives are recognized in the preamble as underlying the national systems for the protection of IP. Article 7 refers to certain societal benefits as objectives to be attained through the protection and enforcement of IPRs.¹⁸⁶ In addition to that, the Doha Ministerial Declaration has expressly stated that TRIPS reviews are to be guided by the objectives and principles in Articles 7 and 8,¹⁸⁷ taking full account of the development dimension. Finally, the General Council agreed that reviews should address the trade and development impact on developing countries of the agreement concerned (see above, Section 6.2).

In this vein, the review of the national implementing legislation and of the TRIPS provisions would have to be directed at assessing the suitability of those rules for the promotion of public policy goals as stipulated under Articles 7 and 8. Also, the review exercise should be conducted with a view to assessing the impact of IPR standards on the realization of non-IP development goals, seeking to reconcile possible collisions of interest between these two areas.

Thus, IPR standards in TRIPS should be conceived as a means for the promotion of non-IP public policy objectives, and not as running counter to them. As a result, any review under Article 71 should take account of both public policy goals and the protection of private rights. On the one hand, Members have to examine whether national implementing legislation complies with the TRIPS standards. On the other, the review will have to address the question of whether these standards leave sufficient leeway for the realization of certain non-IPR-related objectives.

Addressing the development dimension while reviewing TRIPS would include considering the implementation of TRIPS in key sectors of concern to developing countries, such as technology transfer,¹⁸⁸ measures to counter anti-competitive abuse of intellectual property rights under Article 40,¹⁸⁹ the digital environment,¹⁹⁰

¹⁸⁴ See C. Correa, *Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?* Draft of March 2003, submitted to a Conference at Duke University [hereinafter Correa, Draft].

¹⁸⁵ For an historical overview of the TRIPS negotiations and the position of developing countries, see UNCTAD-ICTSD Policy Discussion Paper, Part I, Chapter 2 (“The emergence of TRIPS”). For a detailed analysis of the public policy objectives of the TRIPS Agreement, see Chapter 6 (Articles 7 and 8 of this book).

¹⁸⁶ For the text of Article 7 see above, Section 6.2.

¹⁸⁷ For the text of Article 8, as well as the relevant part of the Doha Declaration, see above, Section 6.2. It should be noted that Articles 7 and 8 constitute the “object and purpose” of the Agreement for the purposes of its interpretation, according to Article 31 of the Vienna Convention on the Law of Treaties.

¹⁸⁸ See Chapter 34.

¹⁸⁹ See Chapter 29.

¹⁹⁰ See, Chapter 7.

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IPRs in traditional and indigenous contexts¹⁹¹ and compulsory licensing.¹⁹² It would also include consideration of extending the moratorium of the application to the Agreement of the non-violation complaint remedy¹⁹³ and a debate as to whether it is necessary to include general exceptions clauses in TRIPS.¹⁹⁴

¹⁹¹ See Chapter 21.

¹⁹² See Chapter 25.

¹⁹³ See Chapter 32.

¹⁹⁴ See The South Centre, *Review of TRIPS Agreement under Article 71.1*, Occasional Papers No. 3 by M. Stilwell and C. Monagle, December 2000, also covering the other sectors referred to above.

38: Reservations

Article 72 Reservations

Reservations may not be entered in respect of any of the provisions of this Agreement without the consent of the other Members.

1. Introduction: terminology, definition and scope

Article 72 provides that a Member may not enter a reservation to all or part of the Agreement without the consent of the other Members. A reservation is a statement by which a party to a treaty undertakes to modify its obligations when it becomes party to the treaty (see VCLT, Articles 2(d), 19–23). The allowance of reservations to TRIPS may have created a situation in which different rules applied to different Members. This would not be so different from the situation in which Members enter exceptions in GATS Schedules of Commitments. This is not the approach followed by TRIPS.

2. History of the provision

2.1 Situation pre-TRIPS

The Vienna Convention on the Law of Treaties expressly addresses reservations to treaties and their effect (see Articles 19–23). There is an extensive legal literature on the nature and effect of reservations,¹⁹⁵ and there are decisions of international tribunals that address them. Generally, a reservation to a treaty may be entered by a state adhering to it provided that the treaty does not expressly exclude this, or if this would be inconsistent with the object and purpose of the treaty. If other state parties to the treaty do not object to the reservation, it will take effect. If a party objects to a reservation, it does not take effect with respect to that party. The result for the adhering (i.e., reserving) party's treaty obligations in that situation will vary depending on the circumstances (see Article 21.3 of the VCLT).

¹⁹⁵ See generally, *Parliamentary Participation in the Making and Operation of Treaties: A Comparative Study* (S. A. Riesenfeld & F. M. Abbott, eds. 1994: Martinus Nijhoff/Kluwer).

2. History of the provision

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2.2 Negotiating history

There is no analogue to Article 72 in negotiating texts prior to the Brussels Ministerial Text of December 1990. Up through the Montreal Mid-Term Ministerial in 1988, developing countries on the whole had not accepted that TRIPS would be binding on all Members, and the question of reservations was not especially relevant until the decision to accept the concept of the single undertaking was made.¹⁹⁶ Throughout the TRIPS negotiating process, issues concerning permissible exceptions to obligations, and later on the issue of transitional arrangements, were discussed extensively. These discussions considered differences in developmental circumstances among prospective Members to the agreement. The prospect of differentiated obligation on a Member-by-Member basis does not appear to have been considered in any detail, though this would have been one way to take into account different developmental circumstances.

2.2.1 The Brussels Draft

The Brussels Ministerial Text¹⁹⁷ included a predecessor to Article 72 that would have permitted reservations under limited conditions:

“Article 75: Reservations:

A PARTY may only enter reservations in respect of any of the provisions of this Agreement at the time of entry into force of this Agreement for that PARTY and with the consent of the other PARTIES.”

By referring to reservations in an affirmative way (that is, by indicating when Members may enter them), the Brussels Draft provision implied that Members at least contemplated the possibility of bargaining toward differentiated TRIPS commitments on a Member-by-Member basis. If the negotiating parties had bargained toward acceptable sets of reservations prior to the conclusion of TRIPS, the Agreement might ultimately have taken on a substantially different character than that ultimately achieved.¹⁹⁸ Article 75 of the Brussels Ministerial Text reflects the fact that the “single undertaking” concept embodied in the WTO Agreement was not settled as of late 1990.

2.2.2 The Dunkel Draft

The Dunkel Draft text of late 1991 amended the reservations clause of the Brussels Ministerial Text, substituting for it a “no reservations without consent” clause.¹⁹⁹

¹⁹⁶ On the TRIPS Agreement negotiating process, see Silvia Ostry, *The Uruguay Round North-South Grand Bargain: Implications for future negotiations*, at 285; J. Michael Finger, *The Uruguay Round North-South bargain: Will the WTO get over it?*, at 301; Frederick M. Abbott, *The TRIPS-legality of measures taken to address public health crises: Responding to USTR-State-industry positions that undermine the WTO*, at 311, and; T.N. Srinivasan, *The TRIPS Agreement*, at 343, each in *The Political Economy of International Trade: Essays in Honor of Robert E. Hudec* (eds. D. Kennedy and J. Southwick 2002)(Cambridge University Press).

¹⁹⁷ Document MTN.TNC/W/35/Rev. 1 of 3 December 1990.

¹⁹⁸ TRIPS takes account of differences in the level of development among Members principally, though not exclusively, through its transition provisions (Articles 65, 66 and 70, see Chapters 33, 36).

¹⁹⁹ Recall the final text of Article 72, which provides: “Reservations may not be entered in respect of any of the provisions of this Agreement without the consent of the other Members.”

Though seemingly admitting for the possibility of reservations, the negative drafting of the Dunkel Draft and final TRIPS Agreement reservations text appeared to signal an important distinction between TRIPS and the GATT and GATS. Although neither the GATT nor GATS specifically provides for reservations, commitments on tariff bindings and services market access are made on a Member-by-Member basis, and these commitments are made in the context of individualized reciprocal negotiations. In practical effect, this is similar to the allowance of reservations. The WTO Agreement does not permit reservations to its own terms, and provides that “Reservations in respect of any of the provisions of the Multilateral Trade Agreements [including TRIPS] may only be made to the extent provided for in those Agreements” (Article XVI: 5, WTO Agreement).

3. Possible interpretations

Article 72 Reservations

Reservations may not be entered in respect of any of the provisions of this Agreement without the consent of the other Members.

There is limited practical scope for interpretative disagreement as to the meaning of Article 72 precluding the entry of reservations absent the consent of the other Members. Under the VCLT and customary international law, reservations may only be entered upon adherence to a treaty.²⁰⁰ No Member attempted to enter a reservation to TRIPS when the WTO Agreement was initially concluded. This leaves little possibility that an issue with respect to Article 72 might surface in connection with original WTO membership. An interpretive issue theoretically might arise upon accession of a new Member to the WTO.²⁰¹ However, as a practical matter this is unlikely because a new Member accedes to the WTO (and TRIPS Agreement) on the basis of an accession agreement (a Protocol of Accession), and this agreement is concluded by consensus (absent exceptional circumstances). If there were a consensus among Members as to a waiver or modification of a TRIPS Agreement obligation in an accession agreement, this would be the

²⁰⁰ Article 19, VCLT. Technically, a reservation may be formulated “when signing, ratifying, accepting, approving or acceding to a treaty”, *id.*

²⁰¹ A question might arise whether the consent of the other Members to a reservation must take place by some affirmative act, or might be tacit or passive (i.e., by lack of formal objection to a reservation). Article 72 does not specify the form by which acceptance of other Members must take place, and there is room to argue that the lack of an objection by any of the other Members to a reservation could constitute its acceptance. Article 20(1) of the VCLT provides that if a treaty allows for a particular reservation, no acceptance is required by other parties. Otherwise, acceptance is required. In general (unless the treaty provides otherwise) acceptance will be presumed if the party does not object within 12 months following notification (Article 20(5), VCLT). Article 20(5) of the VCLT makes clear that a reservation must be “notified” to other Members for it to be subject to tacit or passive acceptance, and Article 23(1) indicates that a reservation must be in written form. Since it must be “notified” as a reservation in written form, it is unlikely that a reservation made by an acceding Member could be inadvertently accepted by other Members by failing to object to it.

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substantive equivalent of a reservation with the consent of the other Members. It seems doubtful that such a waiver or modification would be legally framed as a “reservation” but, if it was, the consent of the other Members would be present and an interpretive issue would not arise.²⁰² It is difficult to foresee the context in which an acceding Member might propose to modify the terms of TRIPS by entering a reservation outside its Protocol of Accession.

4. WTO jurisprudence

There have been no WTO disputes on Article 72.

5. Relationship with other international instruments

5.1 WTO Agreements

The WTO Agreement provides at Article XVI:5:

“5. No reservations may be made in respect of any provision of this Agreement. Reservations in respect of any of the provisions of the Multilateral Trade Agreements may only be made to the extent provided for in those Agreements. Reservations in respect of a provision of a Plurilateral Trade Agreement shall be governed by the provisions of that Agreement.”

Article 72, pursuant to Article XVI:5 of the WTO Agreement, governs the extent to which reservations may be entered in respect of TRIPS.

5.2 Other international instruments

The Vienna Convention on the Law of Treaties prescribes rules regarding reservations at Articles 19–23.

6. New developments

6.1 Proposals for review

No proposals have been made to review Article 72.

7. Comments, including economic and social implications

TRIPS does not permit reservations absent the consent of the Members. The same rules generally apply to all Members. Transitional mechanisms are intended to ease potential economic and social dislocations. TRIPS negotiators might have

²⁰² The question might be asked whether consent of the “other Members” means “all” of the other Members, or might mean only “some” or “a few” of the other Members. If negotiators had intended that a limited number of Members might among themselves agree on a reservation, this might better have been made explicit. There might have been reference to a reservation accepted by “another Member”. The consequences of such an individuated arrangement (e.g., from an MFN standpoint) might have been addressed. Absent some persuasive evidence that negotiators intended a fairly dramatic break with the general application of the TRIPS Agreement, there is little reason to suggest that less than all Members might accept a reservation as among themselves.

taken another approach and allowed each Member to negotiate its own intellectual property commitments based on its particular situation. If negotiators had followed this alternative approach, they probably would not have employed the legal formula of allowing reservations. More likely they would have adopted schedules of commitments along the lines of the GATS. Article 72 is significant largely for confirming the single undertaking approach adopted in TRIPS.

39: Security Exceptions

Article 73 Security Exceptions

Nothing in this Agreement shall be construed:

- (a) to require a Member to furnish any information the disclosure of which it considers contrary to its essential security interests; or
- (b) to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests;
 - (i) relating to fissionable materials or the materials from which they are derived;
 - (ii) relating to the traffic in arms, ammunition and implements of war and to such traffic in other goods and materials as is carried on directly or indirectly for the purpose of supplying a military establishment;
 - (iii) taken in time of war or other emergency in international relations; or
- (c) to prevent a Member from taking any action in pursuance of its obligations under the United Nations Charter for the maintenance of international peace and security.

1. Introduction: terminology, definition and scope

Although there is a relatively widespread tendency among scholars to perceive international trade law as a concept differing from the classical idea of state sovereignty and to regard national security, borders and territory as state interests difficult to reconcile with liberalization of markets,²⁰³ the provision of Article 73, almost identical to Article XXI of the GATT and Article XIV *bis* of the GATS, proves that these traditional state interests continue to be a major concern of WTO Members.²⁰⁴

²⁰³ See, for instance, D.M. McRae, *The Contribution of International Trade Law to the Development of International Law*, Collected Courses of The Hague Academy of International Law, 1996, v. 260, pp. 99–238, at pp. 130–131.

²⁰⁴ For a more detailed analysis as to whether international trade law challenges the existing paradigm of public international law, see Mariano Garcia-Rubio, *On the Application of Customary Rules of State Responsibility by the WTO Dispute Settlement Organs – A General International Law Perspective* – Geneva, Studies and Working Papers, Graduate Institute of International Studies, 2000, p. 100, particularly Chapter 1 [in the following: Garcia-Rubio].

There was a clear reluctance among the former Contracting Parties of the GATT 1947 (which still exists as the “GATT 1994” among WTO Members) to activate the institutionalized dispute settlement mechanisms to deal with disputes involving the interpretation of the national security exceptions. The WTO is not perceived as an adequate forum for dealing with national security issues. Under the GATT 1947, only four such cases reached the level of formalized dispute settlement, while no panel established since the creation of the WTO for dealing with these kinds of disputes has succeeded in producing a report.²⁰⁵ Tacit agreement seems to exist among states to exclude the trade distortions originating from unilateral economic sanctions imposed for alleged security reasons from the scope of disputes to be solved through the compulsory dispute settlement system of the WTO.²⁰⁶

Article 73 allows states to take three kinds of measures contrary to their normal obligations under TRIPS: to preserve undisclosed security-sensitive information (para. a); to act in pursuance of obligations flowing from the Charter of the United Nations (para. c); or to take “any action” they “consider [...] necessary for the protection of [their] essential security interests (para. b) relating to nuclear materials (sub-para. i), trade in arms, ammunition and the like (sub-para. ii), or to redress war and other emergencies in international relations (sub-para. iii).

No dispute has been brought before the WTO dispute settlement organs regarding economic sanctions imposed by the Security Council of the United Nations under Chapter VII of the Charter. Although paragraph (c) of Article 73 is in line with Article 103 of the UN Charter, the compatibility of the adopted measures with the UN Security Council orders they are meant to serve could have potentially been the object of a WTO dispute. However, this situation has never arisen.²⁰⁷

2. History of the provision

2.1 Situation pre-TRIPS

At the outset of the negotiations on the establishment of the International Trade Organization, the suggested Charter, as proposed by the United States in 1946, as well as the first draft prepared by the Preparatory Committee in London in October and November of 1946 and the draft prepared by a technical drafting committee in New York in January and February of 1947, provided for national security exceptions only as a part of the general exceptions of the chapters on commercial policy and commodity agreements.²⁰⁸ Only at the meeting of the Preparatory Committee in Geneva from April to October 1947 was it decided to transfer the security

²⁰⁵ See below, Section 4.

²⁰⁶ To illustrate this point, see for instance the list of unilateral economic sanctions adopted by the Council of the European Union (which have never been the object of a dispute before the WTO dispute settlement organs) in Ramses Wessel, *The European Union's Foreign and Security Policy – A Legal Institutional Perspective*, The Hague, Kluwer Law International, 1999, p. 340 and ff.

²⁰⁷ Nevertheless, we share the doubts of Schloemann and Ohloff as to the competence of WTO panels to deal with such cases. See Hannes L. Schloemann, and Stefan Ohloff, ‘*Constitutionalization and Dispute Settlement in the WTO: National Security as an Issue of Competence*, *American Journal of International Law*, v. 93, no. 2, 1999, pp. 424–451, at p. 431 [hereinafter Schloemann/Ohloff]. Also Garcia-Rubio, at p. 52.

²⁰⁸ GATT, *Analytical Index: Guide to GATT Law and Practice* (6th. rev. ed., 1995), at 608 [hereinafter Analytical Index].

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exceptions from the general exceptions to a separate article at the end of the Charter, which was practically identical with the present text of GATT Article XXI.²⁰⁹

Concerns were raised at the Geneva meeting about the applicability of the dispute settlement mechanism to the security exceptions. By placing Article XXI between the general exceptions (Article XX) and the dispute settlement provision (Article XXIII), the Contracting Parties to the GATT 1947 made it clear that the dispute settlement mechanism would apply to the new article.

Countries imposing economic sanctions on Argentina after the Falkland/Malvinas events were of the view that they were exercising an inherent right existing under general international law, which was merely reflected by Article XXI of the GATT. This situation led Argentina to request an interpretation of such Article and the then Contracting Parties, although they did not interpret Article XXI, adopted a Decision Concerning Article XXI of the General Agreement.²¹⁰

Article 73 is essentially identical to Article XXI of the GATT 1947 (1994). By contrast, the major pre-TRIPS intellectual property instruments, the Berne and Paris Conventions, do not contain any provision on security exceptions.

2.2 Negotiating history

Neither the Anell Draft²¹¹ nor the Brussels Draft²¹² contained a provision on security exceptions. The Dunkel Draft,²¹³ by contrast, did provide for security exceptions. This provision was essentially the same as the current Article 73.

3. Possible interpretations

The lack of a general interpretation of the meaning and scope of the provision of Article XXI of the GATT gains relevance when it comes to the analysis of the

²⁰⁹ *Ibid.*

²¹⁰ GATT Doc. L/5426 (1982), GATT B.I.S.D. (29th Supp.), at 23 (1983). The text of the decision reads as follow:

“Considering that the exceptions envisaged in Article XXI of the General Agreement constitute an important element for safeguarding the rights of contracting parties when they consider that reasons of security are involved;

Noting that recourse to Article XXI could constitute in certain circumstances, an element of disruption and uncertainty for international trade and affect benefits accruing to contracting parties under the General Agreement;

Recognising that in taking action in terms of the exceptions provided in Article XXI of the General Agreement, contracting parties should take into consideration the interests of third parties which may be affected;

That until such time as the Contracting Parties may decide to make a formal interpretation of Article XXI it is appropriate to set procedural guidelines for its application;

The Contracting Parties decide that:

1. Subject to the exception in Article XXI:a, contracting parties should be informed to the fullest extent possible of trade measures taken under Article XXI.

2. When action is taken under Article XXI, all contracting parties affected by such action retain their full rights under the General Agreement.

3. The Council may be requested to give further consideration to this matter in due course.”

²¹¹ See composite text of 23 July 1990, circulated by the Chairman (Lars E. R. Anell) of the TRIPS Negotiating Group, document MTN.GNG/NG11/W/76.

²¹² Document MTN.TNC/W/35/Rev. 1 of 3 December 1990.

²¹³ Part of document MTN.TNC/W/FA of 20 December 1991.

possible interpretations of Article 73. By stating that it is for the WTO Members to decide what information is essential for their essential security interests²¹⁴ and to define which are those essential security interests,²¹⁵ Article 73 places itself at the core of the tensions between a traditional decentralized legal order and the institutionalized dispute settlement mechanism embodied in the Dispute Settlement Understanding (DSU) of the WTO.²¹⁶ What is the role left for the dispute settlement organs, if any, when a Member invokes national security as a justification for the failure to comply with its obligations under the “covered agreements”?

One interpretation of Article 73 is to consider it not only as a justification, but also as a procedural jurisdictional defence, making a dispute inadmissible *ipso facto* by the mere invocation of the clause. However, there seem to be no grounds either in the negotiating history of the provision at issue or in their textual and contextual interpretation for upholding such a view.²¹⁷ Article 1 of the DSU states that it “shall apply to disputes brought pursuant to the consultation and dispute settlement provisions of the Agreement listed in Appendix 1”, “subject to such special or additional rules and procedures on dispute settlement contained in the covered agreements as are identified in Appendix 2”. No mention is made in such Appendix of any dispute settlement provision applying particularly to disputes concerning the national security exceptions. Therefore, the DSU itself is not subject to a national security exception and no particular rule applies to disputes on the application or interpretation of Article 73 or the analogous provisions in GATT and GATS. Furthermore, if Members were able to circumvent the application of the DSU merely by invoking the national security exception of GATT 1994, GATS or TRIPS, the purpose of strengthening the system that underlies Article 23 of the DSU could not be achieved.²¹⁸

What is, then, the scope of review that panels and the Appellate Body can exercise over measures taken under Article 73 or its analogous provisions in GATT and GATS? It appears that the political qualification of what constitutes a “national security” issue remains a right reserved for the Members themselves. However, the respect of the objective limits imposed on the exercise of that right by Article 73 is a matter of interpretation and, therefore, subject to judicial review.

One of those objective limits is that neither Article 73 nor its analogous provisions in GATT and GATS serves to protect economic security interests.²¹⁹ In

²¹⁴ Paragraph (a) of Article 73 of the TRIPS Agreement.

²¹⁵ Paragraph (b) of Article 73 of the TRIPS Agreement.

²¹⁶ One of the main features of international law is that “each state establishes for itself its legal situation *vis-à-vis* other states”. See *Air Services Agreement* case, 18 R.I.L.A., Vol. XVIII, p. 443, para. 81. See also Abi-Saab, Georges; *Interprétation et Auto-Interprétation: Quelques réflexions sur leur rôle dans la formation et la résolution du différend international*, in *Recht zwischen Umbruch und Bewahrung*, Festschrift für Rudolf Bernhardt, Springer Verlag, Berlin, 1995, pp. 9–19.

²¹⁷ We refer to the negotiating history of the provision in first place because it was already dealt with in this chapter. However, it must be noted that a correct application of Articles 31 and 32 of the Vienna Convention on the Law of Treaties would call for an analysis of the text in its context before making reference to the preparatory work.

²¹⁸ Schloemann/Ohlhoff, p. 439.

²¹⁹ Article XXI GATT requires a rather delicate balance. As expressed by one of the drafters of the provision: “We have got to have some exceptions. We cannot make it too tight, because we cannot

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some cases, however, it may be particularly difficult to establish a clearly cut borderline between commercial purposes and security reasons. As illustrated by the debate on IPRs and access to essential medicines, pandemics such as HIV may pose fundamental threats to the very existence of vulnerable societies. In such cases, it might be possible to invoke the Article 73 security exception for the protection of a nation's essential security interests. Arguably, pandemics such as HIV could be qualified as "emergencies in international relations" as provided under Article 73(b)(iii) (the international relations component being the failure to obtain adequate supplies of medicines within the framework of the multilateral institutional structure). This being said, the issue requires further thought.

Another example in this context refers to Sweden's introduction of a quota for a certain type of shoes in 1975, arguing that a decrease in its domestic capacity to produce footwear, qualifying as a "vital industry", threatened the country's economic defence strategy and thus its security interests. Many Contracting Parties took the view that this was precisely the kind of justification not available under Article XXI. Sweden terminated the quotas imposed on leather and plastic shoes as of 1 July 1977.²²⁰

The compatibility with Article 73 of a measure allegedly adopted for national security reasons may also involve a test of reasonableness and an interpretation of whether the measure is "necessary" to protect the invoked security interests. This was the view taken by the International Court of Justice in the *Nicaragua* case by stating that

"[T]he concept of essential security interests certainly extends beyond the concept of armed attack, and has been subject to very broad interpretations in the past. The Court has therefore to assess whether the risk run by these 'essential security interests' is reasonable, and secondly, whether the measures presented as being designed to protect these interests are not merely useful but 'necessary'".²²¹

Whether a security threat reasonably exists is also a matter of interpretation, and the margin of discretion given to Members under Article 73 to define their national interests can by no means be considered as an absolute discretion.²²² Some delegates noted, in discussing the embargo measures brought by the United States against Nicaragua, that it "was not plausible that a small country with small resources could constitute an extraordinary threat to the national security of the United States".²²³

prohibit measures which are needed purely for security reasons. On the other hand, we cannot make it so broad that, under the guise of security, countries will put on measures which really have a commercial purpose." Cited in GATT, Analytical Index, p. 600.

²²⁰ GATT, Analytical Index, p. 603.

²²¹ *Case Concerning Military and Paramilitary Activities in and against Nicaragua*, ICJ Reports, 1986, p. 117, para. 224.

²²² On the concept of "reasonableness" in international law, see Olivier Corten, *L'utilisation du "raisonnable" par le juge international: discours juridique, raison et contradictions*, Brussels, Bruylant: Ed. de l'Université de Bruxelles, 1997.

²²³ GATT Council, *Minutes of the Meeting Held May 29, 1985*, GATT Doc. C/7/188 (restricted), at p. 7, as cited by M. Hahn, *Vital Interests in the Law of GATT: An Analysis of GATT's Security Exception*, Michigan Journal of International Law, v. 12, 1991, p. 558.

Therefore, “security interests” that are “essential” must be defined by WTO Members in good faith and preventing any abuse of the right.²²⁴ This requires a minimum degree of proportionality between the threatened individual security interest and the measure taken in response to that threat that is clearly subject to judicial review, according to general international law standards, by the competent WTO organs for the settlement of disputes.²²⁵

4. GATT and WTO jurisprudence

Four cases involving the security exception can be said to have reached the level of formalized dispute settlement under Article XXIII of the GATT 1947:

Shortly after the creation of the GATT, in 1949, the United States, through a system of export licenses, imposed a ban on the export of certain products to Czechoslovakia. Czechoslovakia, in turn, resorted to dispute settlement under Article XXIII and the United States invoked, *inter alia*, Article XXI, not as a procedural defence but as a substantive one. Although the Contracting Parties “decided to reject the contention of the Czechoslovak delegation that the Government of the United States had failed to carry out its obligations under the Agreement through its administration of the issue of export licences”,²²⁶ they did not altogether deny their formal Article XXIII jurisdiction over matters involving Article XXI of the GATT 1947.

The Reagan administration’s Central American policy gave rise to two cases relating to Article XXI. In 1983, the United States decided to drastically reduce the share of sugar imports allocated to Nicaragua. The United States did not block either the establishment of the panel or the adoption of its report. Neither did it invoke Article XXI or attempted to defend its actions in GATT terms. According to the 1984 panel report, “The United States stated that it was neither invoking any exceptions under the provisions of the General Agreement nor intending to defend its actions in GATT terms . . . [and that t]he action of the United States did of course affect trade, but was not taken for trade policy reasons”.²²⁷ Consequently, the panel did not examine whether the action could be justified under the security exception because it had not been invoked. However, this fact did not prevent the panel from finding that the United States was in violation of Article XIII (2).²²⁸

In 1985, the United States decided to impose a complete import and export embargo on Nicaragua, which requested the establishment of a panel again. The position of the United States in this case was considerably different to that adopted in the first dispute with Nicaragua. It managed to exclude from the terms of reference of the panel the possibility “to examine or judge the validity of or motivation

²²⁴ See, in general, Robert Kolb, *La bonne foi en droit international public – Contribution à l’étude des principes généraux de droit*, Paris, PUF, 2000, particularly pp. 429 et seq.

²²⁵ See J. Delbrück, *Proportionality*, in R. Bernhardt (ed), *Encyclopedia of Public International Law*, v. 7, 1984, p. 396.

²²⁶ Decision of June 8, 1949, 2 GATT B.I.S.D. 28 (1952).

²²⁷ *United States – Imports of Sugar from Nicaragua*, March 13, 1984, GATT B.I.S.D. (31st. Supp.), at para. 3.10.

²²⁸ *Ibid.* paras. 4.3, 4.5 and 4.7.

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for the invocation of Article XXI:(b)(iii) by the United States . . . ”²²⁹ Some other GATT Contracting Parties, such as Canada and the European Communities agreed with the United States that Article XXI issues were political questions not subject to panel scrutiny.²³⁰ The panel nevertheless referred to the question in the following terms:

“If it were accepted that the interpretation of Article XXI was reserved entirely to the contracting party invoking it, how could the CONTRACTING PARTIES ensure that this general exception to all obligations under the General Agreement is not invoked excessively or for the purposes other than those set out in this provision? If the CONTRACTING PARTIES give a panel the task of examining a case involving an Article XXI invocation without authorizing it to examine the justification of that provision, do they limit the adversely affected contracting party’s right to have its complaint investigated in accordance with Article XXIII:2?”²³¹

In 1991, as a consequence of the civil war in the former Socialist Federal Republic of Yugoslavia, the European Communities decided to restrict trade explicitly on the grounds of Article XXI.²³² Yugoslavia requested the establishment of a panel and argued that the requirements of neither Article XXI(b) nor (c) were met. This could have been the first case in which a panel could have properly analyzed the scope of Article XXI. However, given the uncertainties about the status of Serbia and Montenegro (FRY) as Party to the GATT, the proceedings were suspended by a Council decision in 1993.

Two other situations relating to Article XXI during the GATT era deserve to be mentioned, although they did not reach the level of a formalized dispute under GATT Article XXIII. One is the situation arising out of the sanctions imposed on Argentina in 1982 referred to above (Section 2.1). The other relates to the boycott of Portuguese goods imposed by Ghana in 1961. The particularity of this case resides in the fact that Ghana invoked Article XXI, arguing that each contracting party was the sole judge of what was necessary in its essential security interests and, therefore, there could not be an objection to the boycott.²³³

After the establishment of the WTO, there has been no dispute related to Article 73. However, disputes related to the national security exception under other WTO agreements arose in connection with the extra-territorial effects of some U.S. legislation, notably the *Cuban Liberty and Democratic Solidarity Act* of 1996,²³⁴ and the *Iran and Libya Sanctions Act*.²³⁵

²²⁹ GATT Doc. C/M/196, at 7 (1986).

²³⁰ Such interpretation is based on the view that the mere invocation of a clause relating to security exceptions makes a dispute inadmissible, see above, Section 3.

²³¹ *United States – Trade Measures Affecting Nicaragua*, 13 October 1986 (unadopted), GATT Doc. L/6053, par. 5.17.

²³² GATT, Analytical Index, p. 604.

²³³ *Ibid.*, p. 600.

²³⁴ Generally referred to as the “Helms-Burton Act”, International Legal Materials 1996, pp. 357 et seq.

²³⁵ Generally referred to as the “D’Amato-Kennedy Act”, International Legal Materials 1996, pp. 1274 et seq. For a study on this issue, see, among others, Andrea Giardina, *The Economic Sanctions of the United States against Iran and Libya and the GATT Security Exception*,

With regard to the *Cuban Liberty and Democratic Solidarity Act*, the European Communities requested consultations with the United States in connection with trade sanctions imposed on Cuba. The EC claimed that U.S. trade restrictions on goods of Cuban origin, as well as the possible refusal of visas and the exclusion of non-U.S. nationals from U.S. territory, were inconsistent with the U.S. obligations under the GATT 1994 and the GATS. The Dispute Settlement Body (DSB) established a panel at its meeting on 20 November 1996²³⁶ but, at the request of the EC, dated 21 April 1997, the panel suspended its work. The panel's authority lapsed on 22 April 1998, pursuant to Article 12.12 of the Dispute Settlement Understanding (DSU).

More recently, Honduras and Colombia instituted proceedings against the trade sanctions imposed by Nicaragua as a result of a maritime delimitation dispute.²³⁷ The dispute has been at the consultations stage since 26 June 2000, in respect of Law 325 of 1999 whereby a tax is established on goods and services coming from or originating in Honduras and Colombia as well as implementing Decree 129-99 and Ministerial Order 041-99. Honduras considered that Law 325 of 1999 and implementing Decree 129-99 are incompatible with Nicaragua's obligations under the GATT 1994, and in particular Articles I and II thereof, and that the aforementioned measures as well as Ministerial Order 041-99 are incompatible with Nicaragua's obligations under Articles II and XVI of the GATS.²³⁸

5. Relationship with other international instruments

5.1 WTO Agreements

There is no particular relationship between Article 73 and the provisions on security exceptions under other WTO agreements. As mentioned above (Section 1), the text of Article 73 was modelled upon Article XI of the GATT 1947 and is almost identical to Article XIV *bis* of the GATS.

5.2 Other international instruments

There is no particular relationship between Article 73 and the provisions on security exceptions under other international instruments.

in G. Hafner and others (eds), *Liber Amicorum Professor Seidl-Hohenveldern – in Honour of his 80th Birthday*, the Netherlands, Kluwer Law International, 1998; R. Dattu, and J. Boscarior, *GATT Article XXI, Helms-Burton and the Continuing Abuse of the National Security Exception*, Canadian Business Law Journal, v. 28, No. 2, 1997, pp. 198-221; K.J. Kuilwijk, *Castro's Cuba and the U.S. Helms-Burton Act – An Interpretation of the GATT Security Exemption*, Journal of World Trade, v. 31, No. 3, 1997, pp. 49-62; A. Perez, *WTO and U.N. Law: Institutional Comity in National Security*, Yale Journal of International Law, v. 23, No. 2, 1998, pp. 302-381; K. Alexander, *The Helms-Burton Act and the WTO Challenge: Making a Case for the United States under the GATT Security Exception*, Florida Journal of International Law, v. 11, No. 3, 1997, pp. 487-516.

²³⁶ WT/DS38.

²³⁷ WT/DS201/1. The EC requested to join the consultations, see WT/DS201/2.

²³⁸ See <<http://www.wto.org>>.

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6. New developments

6.1 National laws

6.2 International instruments

6.3 Regional and bilateral contexts

6.4 Proposal for review

There are no proposals so far to review Article 73.

7. Comments, including economic and social implications

The rare recourse to security exceptions in the context of international economic relations illustrates the limited importance of such exception for developing countries. The problems these countries will face in the intellectual property area are usually of an economic and a social nature, rather than security-related.

