

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

753

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

755

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

3. Possible interpretations

757

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.

3. Possible interpretations

759

“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).

3. Possible interpretations

761

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.

3. Possible interpretations

763

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.

3. Possible interpretations

765

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. v 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.

3. Possible interpretations

767

(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.

3. Possible interpretations

769

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

3. Possible interpretations

771

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.

3. Possible interpretations

773

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

3. Possible interpretations

775

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*).

4. WTO jurisprudence

777

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.

6. New developments

779

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

781

(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

785

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.