
PART 6: TRANSITIONAL AND INSTITUTIONAL ARRANGEMENTS

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

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

Article 66 Least-Developed Country Members

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

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

2. [...]

1. Introduction: terminology, definition and scope

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

2. History of the provision

2.1 Situation pre-TRIPS

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

2.2 Negotiating history

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

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

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

³ See Article XXXVI:4 of GATT 1994.

⁴ See Article XXXVI:8 of GATT 1994.

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

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

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

2.2.1 The Anell Draft⁸

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

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

1B.1 Developing Countries (73)

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

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

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

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

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

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

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

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

1B.2 Least-Developed Countries (73)

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

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

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

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

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

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

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

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

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

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

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

2.2.2 The Brussels Draft¹³

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

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

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

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

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

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

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

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

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

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

4. *No provision*

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

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

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

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

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

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

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

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

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

2.2.3 The Dunkel Draft¹⁸

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

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

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

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

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

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

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

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

3. Possible interpretations

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

3.1 Article 65.1

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

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

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

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

3.2 Article 65.2

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

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

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

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

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

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

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

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

3.3 Article 65.3

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

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

3.4 Article 65.4

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

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

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

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

3.5 Article 65.5

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

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

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

3.6 Article 66.1

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

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

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

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

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

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

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

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

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

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

6. New developments

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4. WTO jurisprudence

4.1 EC – Protection of Trademarks and GIs

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

5. Relationship with other international instruments

5.1 WTO Agreements

5.2 Other international instruments

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

6. New developments

6.1 National laws

6.2 International instruments

6.2.1 The Doha Declaration

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

³⁰ WT/DS290/18 of 19 August 2003.

³¹ WT/DS174/20 of 19 August 2003.

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

³³ See above, Section 2.1.

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

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

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

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

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

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

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

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

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

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

⁴⁰ *Ibid.*

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

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

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

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

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

⁴⁴ *Ibid.*

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

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

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

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

“1. For the purposes of this Decision:

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

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

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

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

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

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

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

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

6.2.2 The TRIPS Council Decision implementing the extension

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

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

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

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

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

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

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

Decides as follows:

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

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

6.2.3 The waiver of the obligation to provide EMRs

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

“The General Council,

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

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

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

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

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

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

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

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

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

Decides as follows:

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

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

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

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

6.3 Regional and bilateral contexts

6.4 Proposals for review

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

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

7. Comments, including economic and social implications

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

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