25: Patents: Non-Voluntary Uses (Compulsory Licences)

Article 31 Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use* of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

[Footnote]*: "Other use" refers to use other than that allowed under Article 30.

1. Introduction: terminology, definition and scope

Article 31 regulates the practice commonly known as compulsory licensing. A compulsory licence is an authorization granted by a government to a party other than the holder of a patent on an invention to use that invention without the consent of the patent holder. The patent itself is a charter from a government in favour of a particular person that gives that person certain rights. The compulsory licence acts to restrain the exercise of those private rights in the public interest. The compulsory licence is one mechanism through which governments limit the private power that resides in the grant of patents. It acknowledges that in various contexts the public interest in having technical knowledge more immediately accessible should take precedence over other patent interests.

Article 31 addresses "Other Use Without the Authorization of the Right Holder", and refers in its introductory clause to "other use [footnote: "Other use" refers to use other than that allowed under Article 30] of the subject matter of a patent without the authorization of the right holder". This awkward formulation reflects

the effort by the drafters to distinguish between "limited exceptions" that are authorized under Article 30, and compulsory licensing authorized under Article 31. Article 31 (compulsory licensing) addresses the interests of patent holders in particular cases – a compulsory licence is directed to an identified patent and authorized party – while Article 30 exceptions may involve legislation of more general effect on patent holders and authorized parties.

Article 31 does not attempt to specify or limit in any way the grounds upon which such licences may be granted. It sets up procedures that governments are expected to follow when they grant a licence, and describes certain terms that compulsory licences should embody. The procedures and terms vary depending on the contexts in which the compulsory licence is employed.

The Declaration on the TRIPS Agreement and Public Health adopted at the Doha Ministerial Conference states:

> "Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted."[910]

2. History of the provision

2.1 Situation pre-TRIPS

Prior to TRIPS, countries throughout the world maintained legislation authorizing the grant of compulsory licences. The terms of this legislation varied considerably. A number of countries, such as Canada[911] and India,[912] provided for "licences of right" in certain subject matter areas, such as food and pharmaceutical patents, so that after a minimum time period prescribed by the Paris Convention, any person with an interest in exploiting a patent was automatically entitled to a compulsory licence.[913] The laws of most or all countries allowed the government to use any patent for national security purposes. Patent laws included various other public interest grounds on which compulsory licences might be granted. These grounds included non-working of the patent within the national territory, failure to meet demand for the patented invention on reasonable terms, and as remedy for anticompetitive practices. For instance, a large number of compulsory licences have been granted in the USA in order to remedy anticompetitive practices.[914]

[910] Declaration on TRIPS and Public Health, WTO Ministerial Conference, Fourth Session, Doha, 9–14 Nov. 2001, WT/MTN(01)/DEC/W/2, 14 Nov. 2001, at para. 5(b).

[911] See description of Canada's pre-1993 compulsory licensing system in *Canada – Patent Protection of Pharmaceutical Products*, Report of the Panel, WT/DS114/R, March 17, 2000 (hereinafter "*EC-Canada*"), at para. 4.6. See in particular Reichman, Hasenzahl, *The Canadian Experience*. See also the "Common Industrial Property Regime" (Decision 85) of the Andean Community.

[912] See Elizabeth Henderson, *TRIPs and the Third World: The Example of Pharmaceutical Patents in India*, 19 EUR J. INT. PROP. REV. 651, 658–59 (1997), discussing Patents Act of 1970. Note that since India did not grant food and pharmaceutical product patents, the licence of right related only to process patents in these areas.

[913] Canada's legislation was modelled on British patent law that provided for licences of right in the pharmaceutical and food sectors prior to amendment in 1977. See Cornish, 1998, pp. 7–43

[914] See, e.g., Carlos Correa, *Intellectual property rights and the use of compulsory licences: options for developing countries*, Trade-Related Agenda, Development and Equity, Working Papers,

The principal international agreement concerning patents, the Paris Convention, recognizes the right of its state parties to grant compulsory licences to remedy abuses of patent rights, including failure to work the patent (Paris Convention, Article 5A). Although the Paris Convention prescribes a minimum period of time before a compulsory licence may be applied for (3 or 4 years depending on the circumstances), it does not otherwise limit the grant of such licences, and does not establish a right of compensation on behalf of patent holders. Controversy over the appropriate scope of compulsory licensing is cited as one of the reasons TRIPS negotiations were initiated.[915] In the late 1970s and early 1980s, developing country demands for a New International Economic Order included greater access to technology. These demands were manifest in negotiations on revision of the Paris Convention. These negotiations broke down in 1982, in significant part because of competing demands concerning compulsory licensing. The failure of these negotiations convinced industry interests that they would not succeed in solving what they viewed as the "intellectual property problem" at WIPO. This led to a refocusing of IPR efforts towards the GATT.

2.2 Negotiating history

2.2.1 Early national proposals

The United States played a major role in the inclusion of the TRIPS negotiations in the Uruguay Round, and its initial November 1987 "Proposal for Negotiations on Trade-Related Aspects of Intellectual Property Rights" stated in regard to compulsory licensing:

> "Governments should generally not grant compulsory licenses to patents and shall not grant a compulsory license where there is a legitimate reason for not practicing the invention such as government regulatory review. If a government grants a compulsory license, it shall not discriminate against inventions in particular fields of technology and it shall provide for full compensation to the patentee for the license. No compulsory license shall be exclusive."[916]

In July 1988, the European Community submitted to the TRIPS Negotiating Group an alternate proposal regarding an agreement, stating in respect to compulsory licensing:

> "The granting of compulsory licences for lack or insufficiency of exploitation, compulsory licences in respect of dependent patents, official licences, and any

South Centre, Geneva 1999. See also UNCTAD-ICTSD, Jerome H. Reichman and Catherine Hasenzahl, *Non-Voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the United States of America*, also available at <http://www.iprsonline.org/unctadictsd/projectoutputs.htm#casestudies>. See also the case study by the same authors specifically focusing on the U.S experience, forthcoming.

[915] *Id.*, at 3–17 to 3–18. See also Frederick Abbott, Thomas Cottier, and Francis Gurry, *The International Intellectual Property System: Commentary and Materials*, Kluwer Law 1998, pp. 717–718.

[916] Suggestion by the United States for Achieving the Negotiating Objective, United States Proposal for Negotiations on Trade-Related Aspects of Intellectual Property Rights, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, MTN.GNG/NG11/W/14, 20 Oct. 1987, Nov. 3, 1987.

right to use patented inventions in the public interest shall, in particular in respect of compensation, be subject to review by a court of law."[917]

In July 1989, India submitted a detailed paper that proposed an approach to compulsory licensing that would authorize licensing for non-working, and licences of right in areas such as food, pharmaceuticals and agricultural chemicals.[918] Fair compensation under a licence of right would be determined as a matter of local law.[919]

At a meeting of the TRIPS Negotiating Group in July 1989, the subject of compulsory licensing was discussed extensively, particularly in relation to the issue of non-working of patents,[920] and it was further considered at a meeting in October-November 1989.[921]

2.2.2 The Anell Draft

Under the Anell Draft, the "A" text introductory clause on compulsory licensing stated: "PARTIES shall minimize the grant of compulsory licences in order not to impede adequate protection of patent rights".[922] It listed specific and limited grounds on which licences might be granted, including "On the grounds of the public interest concerning national security, or critical peril to life of the general public or body thereof".[923] This text specifically addressed the local working requirement, providing "Compulsory licences for non-working or insufficiency of working on the territory of the granting authority shall not be granted if the right holder can show that the lack or insufficiency of local working is justified by the existence of legal, technical or commercial reasons".[924] Compulsory licensees would have been allowed only to supply the local market ("Compulsory licences shall be granted to permit manufacture for the local market only").[925] At this stage, the authority that would be responsible for reviewing the grant was bracketed: ("Any decision relating to the grant and continuation of compulsory licences and the compensation provided therefore shall be subject to [judicial review] [review by a distinct higher authority]").[926]

[917] Guidelines and Objectives Proposed by the European Community for the Negotiations on Trade-Related Aspects of Substantive Standards of Intellectual Property Rights, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, MTN.GNG/NG11/W/26, July 1988, at III.D.3.a(iv).

[918] Communication from India, Standards and Principles Concerning the Availability, Scope and Use of Trade-Related Intellectual Property Rights, MTN.GNG/NG11/W/37, 10 July 1989.

[919] At that stage in the TRIPS negotiations, India objected to the establishment of "any new rules and disciplines pertaining to standards and principles concerning the availability, scope and use of intellectual property rights."

[920] Note by the Secretariat, Meeting of Negotiating Group of 12–14 July 1989, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, MTN.GNG/NG11/14, 12 September 1989.

[921] Note by the Secretariat, Meeting of Negotiating Group of 30 October–2 November 1989, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, MTN.GNG/NG11/16, 4 December 1989, at para. 34.

[922] See document MTN.GNG/NG11/W/76, Section 5: Patents, 5A.1.

[923] Section 5A.2.2b.

[924] Section 5A.3.2.

[925] Section 5A.3.5.

[926] Section 5A.3.10.

In the Anell Draft, the only compulsory licensing text specifically designated "B" was the following:

> "5B Nothing in this Agreement shall be construed to prevent any PARTY from taking any action necessary: (i) for the working or use of a patent for governmental purposes; or (ii) where a patent has been granted for an invention capable of being used for the preparation or production of food or medicine, for granting to any person applying for the same a licence limited to the use of the invention for the purposes of the preparation or production and distribution of food and medicines. (See also point 2.1B(c) above and Section 8 below)"

Records of the meeting of the TRIPS Negotiating Group subsequent to the Chairman's summary indicate substantial resistance on the part of developing countries to the strict limits suggested by the developed countries regarding grounds for compulsory licensing.

2.2.3 The Brussels Draft

The Brussels Ministerial Text[927] included an article on compulsory licensing (Article 34) that approximated the Dunkel Draft and final TRIPS Agreement text, but with several important differences.[928] The Brussels Draft eliminated any enumeration of permissible grounds for granting compulsory licences, and instead

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

[928] Article 34, Brussels Draft, provided:

"Article 34: Other Use Without Authorisation of the Right Holder

Where the law of a PARTY allows for other use[6] of the subject matter of a patent without the authorisation of the right holder, including use by the government or third parties authorised by the government, the following provisions shall be respected:

(a) Each case of such use shall be considered on its individual merits.

(b) Such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorisation from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a PARTY in the case of a national emergency or other circumstances of extreme urgency. In such situations, the right holder shall, nevertheless, be notified as soon as is reasonably practicable.

(c) The scope and duration of such use shall be limited to the purpose for which it was authorised.

(d) Such use shall be non-exclusive.

(e) Such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use.

(f) Any such use shall be authorised predominantly for the supply of the domestic market of the PARTY authorising such use.

(g) Authorisation for such use shall be liable to be terminated when the circumstances which led to it cease to exist and are unlikely to recur, subject to adequate protection of the legitimate interests of the persons so authorised. The competent authority shall have the authority to review, upon request, the continued existence of these circumstances.

(h) The right holder shall be paid fair and equitable adequate remuneration in the circumstances of each case, taking into account the economic value of the licence.

(i) The legality of any decision relating to the authorisation of such use shall be subject to judicial review or other independent review by a distinct higher authority in that PARTY.

(j) Any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that PARTY.

(k) Laws, regulations and requirements relating to such use may not discriminate between fields of technology or activity in areas of public health, nutrition or environmental protection or where necessary for the purpose of ensuring the availability of a product to the public at the lowest possible price consistent with giving due reward for the research leading to the invention.

focused on the processes by which such licences might be granted and the terms that such licences should contain.

In the Brussels Draft, "public non-commercial use" is addressed in a clause (Article 34(o)), separate from the provision regarding national emergency and circumstances of extreme urgency (compare Article 31(b), TRIPS Agreement). It was envisaged that public non-commercial use might provide exemption from at least some requirements of the compulsory licensing rules applicable in other contexts. Language intended to address U.S. legislation under which notice to the patent holder is not required was included.

The terms "fair and equitable" appeared before "adequate" in the general clause on remuneration of the patent holder (Article 34(h), Brussels Draft), as well as in the clause on public non-commercial use.

At the Brussels Draft stage, the principle that reviews would be undertaken either by a judicial authority or a distinct higher authority was accepted.

A provision on non-discrimination was at this stage incorporated directly in the draft article on compulsory licensing, rather than in the draft article on patentable subject matter (as it appears in the final TRIPS Agreement text). That clause of Article 34, Brussels Draft, provided:

> "(k) Laws, regulations and requirements relating to such use may not discriminate between fields of technology or activity in areas of public health, nutrition or environmental protection or where necessary for the purpose of ensuring the availability of a product to the public at the lowest possible price consistent with giving due reward for the research leading to the invention."

The language of draft clause (k) is ambiguous. For example, it is not clear what the phrase beginning "or where necessary for the purpose of ensuring the

(l) PARTIES are not obliged to apply the conditions set forth in sub-paragraphs (b) and (f) above where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. Appropriate remuneration may be awarded in such cases.
(m) Where such use is authorised to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:
(i) the invention claimed in the second patent shall involve an important technical advance in relation to the invention claimed in the first patent and, where the invention claimed in the second patent is a process, such process shall be one of considerable economic significance;
(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and
(iii) the use authorised in respect of the first patent shall be non-assignable except with the assignment of the second patent.
(n) Authorisation by a PARTY of such use on grounds of failure to work or insufficiency of working of the patented product or process shall not be applied for before the expiration of a period of four years from the date of filing of the patent application or three years from the date of grant of the patent, whichever period expires last. Such authorisation shall not be granted where importation is adequate to supply the local market or if the right holder can justify failure to work or insufficiency of working by legitimate reasons, including legal, technical or economic reasons.
(o) Notwithstanding the provisions of sub-paragraphs (a)–(k) above, where such use is made for public non-commercial purposes by the government or by any third party authorised by the government, PARTIES are not obliged to apply the conditions set forth in sub-paragraphs . . . above in such cases. Where it comes to the knowledge of the government that a patent is being exploited under the provisions of this sub-paragraph, the government shall ensure that the patent owner is informed and is fairly and equitably adequately compensated."

availability. . . " is directed toward. It might have been intended to prohibit the use of compulsory licensing to address pricing in particular fields, such as pharmaceutical products. Yet the combination of the phrase "may not discriminate" with "where necessary" produces a confusing result. Exceptions under Article XX, GATT 1947, were typically framed in the context of "necessity". The preclusion of "necessary" measures for public health would seem a result inconsistent with GATT practice. In the final TRIPS Agreement text, language requiring consistency of "necessary" public health measures with the terms of TRIPS appears in Article 8 (Principles).

Clause (l), Brussels Draft, provides in relation to remedying anticompetitive practices that Members "may" award appropriate remuneration. In Article 31(k), TRIPS, the need to correct anticompetitive practices "may be taken into account" in determining remuneration.

Clause (n), Brussels Text, expressly addressed non-working of patents, providing:

> "(n) Authorisation by a PARTY of such use on grounds of failure to work or insufficiency of working of the patented product or process shall not be applied for before the expiration of a period of four years from the date of filing of the patent application or three years from the date of grant of the patent, whichever period expires last. Such authorisation shall not be granted where importation is adequate to supply the local market or if the right holder can justify failure to work or insufficiency of working by legitimate reasons, including legal, technical or economic reasons."

This clause was not included in the Dunkel Draft or final TRIPS Agreement text. The first sentence would have essentially incorporated the time period prescribed by Article 5A(4), Paris Convention (which was effectively incorporated by reference in Article 2, Brussels Text, and Article 2, TRIPS Agreement text). The second sentence would have substantially affected "local working" requirements. The final TRIPS text, as discussed above, incorporates in Article 27.1 a rule that patent rights shall be enjoyable without discrimination as to whether products are imported or locally produced.

There were virtually no changes between the Dunkel Draft and the final TRIPS text on compulsory licensing.

As reflected in the statements by delegations, one of the main obstacles to conclusion of the text on compulsory licensing concerned debate over the right of governments to grant such licences on grounds of non-working. There were a number of negotiating texts on this subject proposed throughout the negotiations, but negotiators could not agree on a direct solution. The issue was indirectly addressed by Articles 27.1[929] and Article 70.6 of TRIPS.[930]

[929] See Chapter 18.

[930] This Article states that "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."

3. Possible interpretations

Article 31 does not purport to limit the grounds on which compulsory licences may be granted. If a WTO Member chooses to provide for such licences, then certain conditions must be fulfilled.

3.1 Individual merits

> (a) authorization of such use shall be considered on its individual merits;

The first of these conditions is that each licence should be considered on its individual merits (Article 31(a)). The ordinary sense of this would be that governments should not attempt to grant blanket authorizations of compulsory licences pertaining to types of technologies or enterprises, but instead should require each application for a licence to undergo a process of review to determine whether it meets the established criteria for the granting of a licence.

The practice of the United States in authorizing government use of patents, well known at the time of the adoption of Article 31 (and accounting for much of its peculiar language), indicates that the requirement of review of individual merits may be interpreted flexibly. Under U.S. law, the government may use any patented invention (or authorize its contractor to use such invention) without providing prior notification to the patent holder, subject only to the patent holder's right to initiate a proceeding before the Court of Claims for compensation. The U.S. patent holder may not obtain an injunction against such government use. This suggests that in cases of government use of a patent the consideration of individual merits can take place after the licence is granted and relate only to the question of compensation.

The requirement that licences be considered on their individual merits does not mean that presumptions may not be established in favour of granting licences in particular contexts, placing the burden on patent holders to overcome the presumptions. For example, a compulsory licensing statute might provide that the absence of supply on the local market of a patented product at an affordable price justifies the grant of a compulsory licence, placing the burden on the patent holder to demonstrate that there are adequate supplies of products on the local market at affordable prices.

The question of who must consider the individual merits of the licence is addressed below.

3.2 Prior negotiations

> (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency

> or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

Article 31 generally requires that a party seeking a compulsory licence first undertake negotiations with the patent holder for a voluntary licence on "reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time". This requirement is inherently flexible since the concept of reasonable terms and period of time will depend on context.

3.2.1 Commercial terms and conditions

If the applicant for a compulsory licence claims that it sought and failed to obtain a licence from the patent holder on reasonable commercial terms, the authority considering the application may need to decide whether the patent holder's position on compensation was reasonable.

Patent licences generally involve the payment of a royalty from the licensee to the patent holder. A royalty is a usage fee the amount of which may be calculated on different bases. As examples, a royalty may be payable based on the number of units of a licensed product made or sold, or it may be payable based on the licensee's net income from sales of the product. A royalty may be a fixed amount payable at periodic intervals.

The customary royalty for licensing of a patented product or process will vary from industry to industry, and within each industry, depending on the value of the particular technology involved. The royalty on a highly advanced new technology that was developed through substantial expenditures on research and development (R&D) is generally going to be higher than the royalty on a mature technology that might be nearing the end of its life-cycle. The level of royalty will also depend upon either the proven or anticipated success of the product in the market place.

Much of the global flow of patent royalties is internal to multinational enterprises that are transferring income and expenses among their operating units in different countries, and will often depend on factors such as minimization of tax burdens. In order to derive a reasonable royalty based on customary practices in an industry, it may be necessary to disregard evidence of intra-enterprise royalty payments.[931]

Royalty rates are discussed further below in regard to payment of compensation to patent holders.

[931] Typically, the negotiator seeking a commercial patent licence will seek to minimize the level of payments to the patent holder, and the patent holder will seek to maximize its stream of income. The patent holder might not seek the highest possible royalty rate since the aggregate amount of its income stream may depend on the level of sales of the patented product, and an excessive royalty might diminish its overall return.

The rate of royalty to be paid is not the only commercial term or condition that is important to a party seeking a licence. Other important elements include:

1. Duration of the licence term. The licensee must make sure that it will be able to use the technology for as long as is necessary to recover and earn a reasonable return on any investments it will be making.

2. Additional technology. Patent applications often do not disclose enough information to allow the practical exploitation of the technology without additional trade secret or other knowledge gained by the patent holder through practical experience. The extent to which the patent holder will aid in the implementation of technological solutions may substantially affect the value of the patent to the licensee.

3. Grant-backs. Patent licensees often develop improvements on inventions which have substantial commercial value. A patent licensor may seek to require that the licensee "grant back" to it any improvement on the invention. The extent of the licensee's obligations in this area will affect the value of the licence to both parties.

4. Tying Arrangements. Patent holders may seek to require licensees to purchase components of the patented product, ancillary products, unrelated products, or support services as conditions of granting a licence. Licensees risk being locked into higher than market commitments through these kinds of arrangements, and demands for undertaking such commitments will affect the value of a licence.

5. Export restrictions. Patent owners often impose on voluntary licences restrictions on the export of the licensed product. This may limit the ability of the licensee to achieve economies of scale in its production facilities.

3.2.2 Reasonable period of time

A patent holder that does not wish to licence its technology, but that also does not wish to see a compulsory licence granted, may well attempt to prolong negotiations using a variety of tactics. Such tactics may include appearing to be engaged in serious negotiations over detailed terms and conditions that do not reach a conclusion. Negotiators seeking licences on reasonable commercial terms are perfectly justified in setting an outer limit for successfully concluding licences, and refusing to negotiate beyond that point.

The reasonable time for negotiations may depend on the purpose for which the licence is sought. As example, a negotiator seeking to commence production of a life-saving pharmaceutical would be justified in seeking a more rapid conclusion of negotiations than a negotiator seeking to commence production of an improved fishing rod.

3.2.3 Waiver of prior negotiations

Under certain conditions, prior negotiation with the patent holder need not be pursued. These are the cases of:

1. "national emergency";
2. "other circumstances of extreme urgency"; or
3. "public non-commercial use".

The language used to define each of these cases leaves room for interpretation. Many countries have laws under which the executive or other authority may formally declare a situation of national emergency, and this declaration may lead to the suspension of certain otherwise applicable constraints. For example, in a situation of national emergency the executive may be able to rule by decree in areas that would normally require parliamentary assent. The terms "other circumstances of extreme urgency" make clear that a waiver of the prior negotiations requirement does not depend upon a formal declaration of national emergency. Even if a country's laws make specific provision for declarations of national emergency from which defined consequences flow, this does not mean that this specific provision needs to be invoked. As example, a government might declare the pandemic spread of a disease to constitute a national emergency, although it is not generally intending to alter the normal pattern of constitutional government.

The use of the term "extreme" in connection with "urgency" suggests that more than a preference to move quickly to authorize a licence is involved in invoking this waiver. The term "extreme" refers to the far end of the spectrum of urgency, but it is not possible to lay out a general rule as to what differentiates extreme urgency from moderate urgency.

The waiver of prior negotiations in the context of national emergency or extreme urgency applies to grants of compulsory licences for private commercial as well as public purposes.

The waiver of prior negotiations also applies when patents are used for public purposes. In many cases it will not be necessary to rely on "national emergency" or "extreme urgency" as the basis for a waiver. There are many ways that the terms "public non-commercial use" may be defined in good faith. The term "public" could refer to use by a government, as opposed to private, entity.[932] The term may refer also to the purpose of the use, that is, use for "public" benefit. A private entity could be charged with exploiting a patent for the benefit of the public.

"Non-commercial use" may be defined either in relation to the nature of the transaction, or in relation to the purpose of the use. Regarding the nature of the transaction, "non-commercial" may be understood as "not-for-profit" use. A commercial enterprise does not ordinarily enter the market without intending to earn a profit. Regarding the purpose of the use, "non-commercial" may refer to the supply of public institutions that are not functioning as commercial enterprises. The supply of a public hospital operating on a non-profit basis may be a "non-commercial" use of the patent.

"Public non-commercial use" is a flexible concept, leaving governments with considerable flexibility in granting compulsory licences without requiring

[932] For example, in the United States, a private contractor for the government may be authorized to use a third party's patent without prior negotiation.
There are many instances where the WTO Agreements refer to "governmental" use. For example GATT Article III:8(a) provides: "The provisions of this Article shall not apply to laws, regulations or requirements governing the procurement by governmental agencies of products purchased for governmental purposes and not with a view to commercial resale or with a view to use in the production of goods for commercial sale."
The Agreement on Government Procurement refers to identified "government" entities, not to "public" entities.

commercial negotiations in advance. Note, however, that the waiver of prior negotiations does not extinguish the requirement that adequate compensation in the circumstances be paid to the patent holder (discussed later).

3.2.4 Notification

In cases of national emergency or extreme urgency, the government is obligated to notify the patent holder of the grant of the compulsory licence as soon as reasonably practicable. Reasonable practicability will depend on the circumstances of the case, and need not precede grant of the license. Regarding public non-commercial use, Article 31(b) says: "where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly." The peculiar wording derives from law and practice in the United States that allows the government and its contractors to make use of patents without advance notice to patent holders.[933] Although U.S. law does not require that a patent holder be notified even if the government knows of a valid patent, it would nonetheless appear that if a government or a private entity is aware of the existence of a valid patent (without a patent search) when a compulsory licence is to be granted for public non-commercial use, it should notify the patent holder.

3.2.5 Competition law remedy

It is important to note that, pursuant to Article 31(k), when compulsory licences are used by the governments to remedy anticompetitive practices[934] (pursuant to findings by judicial or administrative bodies) there is no requirement of prior negotiations with or notification of the patent holders under Article 31(b).

3.3 Scope and duration

> (c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;[935]

The purpose of the authorization is intended to determine the scope of the licence. This suggests that compulsory licences should not necessarily provide the licensee with an unencumbered field of application. A compulsory licence granted to an aircraft parts supplier regarding military aircraft components might not, for example, authorize the supplier to sell the same patented parts for use in civilian aircraft.

[933] But subsequently allowing the patent holders to seek compensation.

[934] On the relationship between competition law and intellectual property in developing countries, see Carlos Correa, *The strengthening of IPRs in developing countries and complimentary legislation* (2000), prepared upon the request of DFID (UK), available at <www.dfid.gov.uk>.

[935] The special provision regarding semiconductor technology is of limited application and not discussed further here.

The duration of the licence should also be limited in terms of purpose, but this does not prevent a compulsory licensee from receiving a grant that is of sufficiently long duration to justify its investment in production from a commercial standpoint. A licence grant should in any case be long enough to provide adequate incentive for production. Otherwise the purposes of Article 31 will be frustrated.

3.4 Non-exclusivity

> (d) such use shall be non-exclusive;

In the ordinary commercial context, when a patent holder grants a licence for a particular territory, it may agree to refrain from conferring marketing rights over the product covered by the licence in that territory to other parties (i.e., it grants an exclusive licence). Otherwise, the licensee will face the risk of competition from other licensees that might reduce the value of the licence and any investment in exploiting it. The licensee may also face competition by the patent owner, unless he also agrees to exclude himself from the territory.

The requirement that a compulsory licence be non-exclusive raises difficulties from the standpoint of prospective compulsory licensees. They face the possibility that patent holders and possibly other licensees will seek to undercut them in the market, and this will reduce their incentive to invest.

In some contexts it may be possible to alleviate this concern by providing a government contract for assured purchase of the licensed product. In other contexts, the prospective licensee will have to assure itself, for example by negotiating commercial commitments in advance, that its investment in exploiting a compulsory licence will not involve an unreasonable level of risk.

3.5 Non-assignment

> (e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

The objective of this provision is to prevent the development of a market in compulsory licences as instruments with independent value. The creation of such a market would generally enhance the value of compulsory licences, and might encourage parties to seek them. This requirement does not prevent the sale or transfer of businesses that have obtained compulsory licences, and thereby allows investments in the licences to be sustained.

The reference to assignment of the goodwill means that there need not be any tangible assets constituting the party holding the licence. This adds an element of flexibility to the rule against non-assignment. If a party seeking a compulsory licence establishes a legal entity whose assets are largely comprised of the compulsory licence, it would be feasible to assign and transfer the entire entity ("goodwill") as part of a secondary market transaction.

3.6 Predominantly for the domestic market

> (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

The word "predominantly" refers to the majority part, and would generally suggest that more than fifty percent of the production by a compulsory licensee should be intended for the supply of the domestic market.

It is clear that a government may authorize a compulsory licensee to produce for export, provided that the licence includes an undertaking to predominantly produce for the domestic market.

It is generally accepted that a country may issue a compulsory licence within its territory, and allow the licensee to fulfil the terms of the authorization through importation. Thus, if there are off-patent products available outside the country the compulsory licensee may import those products without the consent of the patent holder.

On August 30, 2003, the General Council of the WTO adopted the Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (the "Decision").[936] Adoption of the Decision was preceded by reading of a Chairperson's Statement that expressed certain "shared understandings" of the Members regarding the way it would be interpreted and implemented. The Decision establishes a mechanism under which the restriction of Article 31(f) will be waived for an exporting Member when it is requested by an eligible importing Member to supply products under compulsory license issued in the exporting country. Details regarding this waiver are discussed under New developments (Section 6.2 of this chapter).

It is important to note that, pursuant to Article 31(k), when compulsory licences are used by the governments to remedy anticompetitive practices (pursuant to findings by judicial or administrative bodies) there is no requirement that those licences be granted predominantly for supply of the domestic market.

3.7 Termination

> (g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

As noted above in regard to the terms and conditions of a licence, the compulsory licensee may be required to undertake substantial investment in connection with producing and distributing under a licence. If compulsory licensing

[936] Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health WT/L/540, 2 September 2003 (hereinafter "Decision").

is going to be successful, it must provide sufficient economic incentive for the licensee.

There are a number of mechanisms that might be considered to allow for the termination of a licence under conditions that would adequately protect the legitimate interests of the licensee. For example, the initial grant of the licence could establish the minimum term necessary for the licensee to recover its costs and earn a reasonable return, and also provide for automatic extensions of the licence absent a showing by the patent holder that the conditions that led to the granting of the licence have ceased to exist and are unlikely to recur. The licence could not be terminated during the initial term in which protection of the licensee's interests is assured. Alternatively, the patent holder might be required to compensate the licensee for the remaining value of the licence if the patent holder desires to step in and supply the market in place of the licensee.

A country's compulsory licensing rules should include some mechanism by which the patent holder can petition for a review by the competent authority as to whether the circumstances leading to the granting of the licence have ceased and are unlikely to recur. The compulsory licensee may, of course, be permitted to present its own evidence and justifications for continuing the licence, and might well be entitled to appeal any decision on this matter to the courts.

3.8 Adequate remuneration

> (h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

The requirement of payment of adequate compensation was not part of the Paris Convention rules on compulsory licensing. The requirement applies to government use as well as private party use of the patent.

The TRIPS Agreement rules on compensation embody substantial flexibility as a consequence of use of the terms "in the circumstances of each case", indicating that factors relating to the underlying reasons for the grant of the licence may be taken into account in establishing the level of compensation. Granting authorities are instructed to "take into account the economic value of the authorization", but are not required to base the royalty payable to the patent holder on that value.

The term "adequate" generally is used to indicate something that is sufficient, or meets minimum standards, but not more than that.[937] In the context of payments to patent holders, adequate payment may be defined in a variety of ways.

Granting a compulsory licence is not the same as ordering forfeiture or revocation of a patent. Compulsory licences must be non-exclusive, and the grant of a compulsory licence to a third party (including the government) does not preclude the patent holder from exploiting the national market or exporting the patented product.

[937] A student who does "adequate" work is a student whose work meets the basic minimum standards, but whose work does not demonstrate qualities above that.

One way to approach adequacy of compensation is to ask what the licensee would have been required to pay as compensation to the patent holder for a commercial licence under ordinary circumstances. Assuming that there is a market for licences regarding the type of technology involved in the particular case, the market rate would provide an indication at least as to what patent holders might expect from licensing their technology.

However, the "market rate" may be difficult to determine or misleading for a number of reasons. First, in a market characterized by a limited number of patent-holder actors, there may be active or passive collusion among the patent holders that results in a market rate that is higher than would be the case if the market were functioning efficiently. Second, many, if not most, patent licences are granted among members of the same enterprise group. It may well be in a group's interest to charge high inter-enterprise patent royalties to reduce tax burdens, and it may be very difficult to disaggregate available data so as to establish what market rates would look like without reference to intra-group licences. Even in regard to transactions involving nominal competitors, there may be factors such as joint venture interests that affect what might otherwise be presumed to be market-rate transactions.

Another possible approach involves requiring each patent holder to present a detailed justification for its royalty request. The patent holder could be asked to provide specific data on its research and development costs (including any offsetting tax or accounting benefits), whether it received or made use of any government-supported research in developing its invention, its total global market for the patented invention, the percentage of the global market represented by the country granting the compulsory licence, the average rate of return on its patented products, and so forth. The granting authority could on the basis of this data determine what level of royalty would adequately reflect the patent holder's interest in the country in question.

An international organization might be relied upon to establish royalty guidelines on an industry or product/process basis that might be used as a benchmark by authorities granting compulsory licences.

The licensee's royalty obligation may be calculated as a percentage of its income from sales of the licensed product. That income may be represented, for example, by its wholesale sales, and may be net of tax liabilities.

The level of compensation depends on the circumstances of each case, and there are a number of factors that this potentially brings into play. If a compulsory licence is used to remedy an anticompetitive practice, the level of compensation may be adjusted to reflect the need to remedy past misconduct and to affirmatively promote the entry of new competitors in the market. Although Article 31 does not eliminate the requirement of compensation for compulsory licences to remedy anticompetitive practices, neither does it in any way suggest that this compensation may not be strictly limited to reflect governmental objectives. Article 31(k) expressly recognizes that "The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases."

The authorities granting a compulsory licence may also take into account the public interest in effective exploitation of the licence as compared with the private interest in earning a particular level of return. For example, if a developing country

government is granting a compulsory licence to address a public health crisis that affects a large segment of its population, the government could justify the payment of a minimal royalty on grounds that the public interest in the circumstances of the case warrants a reduced royalty.

The economic value of the authorization is to be "taken into account" in establishing the level of compensation. In cases where a compulsory licence is granted to achieve an industrial policy objective, the value of the licence in the hands of the licensee may be a significant factor in determining the level of payment. Where the licence is granted to address urgent public needs, the economic value of the licence to the licensee may be a much less significant factor.

The Decision on Implementation of Paragraph 6 of the Doha Declaration also provides for a waiver of the requirement for adequate remuneration in the eligible importing Member when remuneration is paid in the exporting Member (Decision, para. 3). This waiver was included to avoid the result that the patent holder would receive double compensation when the system established by the Decision is used. Paragraph 3 of the Decision states that remuneration in the export Member will be established "taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member". The concept of economic value to the importing Member could be understood in a number of ways. The idea for avoiding double remuneration was that the level of compensation should be determined based on the level of economic development and financial capacity in the importing Member, and not the level of economic development and budget capacity in the exporting Member. The approach to remuneration taken by Canada in its implementation of the Decision, discussed in Section 6.1 of this chapter, illustrates one constructive approach to the remuneration issue.

3.9 Review by Judicial or Distinct Higher Authority

> (i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
>
> (j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member.

The procedures adopted for the review of decisions are likely to play a critical role in determining whether compulsory licences are applied for and used. No sensible enterprise deciding whether to seek a compulsory licence is interested in investing a large measure of resources in protracted court battles that represent not only a financial drain, but also a substantial imposition on managerial resources.

Because the legal institutions and procedures of nations differ fairly substantially, the requirements for review are set out in general terms, and provide substantial discretion to countries in implementation.

The review of grant and remuneration decisions may be undertaken by a court, or may be undertaken as an "independent review" by a "distinct higher authority".

Article 31 does not address the nature of the authority that may initially grant a compulsory licence or determine the level of compensation. This decision may be placed in the hands of an executive administrator. Since the WTO Agreements, including TRIPS, require transparency and basic fairness, governments should develop and publish regulatory procedures pursuant to which compulsory licences will be granted. However, since it is anticipated that governments may act to grant compulsory licences under conditions of urgency, there is nothing to prevent them from providing for waivers of generally applicable rules in such circumstances.

The use of a court as an independent review body is fairly self-explanatory. Court systems typically involve courts of first instance, and one or more levels of courts of appeal. Many legal systems employ specialized courts for particular subject matters, and this may include patent courts. Article 31 does not suggest a preference for the character of the court that is to review decisions regarding compulsory licences, and it may be preferable, because of the general-purpose objectives of this provision, that a court other than a specialized court be used for such review.

Article 31(i) and (j) also allow for "independent" review by a "distinct higher authority". "Independent" means that the reviewing person or body should not be subject to control by the person or body that initially grants the licence or determines the payment. Independence implies that the reviewer should be able to modify or reverse the initial decision without threat of political or economic reprisal. The term "higher authority" refers to a more senior level government person or body than the granting person or body. The term "distinct" could refer to a person or body within the same government agency that initially grants the licence, provided that there is adequate separation of personnel and function among the two persons or bodies. If the initial granting authority within a government is an administrator within the patent office, and the patent office is under the jurisdiction of the Minister of Economy and Trade, the Minister might serve as an authority "distinct" from the patent office administrator.

These provisions should be read in conjunction with Article 44.2, TRIPS Agreement, regarding injunctions. Article 44.2 provides in its first sentence that, with respect to government use licensing, remedies may be limited to the payment of remuneration. This means that the government may not be enjoined from using a patent without the consent of the patent holder, subject to the payment of remuneration, as long as it complies with the requirements as to government use licensing set out in Article 31. Since a government may use a patent without prior notice to or negotiations with the patent holder, this means that a patent holder need not have an opportunity to block the grant or use of a license. The drafting of this provision takes into account the U.S. approach to government use licensing.

The second sentence of Article 44.2 states "In other cases, the remedies under this Part shall apply or, where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available." Once a compulsory license is granted, the licensee is not engaging in infringement of the patent holder's rights. Assuming the license is properly granted, there is no basis for injunctive relief. Nevertheless, before the grant of the license the patent holder might seek a court injunction to prevent the patent office from issuing it and, even after the grant, the patent holder might seek a temporary injunction pending a final determination by a court or distinct higher authority. The second sentence of Article 44.2 provides that injunctive remedies need not be available

when they are "inconsistent with a Member's law". This is an ambiguous formulation. One interpretation is that injunctions need not be made available if they are not generally provided for in national law. This would be a strained interpretation since Article 44.1 requires that injunction relief be made available in certain cases. A Member would not be in compliance with its general TRIPS obligations if it did not allow for such remedy in those cases. A second and more coherent interpretation is that a compulsory licensing statute need not allow for preliminary or temporary injunctions pending a determination whether the license is lawful. Instead, the courts or distinct higher authority may be asked to render a declaratory judgement, which means they will set out the rights of the parties without ordering relief, and to provide for compensation.

3.10 Remedies for anticompetitive practices

> (k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

As previously discussed, when a compulsory licence is granted based upon a judicial or administrative finding of anticompetitive practices, the otherwise applicable requirements of prior negotiations, notice and limiting the licence to predominant supply of the domestic market do not apply. In addition, the finding may be reflected in the level of payment to the patent holder. Finally, if it is likely that the anticompetitive conditions that led to the initial grant will recur, competent authorities may refuse to terminate the licence.

In individual cases, authorities considering applications for compulsory licences may be presented with several potential grounds for granting them.[938] A finding of anticompetitive conduct on the part of the patent holder provides flexibility regarding the potential terms of a compulsory licence, and should be made when anticompetitive practices are evidenced.

3.11 Dependent Patents

> (l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:
>
> (i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

[938] A useful listing of potentially anticompetitive practices may be found in the *Set of Multilaterally Agreed Equitable Principles and Rules for the Control of Restrictive Business Practices*, adopted by the UN General Assembly.

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

Article 31(l) addresses the context in which a compulsory licence is granted to permit the exploitation of a second patented invention that depends upon rights to use an existing patented invention. It requires that the second invention involve an important technical advance of considerable economic significance, that the holder of the first patent be granted a cross-licence on reasonable terms to use the second patent, and that the compulsory licence not be assignable except with the assignment of the second patent.

The question whether an invention is an important technical advance involves a subjective judgment that necessarily involves a range of discretion. Patents are granted only if a claimed invention evidences a sufficient "inventive step" over prior art, so a second patent should not be granted in the first place unless there is an inventive step. The idea of an important technical advance is reminiscent of former German patent law that required a vaguely defined quantum of technical progress as a condition of patentability.[939] This idea was abandoned in European patent law because, among other reasons, it is exceedingly difficult to distinguish important and unimportant technical advances.

4. WTO jurisprudence

4.1 EC-Canada

As of today, there is no decision of a WTO dispute settlement panel or the Appellate Body that directly interprets Article 31. As noted above, in the *EC-Canada* decision, 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.[940] Yet the panel in that case left a considerable degree of flexibility in the interpretation of Article 27.1. The panel said:

> "The primary TRIPS provisions that deal with discrimination, such as the national treatment and most-favoured-nation provisions of Articles 3 and 4, do not use the term "discrimination". They speak in more precise terms. The ordinary meaning of the word "discriminate" is potentially broader than these more specific definitions. It certainly extends beyond the concept of differential treatment. It is a normative term, pejorative in connotation, referring to results of the unjustified imposition of differentially disadvantageous treatment."[941] [emphasis added]

[939] See Friedrich-Karl Beier, *The European Patent System*, 14 VAND. J. TRANSNAT'L L. 1 (1981).

[940] The proposition that Article 31 is subject to Article 27.1 was accepted by the parties in the *EC-Canada* case, and the panel confirmed the parties' understanding. *EC-Canada* (WT/DS114/R), at paras. 7.90–7.91.

[941] *Id.*, para. 7.94.

The panel makes clear that the conduct prohibited by Article 27.1 is discrimination, and that "discrimination" is not the same as "differentiation". The panel suggests that governments are permitted to adopt different rules for particular product areas or locations of production, provided that the differences are adopted for *bona fide* purposes. The panel did not attempt to provide a general rule regarding what differences will be considered *bona fide*.

The panel's reasoning is of considerable importance in the implementation of Article 31 because it indicates that there may be distinctions regarding fields of technology, and distinctions regarding imported and locally produced products, made when adopting rules and granting compulsory licences. WTO Members are precluded from adopting or applying rules in a manner that "discriminate". This implies adopting or applying a rule for an improper purpose, such as solely to confer an economic advantage on local producers. There may, however, be *bona fide* reasons for drawing distinctions, such as assuring that compelling public interests are satisfied.

Strongly reinforcing the panel's view that Members may adopt *bona fide* distinctions among fields of technology are paragraphs 6 and 7 of the Doha Declaration on the TRIPS Agreement and Public Health. Paragraph 6 directs the TRIPS Council to specifically consider a situation affecting manufacturing capacity in the "pharmaceutical sector", and paragraph 7 specifically addresses the implementation and enforcement of TRIPS rules relating to "pharmaceutical products".

Moreover, it can be argued 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.[942]

4.2 United States – Brazil

On May 30, 2000, the United States requested consultations with Brazil under the WTO Dispute Settlement Understanding, stating:

> "[The United States] request[s] consultations with the Government of Brazil ... concerning those provisions of Brazil's 1996 industrial property law (Law No. 9,279 of 14 May 1996; effective May 1997) and other related measures, which establish a 'local working' requirement for the enjoyability of exclusive patent rights that can only be satisfied by the local production – and not the importation – of the patented subject matter.
>
> Specifically, Brazil's 'local working' requirement stipulates that a patent shall be subject to compulsory licensing if the subject matter of the patent is not 'worked' in the territory of Brazil. Brazil then explicitly defines 'failure to be worked' as 'failure to manufacture or incomplete manufacture of the product', or 'failure to make full use of the patented process'. The United States considers that such a

[942] In addition, the view of the panel was not shared by all Members, as reflected by the proceedings of the DSB meeting when the report was submitted for adoption.

requirement is inconsistent with Brazil's obligations under Articles 27 and 28 of the TRIPS Agreement, and Article III of the GATT 1994."[943]

The request for consultations was followed by a U.S. request for establishment of a panel.[944] The United States withdrew its complaint in this matter prior to the submission of written pleadings by either party.[945] However, the request for consultations illustrates that provisions authorizing compulsory licensing for "non-working" may be subject to challenge under Article 27.[946]

The Paris Convention authorizes the grant of compulsory licences for failure to work a patent. A major issue in a case such as that brought by the United States against Brazil is whether Article 27.1 was intended to prohibit WTO Members from adopting and implementing local working requirements, and effectively to supersede the Paris Convention rule. The negotiating history of TRIPS indicates that Members differed strongly on the issue of local working. Several delegations favoured a direct prohibition of local working requirements, but TRIPS did not incorporate a direct prohibition. Instead, it says that patent rights shall be enjoyable without discrimination as to whether goods are locally produced or imported. Under the jurisprudence of *EC-Canada*, this leaves room for local working requirements adopted for *bona fide* (*i.e.*, non-discriminatory) purposes.

5. Relationship with other international instruments

5.1 WTO Agreements

5.2 Other international instruments

Article 5.A.2 of the Paris Convention provides:

> "Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licences to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work."

Article 5.A.4 of the Paris Convention provides:

> "A compulsory licence may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date

[943] Request for Consultations by the United States, *Brazil – Measures Affecting Patent Protection*, WT/DS199/1, G/L/385, IP/D/23, 8 June 2000.

[944] Request for the Establishment of a Panel by the United States, *Brazil – Measures Affecting Patent Protection*, WT/DS199/39, January 2001.

[945] See Joint Communication Brazil-United States, June 25, 2001. Following notification of the U.S. decision to withdraw its complaint (without prejudice), the communication stated:

> "the Brazilian Government will agree, in the event it deems necessary to apply Article 68 to grant a compulsory licence on a patent held by a U.S. company, to provide advance notice and adequate opportunity for prior talks on the matter with the United States. These talks would be held within the scope of the U.S.-Brazil Consultative Mechanism, in a special session scheduled to discuss the subject.
>
> "Brazil and the United States consider that this agreement is an important step towards greater cooperation between the two countries regarding our shared goals of fighting AIDS and protecting intellectual property rights."

[946] Article 28, TRIPS Agreement, sets out the basic rights of patent holders. Article III of GATT 1994 is the national treatment provision applicable to trade in goods.

of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory licence shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-licence, except with that part of the enterprise or goodwill which exploits such licence."

The Paris Convention authorizes the grant of compulsory licences, and sets out limited conditions to be applied in cases of non-working.[947] The Paris Convention does not otherwise establish specific conditions or restrictions on the granting of compulsory licences.

6. New developments

6.1 National laws

The entry into force of TRIPS has resulted in the revision of patent laws by a substantial number of countries, including those that anticipate accession to the WTO. Many of these countries have consulted with the World Intellectual Property Organization (WIPO) concerning the terms of their revised intellectual property laws. The model patent law that is generally proposed by WIPO includes provision for compulsory licensing of patents taking into account the rules of Article 31.

6.1.1 Canada

Since the adoption of the Decision on Implementation of Paragraph 6, Canada and Norway have passed implementing legislation, and a number of other countries are proposing to do so. Canada's legislation prescribes a list of products eligible for export under license, but permits additions to the list by action of the executive (in consultation with an expert advisory committee).[948] Remuneration will be based on the level of economic development of the importing country, and royalties will range from less than one percent to four percent. Canada will authorize exports to non-WTO Member countries with an undertaking from the importing country to comply with the rules of the Decision. If exports are priced above a certain threshold in relation to Canadian prices, the patent holder will have the opportunity to challenge the grant and terms of the license.

6.1.2 Norway

The legislation and regulations adopted by Norway do not limit the products that may be exported, relying on the decision of the importing country.[949] Like Canada,

[947] Article 2.1 of the TRIPS Agreement states that the Agreement does not derogate from existing obligations of Members under the Paris Convention. If, for the sake of argument, Article 27.1 were to be construed to restrict or preclude compulsory licensing for non-working, this would derogate from a "right" of Members, not an "obligation". As such, this interpretation would not be precluded by Article 2.2 of TRIPS.

[948] Bill C-9, An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa), passed by the House of Commons, May 4, 2004, by the Senate without amendment, May 13, 2004, receiver Royal Assent, May 14, 2004).

[949] Regulations Amending The Patent Regulations (in accordance with the Decision of the WTO General Council of 30 August 2003, pursuant to sections 49 and 69 of the Act of 15 December 1967 No. 9 relating to patents, the Ministry of Justice and the Police laid down the following regulations by Royal Decree of 14 May 2004). See Consultation – Implementation of paragraph 6

Norway will permit exports to non-WTO Members with an appropriate commitment to abide by the rules of the Decision. Remuneration will be determined on a case-by-case basis.

6.2 International instruments

6.2.1 The decision on implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health[950]

Paragraph 6 of the Doha Declaration recognized the problem that countries with insufficient or no manufacturing capacity in the pharmaceutical sector have in making effective use of compulsory licensing, and directed the TRIPS Council to recommend an expeditious solution.[951] On August 30, 2003, following nearly two years of negotiations, the General Council adopted the Decision, preceded by the reading of a Chairperson's Statement. The Decision is intended to allow countries with manufacturing capacity to make and export pharmaceutical products to countries with public health needs, notwithstanding Article 31(f) of TRIPS that limits compulsory licensing predominantly to the supply of the domestic market. It does this by establishing a mechanism under which the restriction of Article 31(f) is waived for the exporting country, and Article 31(h) (remuneration) is waived for the importing country.

Paragraph 1 of the Decision defines "pharmaceutical product" broadly, and does not limit application of the solution to specific disease conditions. The definition expressly covers active pharmaceutical ingredients (APIs), and diagnostic kits. The definition is sufficiently broad to encompass vaccines. It requires Members other than least-developed country Members (which are automatically included) to submit a notification of their intention to use the system in whole or in part, which notification may be modified at any time. This notification establishes the Member as an "eligible importing Member", and several developed Members have opted out of the system in whole or in a limited way.

Paragraph 2 of the Decision establishes conditions for use of the waiver. The importing Member must notify the TRIPS Council of its needs, and (except for least developed country Members), must indicate that it has determined that it has insufficient or no manufacturing capacity for the product(s) in question. The latter determination is made in accordance with an Annex to the Decision. When there is a patent in the importing Member, it must indicate that it has issued, or intends to issue, a compulsory license (except for least developed country Members that elect not to enforce patents pursuant to Paragraph 7 of the Doha Declaration). The

of the Doha Declaration on the TRIPS Agreement and Public Health in Norwegian law, available at <http://www.dep.no/ud/engelsk/>.

[950] WT/L/540, the "Decision" (reproduced as Annex 1, including Chairperson's Statement).

[951] See Frederick M. Abbott, *The Containment of TRIPS to Promote Public Health: A Commentary on the Decision on Implementation of Paragraph 6 of the Doha Declaration*, manuscript with reference to be provided (forthcoming 2004); Carlos Correa, *Implementation Of The WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WHO 2004 (forthcoming) (hereinafter "Correa 2004"), and; Paul Vandoren and Jean Charles Van Eeckhaute, *The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, 6* J. World Intell. Prop. 779 (2003).

exporting Member must notify the TRIPS Council of the terms of the export license it issues, including the destination, quantities to be supplied and the duration of the license. The products supplied under the license must be identified by special packaging and/or colouring/shaping. Before quantities are shipped, the licensee must post on a publicly accessible website the destination and means it has used to identify the products as supplied under the system.

Paragraph 3 provides for a waiver of the remuneration requirement for the importing country, discussed above in Section 3 of this chapter.

Paragraph 4 requires importing Members to implement measures proportionate to their means to prevent diversion of products imported under the system. Paragraph 4 does not specify the nature of such means, which might include mechanisms pursuant to which patent holders can obtain remedies.

Paragraph 5 requires other Members to take measures already provided for under TRIPS to prevent the importation of diverted products into their territories.

Paragraph 6 provides an additional waiver of Article 31(f) for regional trading arrangements in Africa (i.e., more than half of which were least developed countries when the Decision was adopted). This waiver allows a Member to export to countries throughout the region under a single compulsory license, although it does not expressly waive the requirement for licenses to be issued by importing countries of the region. The main benefit of the waiver may be to allow the import of APIs, formulation into finished products, and export throughout the African region.

Paragraph 7 refers in a general way to transfer of technology.

Paragraph 8 makes clear that the waiver does not require annual renewal.

Paragraph 9 indicates that the Decision is without prejudice to rights that Members may otherwise have under TRIPS (such as the potential for exports under Article 30).

Paragraph 10 precludes non-violation nullification or impairment causes of action with respect to the Decision.

Paragraph 11 provides that the waiver will remain effective for each Member until an amendment has come into effect to replace it there, and that Members will commence negotiations for an amendment to be based, where appropriate, on the waiver. Although the Decision stated that the negotiations would have a view to completion within six months following the end of 2003, in June 2004 the TRIPS Council extended that tentative completion date until the end of March 2005.

The Chairperson's Statement indicates, *inter alia*, that Members will act in good faith in using the Decision, providing:

> "First, Members recognize that the system that will be established by the Decision should be used in good faith to protect public health and, without prejudice to paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial policy objectives."

This statement of good faith does not in any way preclude enterprises from acting for commercial gain. Since it is unlikely that a Member would use importation as the means to effect an industrial or commercial policy, it seems doubtful that this statement of good faith will inhibit use of the system.

6.2.2 Paragraph 5 of the Doha Declaration

Paragraph 5 of the WTO Doha Ministerial Declaration on the TRIPS Agreement and Public Health (Doha Declaration) states in its relevant part:

> "5. [. . .], while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities [i.e. the ones contained in the TRIPS Agreement] include: [. . .]
>
> (b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
>
> (c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, . . . "

This statement does not provide for any substantive modifications of TRIPS but only reiterates what is already stipulated therein. Paragraph (b) relates to Members' discretion with regard to the grounds upon which compulsory licences are granted. Paragraph (c) refers to Article 31(b), making clear that the definition of the terms "national emergency" and "other circumstances of extreme urgency" is up to Members' discretion. This leaves Members considerable room for the pursuit of public policy objectives, especially those related to public health.

6.3 Regional context

6.3.1 FTAA

Countries of the western hemisphere have proposed to enter into a Free Trade Area of the Americas (FTAA) Agreement by 2005. A preliminary draft text of the FTAA includes a chapter on intellectual property rights.[952] That chapter includes a number of proposals regarding compulsory licensing.

6.3.2 The Andean Community

In September 2000, the Andean Community (Bolivia, Colombia, Ecuador, Peru and Venezuela) adopted Decision 486 establishing a new IPR system. This Decision contains a separate chapter on compulsory licensing.[953]

6.3.3 The Bangui Agreement

Finally, the African Intellectual Property Organization (OAPI) in 1999 revised the 1977 Bangui Agreement on the Creation of an African Intellectual Property Organization. Annex 1, Title IV to the 1999 Agreement regulates non-voluntary licenses.[954]

6.4 Proposals for review

As noted earlier, the Decision on Implementation of Paragraph 6 provides for negotiation of an amendment to be based, where appropriate, on the Decision. It

[952] FTAA – Free Trade Area of the Americas, Draft Agreement, Chapter on Intellectual Property Rights, Derestricted, FTAA.TNC/w/133/Rev.1, July 3, 2001.

[953] See <http://www.ftaa-alca.org/intprop/natleg/Decisions/dec486_e.asp>.

[954] See <http://www.oapi.wipo.net/en/textes/pdf/accord_bangui.pdf>.

is expected that some developing Members will propose changes to the Decision, but as of July 2004, no formal proposals to this effect had been made to the TRIPS Council.[955]

7. Comments, including economic and social implications

Compulsory licensing of patents is one of the most important economic instruments for developing countries attempting to address the technology gap with developed countries. In her classic 1951 work, *The Economics of the International Patent System*, Edith Penrose observed:

> "The second method of reducing the cost of the patent monopoly is that of compulsory licensing. This is by far the most effective and flexible method and enables the state to prevent most of the more serious restrictions on industry. It could be used very effectively to undermine the monopoly power of several of the more powerful international cartels whose position is largely based on their control of the patent rights to industrial processes in the larger industrial countries; and it could be used to ensure that patented new techniques developed abroad are available to domestic industries wishing to use them.
>
> The International [Paris] Convention places restrictions on the right of countries to subject patents to compulsory licensing. These restrictions should be eliminated and countries should be encouraged to use this device to break up some of the more serious of the monopolistic restrictions on the use of new techniques."[956]

Ownership of technology remains concentrated in the developed countries where large amounts of capital are invested in research and development (R&D). Industries in developing countries have great difficulty in competing in R&D because of persistent structural imbalances. Developed country enterprises are often reluctant to licence new technology on terms and conditions that will permit developing country enterprises to effectively compete in world markets. Although TRIPS makes a number of references to encouraging transfers of technology, there is little evidence that programmes to accomplish this are being implemented. Compulsory licensing, and the threat of compulsory licensing, are necessary to make transfer of technology a reality.

Developing countries that grant compulsory licences run the risk of economic retaliation by developed countries. For this reason, compulsory licensing should be undertaken in accord with international obligations. The adoption of the Doha Declaration has unambiguously confirmed the right of Members to define the grounds for granting compulsory licences.

[955] Note that as of August 2004, Members in the Council for TRIPS have not been able to agree on a common approach to amending Article 31, TRIPS Agreement. Main areas of controversy relate to the content of the amendment and its form. As to the content, delegations disagree whether the Chair's statement, issued together with the Decision of 30 August 2003, should be incorporated into the amendment of the TRIPS Agreement. Some Members have expressed concern about enhancing the Chair's statement's legal status by such incorporation. As to the legal form of the envisaged TRIPS amendment, some Members favour a footnote to Article 31 TRIPS, referring to the Decision as a separate document. Others support the inclusion into the TRIPS Agreement of the full text of the Decision, either under a new Article 31*bis*, or as an Annex, or as a footnote.

[956] Penrose.

The argument is made that compulsory licensing reduces incentives for developed country enterprises to engage in R&D, and that reduced R&D diminishes global welfare by lowering the future stock of useful inventions. However, the benefit to developing countries of increased R&D in the developed countries is often remote, and there is no evidence that the granting of compulsory licences has led to a reduction in R&D investment.[957] Compulsory licensing stresses the interest of developing countries in raising current standards of living.

[957] F. M. Scherer, *Comments* in Robert Anderson and Nancy Gallini (Eds.), *Competition policy and intellectual property rights in the knowledge-based economy*, University of Calgary Press, Alberta 1998.

Annex 1: The Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (the "Decision"), including Chairperson's Statement

Decision of 30 August 2003*

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 Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the "Declaration") and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement and to report to the General Council before the end of 2002;

Recognizing, where eligible importing Members seek to obtain supplies under the system set out in this Decision, the importance of a rapid response to those needs consistent with the provisions of this Decision;

Noting that, in the light of the foregoing, exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products;

Decides as follows:

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. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included[958];

(b) "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification[959] to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system set out in this Decision as importing Members[960]

* This Decision was adopted by the General Council in the light of a statement read out by the Chairman, which can be found in JOB(03)/177. This statement will be reproduced in the minutes of the General Council to be issued as WT/GC/M/82.

[958] This subparagraph is without prejudice to subparagraph 1(b).

[959] It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.

[960] Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom and the United States.

and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

(c) "exporting Member" means a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, an eligible importing Member.

2. The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph:

(a) the eligible importing Member(s)[961] has made a notification[959] to the Council for TRIPS, that:

(i) specifies the names and expected quantities of the product(s) needed[962];

(ii) confirms that the eligible importing Member in question, other than a least-developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and

(iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision[963];

(b) the compulsory licence issued by the exporting Member under this Decision shall contain the following conditions:

(i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;

(ii) products produced under the licence shall be clearly identified as being produced under the system set out in this Decision through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and

(iii) before shipment begins, the licensee shall post on a website[964] the following information:

- the quantities being supplied to each destination as referred to in indent (i) above; and
- the distinguishing features of the product(s) referred to in indent (ii) above;

[961] Joint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in paragraph 6 of this Decision on behalf of eligible importing Members using the system that are parties to them, with the agreement of those parties.

[962] The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

[963] This subparagraph is without prejudice to Article 66.1 of the TRIPS Agreement.

[964] The licensee may use for this purpose its own website or, with the assistance of the WTO Secretariat, the page on the WTO website dedicated to this Decision.

(c) the exporting Member shall notify[965] the Council for TRIPS of the grant of the licence, including the conditions attached to it.[966] The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

3. Where a compulsory licence is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid to that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall be waived in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

4. In order to ensure that the products imported under the system set out in this Decision are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

5. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.

6. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products:

(i) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least-developed countries, the obligation of that Member

[965] It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.

[966] The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least-developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question;

(ii) it is recognized that the development of systems providing for the grant of regional patents to be applicable in the above Members should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of the TRIPS Agreement, including in conjunction with other relevant intergovernmental organizations.

7. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem identified in paragraph 6 of the Declaration. To this end, eligible importing Members and exporting Members are encouraged to use the system set out in this Decision in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of the TRIPS Agreement, paragraph 7 of the Declaration and any other relevant work of the Council for TRIPS.

8. The Council for TRIPS shall review annually the functioning of the system set out in this Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council. This review shall be deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.

9. This Decision is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration, and to their interpretation. It is also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the present provisions of Article 31(f) of the TRIPS Agreement.

10. Members shall not challenge any measures taken in conformity with the provisions of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

11. This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision and on the further understanding that it will not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration (WT/MIN(01)/DEC/1).

ANNEX [to the Decision]

Assessment of Manufacturing Capacities in the Pharmaceutical Sector Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector. For other eligible importing Members

insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:

(i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector;

OR

(ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.

The General Council's Chairperson's Statement

The General Council has been presented with a draft Decision contained in document IP/C/W/405 to implement paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. This Decision is part of the wider national and international action to address problems as recognized in paragraph 1 of the Declaration. Before adopting this Decision, I would like to place on the record this Statement which represents several key shared understandings of Members regarding the Decision to be taken and the way in which it will be interpreted and implemented. I would like to emphasize that this Statement is limited in its implications to paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.

First, Members recognize that the system that will be established by the Decision should be used in good faith to protect public health and, without prejudice to paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial policy objectives.

Second, Members recognize that the purpose of the Decision would be defeated if products supplied under this Decision are diverted from the markets for which they are intended. Therefore, all reasonable measures should be taken to prevent such diversion in accordance with the relevant paragraphs of the Decision. In this regard, the provisions of paragraph 2(b)(ii) apply not only to formulated pharmaceuticals produced and supplied under the system but also to active ingredients produced and supplied under the system and to finished products produced using such active ingredients. It is the understanding of Members that in general special packaging and/or special colouring or shaping should not have a significant impact on the price of pharmaceuticals.

In the past, companies have developed procedures to prevent diversion of products that are, for example, provided through donor programmes. "Best practices" guidelines that draw upon the experiences of companies are attached to this statement for illustrative purposes. Members and producers are encouraged to draw from and use these practices, and to share information on their experiences in preventing diversion.

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

• To promote transparency and avoid controversy, notifications under paragraph 2(a)(ii) of the Decision would include information on how the Member

in question had established, in accordance with the Annex, that it has insufficient or no manufacturing capacities in the pharmaceutical sector.

- In accordance with the normal practice of the TRIPS Council, notifications made under the system shall be brought to the attention of its next meeting.
- Any Member may bring any matter related to the interpretation or implementation of the Decision, including issues related to diversion, to the TRIPS Council for expeditious review, with a view to taking appropriate action.
- If any Member has concerns that the terms of the Decision have not been fully complied with, the Member may also utilise the good offices of the Director General or Chair of the TRIPS Council, with a view to finding a mutually acceptable solution.

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

In addition, as stated in footnote 3 to paragraph 1(b) of the Decision, the following Members have agreed to opt out of using the system as importers: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America. Until their accession to the European Union, Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia agree that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency. These countries further agree that upon their accession to the European Union, they will opt out of using the system as importers.

As we have heard today, and as the Secretariat has been informed in certain communications, some other Members have agreed that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency: Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, United Arab Emirates.

Attachment:

"Best Practice" guidelines

Companies have often used special labelling, colouring, shaping, sizing, etc. to differentiate products supplied through donor or discounted pricing programmes from products supplied to other markets. Examples of such measures include the following:

- Bristol Myers Squibb used different markings/imprints on capsules supplied to sub-Saharan Africa.
- Novartis has used different trademark names, one (Riamet®) for an antimalarial drug provided to developed countries, the other (Coartem®) for the same products supplied to developing countries. Novartis further differentiated the products through distinctive packaging.
- GlaxoSmithKline (GSK) used different outer packaging for its HIV/AIDS medications Combivir, Epivir and Trizivir supplied to developing countries. GSK

further differentiated the products by embossing the tablets with a different number than tablets supplied to developed countries, and plans to further differentiate the products by using different colours.

- Merck differentiated its HIV/AIDS antiretroviral medicine CRIXIVAN through special packaging and labelling, i.e., gold-ink printing on the capsule, dark green bottle cap and a bottle label with a light-green background.
- Pfizer used different colouring and shaping for Diflucan pills supplied to South Africa.

Producers have further minimized diversion by entering into contractual arrangements with importers/distributors to ensure delivery of products to the intended markets.

To help ensure use of the most effective anti-diversion measures, Members may share their experiences and practices in preventing diversion either informally or through the TRIPS Council. It would be beneficial for Members and industry to work together to further refine anti-diversion practices and enhance the sharing of information related to identifying, remedying or preventing specific occurrences of diversion.