



**WORKSHOP ON THE INTELLECTUAL PROPERTY
FRAMEWORK AND ADMINISTRATION IN UGANDA**

—
MOCK TRIAL CASE MATERIALS

**Technical Assistance to the Uganda Ministry of Tourism, Trade and
Industry in the Area of Intellectual Property Rights**

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1. CASE FACTS

James Massa is a student at Makerere University in Kampala. He has many friends and keeps in contact with them through his cell phone. No matter where he is, James's phone is constantly ringing. To keep track of which friend is calling him, James decides that he needs distinctive ringtones for each of his ten closest friends. James logs onto his laptop computer and explores the internet, looking for a website that offers all of his favorite songs as ringtones. Although he can find a few of the songs that he would like to use for sale on the Internet, he cannot find some of the desired songs available for sale as ringtones at all.

James soon discovers that Limewire will allow him to download all of the music he likes for free, in a ringtone format. James is a great customer for the recording industry – he owns dozens of CDs and often pays to see local bands play at Kampala clubs. But James just wants an easy way to make his favorite songs into ringtones. So, through the peer-to-peer (P2P) network of Limewire, James downloads ringtone versions of ten (10) of his favorite songs for free directly from the computers of other Limewire users. The ringtone versions are thirty-second excerpts from the songs, without words, which faithfully copy the tunes of the songs as played on an electric piano.

James downloads ringtones based on the following songs: Mukidongo, by Wafagio; Nakudatta, by Mowzey Radio and Weasel; Manzi Wanani, by Clever Jay; Kapapala, by David Lutalo; Mazongoto, by Dr. Hilderman; Katika, by Blu 3; Thriller, by Michael Jackson; Beat It, by Michael Jackson; Billie Jean, by Michael Jackson; and Bad, by Michael Jackson.

James happily enjoys his new ringtones until he receives a letter in the mail from various recording companies threatening to sue for vast amounts of money from him because he has infringed their copyrights. The letter warns James that the recording companies are planning to seek an

injunction against him and seize his cell phone if he does not pay them a settlement fee, equal to the cost of two hundred CDs, in one week.

Disregarding the recording companies' letter, James continues to use Limewire to download music without paying. He also introduces many of his friends to Limewire and they also begin to download music. One day, James decides to use the Limewire P2P network to make a little money for himself and his family. Using a university-owned computer in one of Makerere University's computer labs, he downloads a copy of the 2007 Microsoft Office Professional Suite from a U.S.-based Limewire user and burns it onto a writable CD ROM. He also downloads thirty of his favorite Michael Jackson songs from various users in the U.S. and the E.U. and burns them onto a CD ROM. He then mails both CD ROMs to his friend Ben who lives in Nairobi and who has just purchased a new CD burner with LightScribe disc-labeling capabilities. Using his new burner, Ben makes 1,000 copies of the Microsoft Office Suite and 5,000 copies of the Michael Jackson "Top Hits" CD. To make the Microsoft Office copies appear as authentic products, he burns the following label on each of the 1,000 CDs:



Ben also places the following label on each of the 5,000 Michael Jackson CDs:



Ben then ships the 6,000 CDs back to James in Kampala who sells them to three different music and software stores. James pockets over twenty million Uganda Shillings. He sends five million to Ben to thank him for helping him with the project. With the rest of the money, James pays school fees for five of his seven brothers, buys food supplies for his parents in the village and pays his outstanding debt to Makerere University. James also buys a small farm for his mother, so she can grow vegetables throughout the year to help feed the family on a more regular basis.

In the meantime, Microsoft has brought a trademark and copyright infringement suit against James. Furthermore, Sony BMG has asked the Uganda government to bring charges against: 1) James; 2) Makerere University and; 3) the three stores who sold the Michael Jackson CDs. It turns out that the “Microsoft Office” logo Ben placed on the copies of the Microsoft Office Professional Suite has been registered in Part A of Uganda’s register of trademarks in 2007. Sony BMG, on the other hand, has never sought trademark protection for its label in Uganda or any other African country. The “Sony BMG – Music Entertainment” label has, however, been registered as a trademark with the United States Patent and Trademark Office (USPTO) in 2002 and with the trademark offices of various E.U. Member States in 2003.

James's dormitory room was searched by police officers while James was attending lectures. Among the items seized by the police from James's room are three boxes of antiretrovirals which James had purchased for his sick father and four other family members who have been diagnosed with HIV. The State Attorney now claims that the medications infringe upon a patent that has been registered in Uganda and that the local pharmacy that sells these drugs has no legal grounds to import them into the country. It appears that the drugs were manufactured in India and Uganda Revenue Authority (URA) Customs agents have tried unsuccessfully to stop the importation to Uganda.

This case has generated immense attraction from multinational corporations seeking to invest in Uganda, human rights groups concerned about access to medicines for Uganda citizens, civil society activists, and many other groups. The case presents a seminal opportunity to interpret and apply Uganda's new IP laws in light of Uganda's treaty obligations while considering Uganda's position as a least-developed country.

2. RELEVANT STATUTORY PROVISIONS

A. The Uganda Copyright and Neighboring Rights Act (2006)

PART I—PRELIMINARY

2. Interpretation

In this Act, unless the context otherwise requires—

“author” means the physical person who created or creates work protected under section 5 and includes a person or authority commissioning work or employing a person making work in the course of employment;

“computer programme” means a set of instructions expressed in any language, code or notation, intended to cause the device having an information processing capacity to indicate, perform or achieve a particular function, task or result;

“copy” means a production of a work in a written, recorded or fixation form or in any other material form, but an object shall not be taken to be a copy of an architectural work unless the object is a building or a model;

“derivative work” means work resulting from adaptation, translation or other transformation of an original work but which constitutes an independent creation in itself;

“economic rights” means the rights specified under section 9;

“fixation” means the embodiment of images or sound or both images and sound in a material form sufficiently stable or permanent, to permit them to be perceived, reproduced or otherwise communicated through a device during a period of more than transitory duration;

“literary work” includes—

- (a) novels, stories or poetic work;
- (b) plays, stage directions, audio-visual scenarios or broadcasting scripts;
- (c) textbooks, histories, biographies, essays or articles;
- (d) encyclopaedias, dictionaries, directories or anthologies;
- (e) letters, reports or memoranda;
- (f) lectures, addresses or sermons; and
- (g) any other work of literature;

“neighbouring rights” include rights of performing artistes in their performances, rights of producers and music publishers and rights of broadcasting companies in their programmes and others as is provided under Part IV;

“producer” means a person who organises and finances the production of an audio visual fixation or sound recording;

“reproduction” means the making of one or more copies of a work or sound recording in any manner or form including any permanent or temporary storage of the work or sound recording in electronic form.

“sound recording” means any exclusively aural fixation of sound in a material carrier such as a tape, disc or other similar material but does not include audio visual work including sound.

3. Application of the Act

This Act applies to any work, including work, created or published before the commencement of this Act, which has not yet fallen into the public domain where the work is—

- (a) created by a citizen of Uganda or a person resident in Uganda;
- (b) first published in Uganda, irrespective of the nationality or residence of the author;
- (c) created by a person who is a national of or resident in a country referred to in section 81 or;
- (d) first published in a country referred to in section 81.

PART II—COPYRIGHT PROTECTION AND RIGHTS

4. Author entitled to copyright protection.

- (1) The author of any work specified in section 5 shall have a right of protection of the work, where work is original and is reduced to material form in whatever method irrespective of quality of the work or the purpose for which it is created.
- (2) The protection of the author’s work under subsection (1) shall not be subject to any formality.
- (3) For the purpose of this section, a work is original if it is the product of the independent efforts of the author.

5. Work eligible for copyright.

- (1) The following literary, scientific and artistic works are eligible for copyright—
 - (a) articles, books, pamphlets, lectures, addresses, sermons and other works of a similar nature;
 - (b) dramatic, dramatic-musical and musical works;
 - (c) audio-visual works and sound recording, including cinematographic works and other work of a similar nature;

- (d) choreographic works and pantomimes;
- (e) computer programmes and electronic data banks and other accompanying materials;
- (f) works of drawing, painting, photography, typography, mosaic, architecture, sculpture, engraving, lithography and tapestry;
- (g) works of applied art, whether handicraft or produced on industrial scale, and works of all types of designing;
- (h) illustrations, maps, plans, sketches and three dimensional works relative to geography, topography, architecture or science;
- (i) derivative work which by selection and arrangement of its content, constitute original work;
- (j) any other work in the field of literature, traditional folklore and knowledge, science and art in whatever manner delivered, known or to be known in the future.

(2) Derivative works such as—

- (a) translations, adaptations and other transformations of pre-existing works under subsection (1); and
 - (b) collections of pre-existing works like encyclopaedia and anthologies;
- which by selection and arrangement of their contents constitute original works, shall be protected under this Act as original works.

(3) The protection of a derivative work under subsection (2) shall not affect the protection of the pre-existing work used by a person for derivation purposes.

9. Economic rights of author.

The owner of a protected work shall have, in relation to that work, the exclusive right to do or authorise other persons to do the following—

- (a) to publish, produce or reproduce the work;
- (b) to distribute or make available to the public the original or copies of the work through sale or other means of transfer of ownership;
- (c) to perform the work in public;
- (d) to broadcast the work;
- (e) to communicate the work to the public by wire or wireless means or through any known means or means to be known in the future, including making the work available to the public through the internet or in such a way that members of the public may access the work from a place and at a time individually chosen by them;

- (f) where the work is a pre-existing work, to make a derivative work;
- (g) to commercially rent or sell the original or copies of the work;
- (h) to do, in relation to that work any act known or to be known in the future;
- (i) to reproduce transcription into braille which is accessible to blind persons.

PART III—DURATION OF COPYRIGHT AND AUTHORIZED USES OF PROTECTED WORKS

15. Fair use of works protected by copyright

(1) The fair use of a protected work in its original language or in a translation shall not be an infringement of the right of the author and shall not require the consent of the owner of the copyright where—

- (a) the production, translation, adaptation, arrangement or other transformation of the work is for private personal use only;

(2) In determining whether the use made of a work in any particular case is a fair use the following factors shall be considered—

- (a) the purpose and character of the use, including whether the use is of a commercial nature or is for non-profit educational purposes;
- (b) the nature of the protected work;
- (c) the amount and substantiality of the portion used in relation to the protected work as a whole; and
- (d) the effect of the use upon the potential market for value of the protected work.

(3) The fact that a piece of work is not published shall not of itself prejudice the requirement of fair use in accordance with subsection (2).

PART IV—NEIGHBOURING RIGHTS

28. Rights of producer

(1) A producer of a sound recording or audio-visual fixation shall have a right to authorise the reproduction of that sound recording or audio-visual fixation.

(2) A producer of sound recording or audio-visual fixation shall have the right to authorise the distribution or making available to the public of the original or copies of the fixation through sale or other transfer of ownership.

(3) A producer of sound recording or audio-visual fixation shall have the right to authorise the commercial rental to the public of the original or copies of the fixation even after the distribution or making available to the public of the original or copies of the fixation by the producer.

(4) A producer of sound recording or audio visual fixation shall have the right to authorise making available to the public of the fixation, by wire or wireless means, in such a way that members of the public may access the fixation from a place and at a time individually chosen by them.

(5) No person shall reproduce, distribute or make available to the public a sound recording or audio-visual fixation without the authorisation of the producer under this section.

(6) For the purposes of this section, reproduction of a copy of a sound recording or an audio-visual fixation shall be unlawful if, with or without imitating the outward characteristics of the original work, it incorporates all or part of the sound or image with or without sound and without authorisation.

(7) Where a sound recording or audio-visual fixation for commercial advertisement or its reproduction is used for broadcasting or for any other form of communication to the public, the user shall not require the authorisation of the producer, but shall pay an equitable remuneration to the producer and the performer.

(8) The rights of the producer under this section shall be protected for fifty years from the date of the cutting of the matrix.

30. Notice of protection of producer's rights

(1) Where copies of a sound recording or audio-visual fixation are made for commercial purposes there shall be printed on the copies a notice consisting of—

(a) the symbol ©; and

(b) the year of first publication of the sound recording or audio-visual fixation placed in a manner that gives reasonable notice of claim of protection of the rights of the producer.

34. Limitation on neighbouring rights

The provisions of sections 24, 27, 28, 29, 30, 33 shall not apply where the acts done are for—

(a) private use;

PART VIII—GENERAL PROVISIONS

81. Reciprocal protection

A copyright or neighbouring rights owner who is not a citizen or resident of Uganda shall be protected under this Act if the work was first published in a country which is—

(a) a member of any of the organisations specified in Part I of the Second Schedule to this Act; or

(b) a signatory to any of the international conventions specified in Part II of the Second

Schedule to this Act.

SECOND SCHEDULE

PART I—ORGANISATIONS

1. World Intellectual Property Organisation (WIPO)
2. Africa Region Intellectual Property Organisation (ARIPO)
3. The United Nations Educational Scientific and Cultural Organisation (UNESCO)
4. The World Trade Organisation.

PART II—INTERNATIONAL CONVENTIONS

1. The Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement).

B. The Uganda Trademarks Act, Cap. 217 (1953)

1. Interpretation

(1) In this Act, unless the context otherwise requires—

- (d) “mark” includes a device, brand, heading, label, ticket, name, signature, word, letter, numeral or any combination of them;
- (h) “registered trademark” means a trademark that is actually on the register;
- (l) “trademark” means, except in relation to a certification trademark, a mark used or proposed to be used in relation to goods for the purpose of indicating, or so as to indicate, a connection in the course of trade between the goods and some

(2) References in this Act to the use of a mark shall be construed as references to the use of a printed or other visual representation of the mark, and references in this Act to the use of a mark in relation to goods shall be construed as references to the use of the mark upon, or in physical or other relation to, goods.

4. No action for infringement of unregistered trademark

No person shall be entitled to institute any proceeding to prevent, or to recover damages for, the infringement of an unregistered trademark, but nothing in this Act shall be deemed to affect rights of action against any person for passing off goods as the goods of another person or the remedies in respect of those rights of action.

5. Registration to be in respect of particular goods

A trademark must be registered in respect of particular goods or classes of goods, and any question arising as to the class within which any goods fall shall be determined by the registrar, whose decision shall be final.

6. Right given by registration in Part A, and infringement of it

(1) Subject to this section and sections 9 and 10, the registration (whether before or after the commencement of this Act), of a person in Part A of the register as proprietor of a trademark (other than a certification trademark) in respect of any goods shall, if valid, give or be deemed to have given to that person the exclusive right to the use of the trademark in relation to those goods and, without prejudice to the generality of the foregoing provisions, that right shall be deemed to be infringed by any person, who, not being the proprietor of the trademark or a registered user of the trademark using by way of the permitted use, uses a mark identical with it or so nearly resembling it as to be likely to deceive or cause confusion in the course of trade in relation to any goods in respect of which it is registered and in such manner as to render the use of the mark likely to be taken either—

- (a) as being use as a trademark; or
- (b) in a case in which the use is use upon the goods or in physical relation to them or in an advertising circular or other advertisement issued to the public, as importing a reference to some person having the right either as proprietor or as registered user to

use the trademark or to goods with which that person is connected in the course of trade.

(2) The right to the use of a trademark given by registration in Part A of the register shall be subject to any conditions or limitations entered on the register, and shall not be deemed to be infringed by the use of that mark in any mode, in relation to goods to be sold or otherwise traded-in in any place, in relation to goods to be exported to any market, or in any other circumstances, to which, having regard to any such limitations, the registration does not extend.

(3) The right to the use of a trademark given by registration in Part A of the register shall not be deemed to be infringed by the use of that mark by any person—

- (a) in relation to goods connected in the course of trade with the proprietor or a registered user of the trademark if, as to those goods or a bulk of which they form part, the proprietor or the registered user conforming to the permitted use has applied the trademark and has not subsequently removed or obliterated it, or has at any time expressly or impliedly consented to the use of the trademark; or
- (b) in relation to goods adapted to form part of, or to be accessory to, other goods in relation to which the trademark has been used without infringement of the right given as aforesaid or might for the time being be so used, if the use of the mark is reasonably necessary in order to indicate that the goods are so adapted and neither the purpose nor the effect of the use of the mark is to indicate otherwise than in accordance with the fact a connection in the course of trade between any person and the goods.

3. RELEVANT INTERNATIONAL INSTRUMENTS

A. The TRIPS Agreement (1994)

AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS

Preamble

Members,

Desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade;

Recognizing, to this end, the need for new rules and disciplines concerning:

- (a) the applicability of the basic principles of GATT 1994 and of relevant international intellectual property agreements or conventions;
- (b) the provision of adequate standards and principles concerning the availability, scope and use of trade-related intellectual property rights;
- (c) the provision of effective and appropriate means for the enforcement of trade-related intellectual property rights, taking into account differences in national legal systems;
- (d) the provision of effective and expeditious procedures for the multilateral prevention and settlement of disputes between governments; and
- (e) transitional arrangements aiming at the fullest participation in the results of the negotiations;

Recognizing the need for a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods;

Recognizing that intellectual property rights are private rights;

Recognizing the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives;

Recognizing also the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base;

Emphasizing the importance of reducing tensions by reaching strengthened commitments to resolve disputes on trade-related intellectual property issues through multilateral procedures;

Desiring to establish a mutually supportive relationship between the WTO and the World Intellectual Property Organization (referred to in this Agreement as "WIPO") as well as other relevant international organizations;

Hereby agree as follows . . .

Article 7

Objectives

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

Article 8

Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

Article 30

Exceptions to Rights Conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Article 31

Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use¹ 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;

¹ "Other use" refers to use other than that allowed under Article 30.

- (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.

ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS

SECTION 1: GENERAL OBLIGATIONS

Article 41

1. Members shall ensure that enforcement procedures as specified in this Part are available under their law so as to permit effective action against any act of infringement of intellectual property rights covered by this Agreement, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements. These procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.

2. Procedures concerning the enforcement of intellectual property rights shall be fair and equitable. They shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays.

3. Decisions on the merits of a case shall preferably be in writing and reasoned. They shall be made available at least to the parties to the proceeding without undue delay. Decisions on the merits of a case shall be based only on evidence in respect of which parties were offered the opportunity to be heard.

4. Parties to a proceeding shall have an opportunity for review by a judicial authority of final administrative decisions and, subject to jurisdictional provisions in a Member's law concerning the importance of a case, of at least the legal aspects of initial judicial decisions on the merits of a case. However, there shall be no obligation to provide an opportunity for review of acquittals in criminal cases.

5. It is understood that this Part does not create any obligation to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of Members to enforce their law in general. Nothing in this Part creates any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general.

SECTION 2: CIVIL AND ADMINISTRATIVE PROCEDURES AND REMEDIES

Article 42

Fair and Equitable Procedures

Members shall make available to right holders² civil judicial procedures concerning the enforcement of any intellectual property right covered by this Agreement. Defendants shall have the right to written notice which is timely and contains sufficient detail, including the basis of the claims. Parties shall be allowed to be represented by independent legal counsel, and procedures shall not impose overly burdensome requirements concerning mandatory personal appearances. All parties to such procedures shall be duly entitled to substantiate their claims and to present all relevant evidence. The procedure shall provide a means to identify and protect confidential information, unless this would be contrary to existing constitutional requirements.

Article 44

Injunctions

1. The judicial authorities shall have the authority to order a party to desist from an infringement, *inter alia* to prevent the entry into the channels of commerce in their jurisdiction of imported goods that involve the infringement of an intellectual property right, immediately after customs clearance of such goods. Members are not obliged to accord such authority in respect of protected subject matter acquired or ordered by a person prior to knowing or having reasonable

² For the purpose of this Part, the term "right holder" includes federations and associations having legal standing to assert such rights.

grounds to know that dealing in such subject matter would entail the infringement of an intellectual property right.

2. Notwithstanding the other provisions of this Part and provided that the provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with, Members may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Article 31. 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.

Article 45

Damages

1. The judicial authorities shall have the authority to order the infringer to pay the right holder damages adequate to compensate for the injury the right holder has suffered because of an infringement of that person's intellectual property right by an infringer who knowingly, or with reasonable grounds to know, engaged in infringing activity.

2. The judicial authorities shall also have the authority to order the infringer to pay the right holder expenses, which may include appropriate attorney's fees. In appropriate cases, Members may authorize the judicial authorities to order recovery of profits and/or payment of pre-established damages even where the infringer did not knowingly, or with reasonable grounds to know, engage in infringing activity.

Article 46

Other Remedies

In order to create an effective deterrent to infringement, the judicial authorities shall have the authority to order that goods that they have found to be infringing be, without compensation of any sort, disposed of outside the channels of commerce in such a manner as to avoid any harm caused to the right holder, or, unless this would be contrary to existing constitutional requirements, destroyed. The judicial authorities shall also have the authority to order that materials and implements the predominant use of which has been in the creation of the infringing goods be, without compensation of any sort, disposed of outside the channels of commerce in such a manner as to minimize the risks of further infringements. In considering such requests, the need for proportionality between the seriousness of the infringement and the remedies ordered as well as the interests of third parties shall be taken into account. In regard to counterfeit trademark goods, the simple removal of the trademark unlawfully affixed shall not be sufficient, other than in exceptional cases, to permit release of the goods into the channels of commerce.

SECTION 4: SPECIAL REQUIREMENTS RELATED TO BORDER MEASURES

Article 59

Remedies

Without prejudice to other rights of action open to the right holder and subject to the right of the defendant to seek review by a judicial authority, competent authorities shall have the authority to order the destruction or disposal of infringing goods in accordance with the principles set out in Article 46. In regard to counterfeit trademark goods, the authorities shall not allow the re-exportation of the infringing goods in an unaltered state or subject them to a different customs procedure, other than in exceptional circumstances.

SECTION 5: CRIMINAL PROCEDURES

Article 61

Members shall provide for criminal procedures and penalties to be applied at least in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale. Remedies available shall include imprisonment and/or monetary fines sufficient to provide a deterrent, consistently with the level of penalties applied for crimes of a corresponding gravity. In appropriate cases, remedies available shall also include the seizure, forfeiture and destruction of the infringing goods and of any materials and implements the predominant use of which has been in the commission of the offence. Members may provide for criminal procedures and penalties to be applied in other cases of infringement of intellectual property rights, in particular where they are committed wilfully and on a commercial scale.

B. Doha Declaration on the TRIPS Agreement and Public Health (2001)

DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Adopted on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.
2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.
3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.
4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:
 - (a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
 - (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, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
 - (d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

C. WTO General Council Decision of 30 August 2003

IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

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:

"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

* 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.

that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included³;

"eligible importing Member" means any least-developed country Member, and any other Member that has made a notification⁴ 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 Members⁵ 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;

"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.

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:

the eligible importing Member(s)⁶ has made a notification² to the Council for TRIPS, that:

- (i) specifies the names and expected quantities of the product(s) needed⁷;
- (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 Decision⁸;

³ This subparagraph is without prejudice to subparagraph 1(b).

⁴ 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.

⁵ 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.

⁶ 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.

⁷ The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

⁸ This subparagraph is without prejudice to Article 66.1 of the TRIPS Agreement.

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

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;

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

before shipment begins, the licensee shall post on a website⁹ 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;

the exporting Member shall notify¹⁰ the Council for TRIPS of the grant of the licence, including the conditions attached to it.¹¹ 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.

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 in 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.

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

⁹ 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.

¹⁰ 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.

¹¹ The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

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.

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.

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 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.

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.

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.

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.

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.

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

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.

D. WTO General Council Decision of 6 December 2005

AMENDMENT OF THE TRIPS AGREEMENT

Decision of 6 December 2005

The General Council;

Having regard to paragraph 1 of Article X 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) 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;

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

Recalling paragraph 11 of the General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health;

Having considered the proposal to amend the TRIPS Agreement submitted by the Council for TRIPS (IP/C/41);

Noting the consensus to submit this proposed amendment to the Members for acceptance;

Decides as follows:

1. The Protocol amending the TRIPS Agreement attached to this Decision is hereby adopted and submitted to the Members for acceptance.
2. The Protocol shall be open for acceptance by Members until 1 December 2007 or such later date as may be decided by the Ministerial Conference.

3. The Protocol shall take effect in accordance with the provisions of paragraph 3 of Article X of the WTO Agreement.

ATTACHMENT

PROTOCOL AMENDING THE TRIPS AGREEMENT

Members of the World Trade Organization;

Having regard to the Decision of the General Council in document WT/L/641, adopted pursuant to paragraph 1 of Article X of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

Hereby agree as follows:

The Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement") shall, upon the entry into force of the Protocol pursuant to paragraph 4, be amended as set out in the Annex to this Protocol, by inserting Article 31*bis* after Article 31 and by inserting the Annex to the TRIPS Agreement after Article 73.

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

This Protocol shall be open for acceptance by Members until 1 December 2007 or such later date as may be decided by the Ministerial Conference.

This Protocol shall enter into force in accordance with paragraph 3 of Article X of the WTO Agreement.

This Protocol shall be deposited with the Director-General of the World Trade Organization who shall promptly furnish to each Member a certified copy thereof and a notification of each acceptance thereof pursuant to paragraph 3.

This Protocol shall be registered in accordance with the provisions of Article 102 of the Charter of the United Nations.

Done at Geneva this sixth day of December two thousand and five, in a single copy in the English, French and Spanish languages, each text being authentic.

ANNEX TO THE PROTOCOL AMENDING THE TRIPS AGREEMENT

Article 31bis

1. The obligations of an exporting Member under Article 31(f) shall not apply 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 in paragraph 2 of the Annex to this Agreement.
2. Where a compulsory licence is granted by an exporting Member under the system set out in this Article and the Annex to this Agreement, adequate remuneration pursuant to Article 31(h) shall be paid in 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 not apply in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.
3. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products: 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 under Article 31(f) shall not apply 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.
4. Members shall not challenge any measures taken in conformity with the provisions of this Article and the Annex to this Agreement under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.
5. This Article and the Annex to this Agreement are without prejudice to the rights, obligations and flexibilities that Members have under the provisions of this Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2), and to their interpretation. They are also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the provisions of Article 31(f).

ANNEX TO THE TRIPS AGREEMENT

1. For the purposes of Article 31*bis* and this Annex:

"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 on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2). It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included¹²;

"eligible importing Member" means any least-developed country Member, and any other Member that has made a notification¹³ to the Council for TRIPS of its intention to use the system set out in Article 31*bis* and this Annex ("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 as importing Members¹⁴ 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;

"exporting Member" means a Member using the system to produce pharmaceutical products for, and export them to, an eligible importing Member.

2. The terms referred to in paragraph 1 of Article 31*bis* are that:

the eligible importing Member(s)¹⁵ has made a notification² to the Council for TRIPS, that:

- (iv) specifies the names and expected quantities of the product(s) needed¹⁶;
- (v) 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 Appendix to this Annex; and

¹² This subparagraph is without prejudice to subparagraph 1(b).

¹³ It is understood that this notification does not need to be approved by a WTO body in order to use the system.

¹⁴ Australia, Canada, the European Communities with, for the purposes of Article 31*bis* and this Annex, its member States, Iceland, Japan, New Zealand, Norway, Switzerland, and the United States.

¹⁵ Joint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in paragraph 3 of Article 31*bis* on behalf of eligible importing Members using the system that are parties to them, with the agreement of those parties.

¹⁶ The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to the system.

- (vi) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Articles 31 and 31*bis* of this Agreement and the provisions of this Annex¹⁷;

the compulsory licence issued by the exporting Member under the system shall contain the following conditions:

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;

products produced under the licence shall be clearly identified as being produced under the system 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

before shipment begins, the licensee shall post on a website¹⁸ 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;

the exporting Member shall notify¹⁹ the Council for TRIPS of the grant of the licence, including the conditions attached to it.²⁰ 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. In order to ensure that the products imported under the system 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

¹⁷ This subparagraph is without prejudice to Article 66.1 of this Agreement.

¹⁸ 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 the system.

¹⁹ It is understood that this notification does not need to be approved by a WTO body in order to use the system.

²⁰ The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to the system.

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.

4. 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 and diverted to their markets inconsistently with its provisions, using the means already required to be available under this 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.

5. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products, it is recognized that the development of systems providing for the grant of regional patents to be applicable in the Members described in paragraph 3 of Article 31*bis* should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of this Agreement, including in conjunction with other relevant intergovernmental organizations.

6. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem faced by Members with insufficient or no manufacturing capacities in the pharmaceutical sector. To this end, eligible importing Members and exporting Members are encouraged to use the system 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 this Agreement, paragraph 7 of the Declaration on the TRIPS Agreement and Public Health and any other relevant work of the Council for TRIPS.

7. The Council for TRIPS shall review annually the functioning of the system with a view to ensuring its effective operation and shall annually report on its operation to the General Council.

APPENDIX TO THE ANNEX TO THE TRIPS AGREEMENT

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.