MODULE I

INTRODUCTION TO THE TRIPS AGREEMENT

A Introduction

1 General

This module provides an overview of the TRIPS Agreement. It first explains the historical and legal background of the Agreement and its place in the World Trade Organization (WTO). It then turns to the general provisions and basic principles, as well as other provisions and institutional arrangements, that apply to all the categories of intellectual property rights (IPRs) covered by TRIPS. Modules II to VIII then discuss each of these categories, their essential principles, and their administration and enforcement, in more detail.

However, in order to understand the TRIPS Agreement it is important to first review the background to the intellectual property (IP) system: what the main forms of IPRs are, why these 'rights' are recognized, and how they are protected. These questions have been at the core of IP policy discussions since the adoption of the earliest IP laws, and continue to spark active debate. This module attempts neither to summarize various relevant legal and economic theories, nor to survey the range of views presented in the debate, but merely highlights some of the general concepts and approaches.

IPRs can be characterized as rights given to persons over the creations of their minds. They usually take the form of a limited 'exclusive right' granted under national law to a creator over the use of the creation for a certain period of time. Such a right allows the creator to exclude others from using the creation in certain ways without the creator's authorization. The right holder can then extract economic value from the IPRs by using them directly or by authorizing others to do so. Agreement on the licensing of IPRs can form the basis of commercial and technological partnerships, and the digital environment has also lent itself to trading in valuable content protected by IPRs.

IPRs are territorial rights, which means that they are valid only in the jurisdiction where they have been registered or otherwise acquired. In other words, the existence of a right in one country will normally provide no guarantee of the existence or validity of an equivalent right in any other country (exceptions include systems of regional rights).

IPRs are customarily clustered into two categories: copyright and industrial property.

Copyright can usefully be divided into two main areas:

1. Copyright (or 'authors' rights' in some systems) refers to the rights of authors of literary and artistic works (such as books and other writings, musical compositions,

paintings, sculptures, computer programs and films). Authors, or those who derive the right from authors (such as publishers), have the right to determine how their works are used for a minimum period of time after the death of the author.

2. Copyright in a wider sense also includes related rights (sometimes called 'neighbouring rights'), especially the rights of performers (e.g. actors, singers and musicians) over their performances, producers over phonograms (sound recordings), and broadcasting organizations over broadcasts. These rights are also limited in time.

Industrial property can be divided into two fields:

- 1. The first is the protection of distinctive signs. Trademarks distinguish the goods or services of one undertaking (normally a firm or individual trader) from those of other undertakings. Geographical indications ('GIs') identify a good as originating in a place where a given characteristic of the good is essentially attributable to its geographical origin. Trademark protection may last indefinitely, provided the sign in question continues to be distinctive; it is often necessary for a firm actively to use the trademark, or rights can be lost or subject to challenge. A GI can also be protected indefinitely, provided it continues to identify the geographical origin and remains in force in the country of origin.
- 2. Other types of industrial property are protected primarily to recognize and stimulate technological innovation and industrial design, and to provide the legal framework for the creation of new technologies and products. In this category fall inventions (protected by patents, although, in a number of countries, innovations that could embody lesser technical progress than patentable inventions may be protected by utility models), industrial designs and trade secrets (also termed confidential or undisclosed information). The protection is usually given for a finite term (now typically twenty years in the case of patents), although trade secrets can be protected as long as they remain secret. Industrial property also includes the legal means to suppress acts of unfair competition a general concept that embraces various forms of misleading, deceptive or free-riding commercial behaviour.

The IP system is a tool of public policy: generally, it is intended to promote economic, social and cultural welfare by stimulating creative work and technological innovation, and by enabling their benefits to reach the public. More specifically, the main social purpose of protection of copyright and related rights is to encourage and reward creative work. It gives an opportunity for authors and artists to earn their living from creative work. Other than serving as an incentive to authors, copyright essentially provides an economic foundation for cultural industries and the market for cultural products once the rights are licensed or assigned to publishers and producers. Similarly, patents and certain other industrial property rights are designed to provide protection for innovations resulting from investment in research and development (R&D), thus giving the incentive and means to finance applied R&D.

These standard policy objectives are supported by the economic theory that suggests that works and information resulting from creative work and innovation have characteristics of public goods in the sense that they are 'non-excludable' and 'nonrivalrous' in consumption - in other words, once created, absent specific measures, no one can be excluded from 'consuming' them. In addition, one's use of a work or an invention does not deprive another of its use and it can be freely used by anyone (unless there are specific legal constraints), unlike physical property such as land that can be fenced off. Therefore, in the absence of IP protection, it is difficult for creators to extract economic value from, or 'appropriate', financial returns from their work, or indeed to influence how they are utilized. Thus, from society's perspective, there is a risk of 'market failure' - that is, underinvestment in socially beneficial creative and innovative work. The IP system also allows market-driven decentralized decisionmaking, where products are created and technology developed in response to demand. The IP system offers a range of options, but does not preclude the need for other forms of financing mechanisms, in particular in areas where the market alone may not provide adequate incentives (for example, contemporary concert music or cures for neglected diseases).

Another objective of IP protection is the transfer and dissemination of technology. A well-functioning IP regime should, other things being equal, facilitate the direct and indirect transfer of technology, by means such as foreign direct investment (FDI), trade and licensing. The legal titles provided by the IP system are used to define and structure the distinct rights and responsibilities in technology partnerships, such as research cooperation or technology sharing or transfer arrangements. One of the purposes of the patent system is to disseminate technological information by requiring inventors to disclose new technology in their patent applications rather than attempt to keep it secret, so that new technology can become part of the common pool of knowledge of mankind and be freely used once patents expire. Improved information technology tools that facilitate, for example, the availability of patent information on the Internet, means that this 'teaching' function of the patent system is becoming increasingly more effective and accessible in practice.

Trademarks, GIs and other distinctive signs are protected so as to inform consumers and prevent consumer deception. In addition, these forms of IP help to ensure fair competition among producers. They provide an incentive for companies to invest in their reputation through the provision of quality products and services. An equally important objective is to enable consumers to make informed choices between various goods and services.

Reflecting their role as tools of public policy, IPRs are not absolute and unlimited, but are generally subject to a number of limitations and exceptions that aim to balance the legitimate interests of right holders and users. These limitations and exceptions, together with the carefully defined scope of protectable subject matter and a limited term of protection, are intended to maintain an appropriate balance between

competing public policy interests so that the system as a whole can be effective in meeting its stated objectives.

2 Historical and legal background

The WTO is the legal and institutional foundation for the administration and development of trade relations among its 164 members at the multilateral level. It aims to provide fair and stable conditions for the conduct of international trade with a view to encouraging trade and investment that raises living standards worldwide. It is the successor to the former General Agreement on Tariffs and Trade (GATT), a multilateral trade agreement that was concluded in 1947. In the period from that time to 1994, further trade liberalization and the development of trade rules were pursued under the auspices of the GATT through 'trade rounds' aiming at further tariff cuts and strengthened rules. The Uruguay Round was the eighth round of trade negotiations and by far the most comprehensive: it was launched in 1986 and completed in 1994.

The main outcomes of the Uruguay Round included a further major reduction of customs tariffs worldwide, and the liberalization of, and development of better rules governing trade in textiles and agriculture – two areas previously largely excluded from the GATT. The trading system was also extended into new areas of trade relations not previously dealt with, notably trade in services and IP. This reflected the growing economic importance of these two areas and their increased share of international trade. Furthermore, the results included the development of a reinforced and integrated dispute settlement system. The Uruguay Round also resulted in the creation of a new organization – the WTO – to administer the agreements. The Marrakesh Agreement Establishing the World Trade Organization (WTO Agreement) entered into force on 1 January 1995. The 'GATT' now refers to an updated agreement on trade in goods, dubbed 'GATT 1994' to distinguish it from the earlier GATT, now designated 'GATT 1947'. The GATT 1994 is only one of a number of multilateral trade agreements annexed to the WTO Agreement – like TRIPS, therefore, it does not have a separate legal existence outside the framework of the overarching WTO Agreement.

The GATT 1947 included several provisions that made reference to IP. For instance, the GATT 1947 confirmed that Contracting Parties could have rules on the protection of certain IPRs provided that they were consistent with principles of non-discrimination and were not disguised restraints on trade. Article III:4 requires treatment for imported products that is no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements; this includes IP laws. More specifically, Article XX(d) allows a general exception to the application of GATT obligations with respect to compliance with laws and regulations that are not inconsistent with GATT provisions, including those that deal with patents, trademarks and copyrights and the prevention of deceptive practices. Additionally, Article IX:6 contains a positive obligation on Contracting Parties to cooperate with each other to prevent the use of trade names in a manner that would misrepresent the true origin of

a product, or that would be to the detriment of distinctive regional or geographical names of products protected in other parties' territories by national legislation.

In the Tokyo Round of multilateral trade negotiations (1973 to 1979), which immediately preceded the Uruguay Round, a proposal was put forward to negotiate rules on trade in counterfeit goods. This resulted in a draft Agreement on Measures to Discourage the Importation of Counterfeit Goods. However, negotiators did not reach agreement and this subject was not included in the results of the Tokyo Round when it concluded in 1979. Instead, in 1982, pursuant to a work programme agreed on by trade ministers, a revised version of a draft agreement on trade in counterfeit goods was submitted. This draft was referred to a group of experts in 1984, which submitted its report a year later. The group met six times in 1985. It produced a report on trade in counterfeit goods which recommended that joint action was probably needed. The group, however, could not decide on the appropriate forum and left it to the GATT Council to make a decision.

During the early 1980s, negotiators worked on a mandate for negotiations for a new Round, including on aspects of IP. Trade ministers met at Punta del Este, Uruguay, in September 1986, and adopted a decision on future trade negotiations, which included the following mandate under the title 'Trade-related aspects of intellectual property rights, including trade in counterfeit goods':

In order to reduce the 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, the negotiations shall aim to clarify GATT provisions and elaborate as appropriate new rules and disciplines.

Negotiations shall aim to develop a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods, taking into account work already undertaken in the GATT.

These negotiations shall be without prejudice to other complementary initiatives that may be taken in the World Intellectual Property Organization and elsewhere to deal with these matters.

A negotiating group on 'trade-related aspects of intellectual property rights', or TRIPS, was formed to pursue this mandate.² From 1986 to April 1989, the group mainly

¹ 'The CONTRACTING PARTIES instruct the Council to examine the question of counterfeit goods with a view to determining the appropriateness of joint action in the GATT framework on the trade aspects of commercial counterfeiting and, if such joint action is found to be appropriate, the modalities for such action, having full regard to the competence of other international organizations. For the purposes of such examination, the CONTRACTING PARTIES request the Director-General to hold consultations with the Director-General of WIPO in order to clarify the legal and institutional aspects involved.'

² A more detailed description of the TRIPS negotiations, comprising informal accounts of individual negotiators and a thematic overview, is available in J. Watal and A. Taubman (eds), *The Making of the TRIPS Agreement* (WTO, 2015), available at: www.wto.org/makingtrips.

discussed whether there was a mandate to negotiate rules on IPRs in general, or only on their trade-related aspects. For the developing countries, such 'trade-related aspects' only included trade in counterfeit goods or anti-competitive practices in relation to IPRs. However, in the mid-term review of the overall Uruguay Round negotiations, undertaken in April 1989, a decision was adopted that gave the negotiating group on TRIPS a full mandate.³ This decision is the basis for the current structure of the TRIPS Agreement.

Between the spring of 1989 and the spring of 1990, several detailed proposals were submitted by all the major players: the United States, the European Communities, Switzerland, Japan and a group of fourteen developing countries (Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Pakistan, Peru, Tanzania, Uruguay and Zimbabwe). A composite text, based on these submissions, was prepared by the Chairman of the Negotiating Group in June 1990. From then until the end of the Brussels Ministerial Conference in December 1990, detailed negotiations were conducted on every aspect of this text. There were six Chairman's drafts of the agreement between July and November 1990. A revised TRIPS text was then sent to the Brussels Ministerial Conference.4 There was commonly agreed upon language for large parts of the agreement, but differences persisted on the forum for lodging the agreement and on dispute settlement, as well as on some 25 other outstanding issues, mainly relating to certain provisions on patents and undisclosed information, copyright, Gls and transition periods. Work continued in Brussels until a sudden breakdown of negotiations in the overall Round due to the failure to reach an understanding on agriculture.

Progress was made on the patent provisions, particularly in autumn 1991 – including on the scope and timing of rights, exceptions to patentability, compulsory licensing/government use, exhaustion of rights, term of protection, protection of test data, transition periods, and the protection of existing subject matter. The question of forum was resolved with the decision to encapsulate the results of the negotiations

³ Following is an extract from the mandate:

^{3.} Ministers agree that the outcome of the negotiations is not prejudged and that these negotiations are without prejudice to the views of participants concerning the institutional aspects of the international implementation of the results of the negotiations in this area, which is to be decided pursuant to the final paragraph of the Punta del Este Declaration.

^{4.} Ministers agree that negotiations on this subject shall continue in the Uruguay Round and shall encompass the following issues:

⁽a) the applicability of the basic principles of the GATT 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, including the applicability of GATT procedures;

⁽e) transitional arrangements aiming at the fullest participation in the results of the negotiations.

^{5.} Ministers agree that in the negotiations consideration will be given to concerns raised by participants related to the underlying public policy objectives of their national systems for the protection of intellectual property, including developmental and technological objectives.

^{6.} In respect of 4(d) above, Ministers emphasise the importance of reducing tensions in this area by reaching strengthened commitments to resolve disputes on trade-related intellectual property issues through multilateral procedures.

⁴ GATT document MTN.TNC/W/35/Rev.1.

within a Single Undertaking, which would also establish a new organization, provisionally termed the Multilateral Trade Organization (MTO). A Draft Final Act was released by the then Director-General of the GATT, Arthur Dunkel, on 20 December 1991, and came to be known as the 'Dunkel Text'. Only two changes were made to TRIPS provisions between the 1991 Draft Final Act and the 1993 Final Act: first, introducing the text on the moratorium on so-called 'non-violation complaints' in dispute settlement cases (Article 64.2-64.3); and, second, limiting the scope of compulsory licensing of semi-conductor technology (Article 31(c)).

3 Place of TRIPS in the WTO

The TRIPS Agreement is Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization (WTO Agreement) of 15 April 1994, which entered into force on 1 January 1995. The TRIPS Agreement is an integral part of the WTO Agreement, and is binding on each member of the WTO from the date the WTO Agreement becomes effective for that country. However, the TRIPS Agreement gave original WTO members transition periods, which differed according to their stage of development, to bring themselves into compliance with its rules (see section D1 of this module for transition periods). The Agreement is administered by the Council for TRIPS (informally called the 'TRIPS Council'), which reports to the WTO General Council. Figure I.1 illustrates where the TRIPS Council fits within the WTO's governance structure.

The Ministerial Conference is the highest decision-making body in the WTO, drawing together ministers representing Member governments. Its sessions are to take place at least once every two years, when all matters under the WTO agreements may be addressed. The General Council constitutes the second tier in the WTO structure. It comprises representatives from all member governments, ambassadors/permanent representatives based in Geneva. It meets some five times in a year. It may adopt decisions on behalf of the Ministerial Conference when the Conference is not in session. The General Council has authority over the Trade Negotiations Committee. The General Council also meets as the Trade Policy Review Body (TPRB), with a distinct chairperson, to carry out trade policy reviews as mandated by the Trade Policy Review Mechanism (Annex 3 of the WTO Agreement), and as the Dispute Settlement Body (DSB), with another chairperson to administer the rules in the Understanding on Rules and Procedures Governing the Settlement of Disputes. The Ministerial Conference and the General Council have direct responsibility for matters regarding the TRIPS Agreement, acting on the recommendation of the TRIPS Council. The DSB deals with all disputes regarding the TRIPS Agreement. And the TPRB includes IP matters in the range of trade policy matters that it reviews.

Ministerial Conference General Council meeting as General Council meeting as Dispute Settlement Trade Policy Review Body **General Council** Body Appellate Body Dispute Settlement panels ---Committees on Council for Council for Council for Trade and Environment Trade in Goods Trade-Related Aspects Trade in Services Trade and Development of Intellectual Dedicated Session Sub-Committee on Property Rights . Least-Developed Countries Committees on Committees on Regional Trade . Trade in Financial Services Market Access Agreements Specific Commitments Agriculture Balance of Payments Sanitary and Phytosanitary = Restrictions Working parties on Measures -Budget, Finance and Domestic Regulation Technical Barriers to Trade Administration -**GATS Rules** Subsidies and Countervailing Measures Working parties on Anti-Dumping Practices Accession ш Customs Valuation = **Plurilaterals** Working groups on Rules of Origin Trade in Civil Aircraft Committee Trade, debt and finance Import Licensing Government Procurement Committee Trade and technology Trade-Related Investment transfer Measures Safeguards Doha Development Agenda Negotiations: (Inactive: Working party on TNC and its bodies Relationship between State-Trading Enterprises Trade and Investment Trade Negotiations Interaction between Trade and Competition Committee Special Sessions of ---------Services Council / TRIPS Council / Dispute Settlement Body / Agriculture Committee / Trade and Development Committee / Trade and Environment Plurilateral Information Technology Agreement Negotiating groups on Market Access / Rules / Trade Facilitation Committee Key Reporting to General Council (or a subsidiary) Reporting to Dispute Settlement Body Plurilateral committees inform the General Council or Goods Council of their activities, although these agreements are not signed by all WTO members

Figure I.1 WTO organizational structure

The TRIPS Council, also consisting of all members, is one of the three sectoral (i.e. subject area) Councils operating under the General Council, the other two being the Council for Trade in Goods and the Council for Trade in Services. It is the body, open to all members of the WTO, responsible for the administration of the TRIPS Agreement and in particular for monitoring the operation of the Agreement. The Council meets in Geneva formally three to four times a year as well as informally as necessary.

Trade Negotiations Committee reports to General Council

The WTO Agreement serves as an umbrella agreement for the TRIPS Agreement and the other trade agreements annexed to it. It includes provisions on the structure and operation of the WTO. Section E of this module explores some of these institutional aspects, namely the cross-cutting decision-making and amendment procedures in the WTO Agreement, and discusses the work of the TRIPS Council.

4 Overview of TRIPS provisions

The TRIPS Agreement is a comprehensive multilateral agreement on IP. It deals with each of the main categories of IPRs, establishes standards of protection as well as rules on administration and enforcement of IPRs, and provides for the application of the WTO dispute settlement mechanism to resolve disputes between members concerning compliance with its standards. The following is a brief introduction to the various parts of the Agreement.

(a) General provisions and basic principles

Part I of the Agreement sets out general provisions and basic principles of the Agreement, such as national treatment and most-favoured-nation (MFN) treatment, and exhaustion of IPRs. These general provisions and basic principles are discussed in section B of this module. It also articulates the link with other international conventions in the field of IP, including specifying the provisions of the Paris Convention that apply under the Agreement.

(b) Standards concerning the availability, scope and use of intellectual property rights

Part II sets out the minimum standards of IP protection to be provided by WTO members in the following fields:

- (1) copyright and related rights (i.e. the rights of performers, producers of sound recordings and broadcasting organizations);
- (2) trademarks, including service marks;
- (3) GIs;
- (4) industrial designs;
- (5) patents, including the protection of new varieties of plants;
- (6) the layout-designs of integrated circuits; and
- (7) undisclosed information, including trade secrets and test data.

Certain of these categories of IP (GIs and undisclosed information) refer to the general concept of unfair competition that is addressed in Article 10*bi*s of the Paris Convention.

Since Article 10*bis* of the Paris Convention is incorporated into the TRIPS Agreement by reference (Article 2.1), dispute settlement proceedings have clarified that members are obliged under the TRIPS Agreement to repress unfair competition in general.⁵ Dispute settlement has also clarified that TRIPS obligations also extend to trade names, a distinct form of IP similar to trademarks, addressed in Article 10*ter* of the Paris Convention.⁶

Part II also contains provisions on the control of anti-competitive practices in contractual licences. These fields of IP and the control of anti-competitive practices are discussed in Modules II to VII of this Guide.

The main elements of protection of each of these fields of IP are defined, namely:

- the subject matter eligible for protection;
- the scope of rights to be conferred;
- permissible exceptions to those rights; and,
- where applicable, the minimum duration of protection.

The TRIPS Agreement sets these standards firstly by requiring compliance with the substantive obligations of the main conventions of the World Intellectual Property Organization (WIPO), namely the Paris Convention and the Berne Convention. All the main substantive provisions of these two conventions are incorporated by reference (by Article 2.1 for the Paris Convention and Article 9.1 for the Berne Convention, which, however, excepts the area of moral rights). These provisions therefore became obligations among WTO members under the TRIPS Agreement, applying separately from obligations they may have to one another directly under those conventions under the administration of WIPO.

The TRIPS Agreement then adds a substantial number of additional obligations on matters where the pre-existing conventions were silent or were seen as being inadequate. The TRIPS Agreement is thus sometimes referred to as a 'Berne-plus' and 'Paris-plus' agreement. As explained in Module II, the TRIPS provisions on related rights contain certain references to the Rome Convention. The Section on the protection of layout-designs of integrated circuits, explained in Module VI, incorporates most of the substantive provisions of the Treaty on Intellectual Property in Respect of Integrated Circuits (IPIC or Washington Treaty). Article 2.2 of the TRIPS Agreement contains a safeguard clause, according to which the provisions of the Agreement cannot be understood to derogate from the existing obligations that members may have to each

⁶ Appellate Body Report, US - Section 211 Appropriations Act.

⁵ Panel Reports, Australia – Tobacco Plain Packaging.

other under the Paris Convention, the Berne Convention, the Rome Convention or the IPIC Treaty.⁷

(c) Enforcement

Part III deals with domestic procedures and remedies for the enforcement of IPRs. The Agreement lays down certain general principles applicable to IP enforcement procedures. In addition, it contains provisions on civil and administrative procedures and remedies, provisional measures, special requirements related to border measures and criminal procedures. These provisions specify, in some detail, the procedures and remedies that must be available so that right holders can effectively enforce their rights. They also provide for safeguards against the abuse of such procedures and remedies as barriers to legitimate trade. These provisions are discussed in Module VIII.

(d) Administration of IP rights

Part IV of the Agreement contains general rules on procedures related to the acquisition and maintenance of IPRs, particularly concerning how applications for IP protection are administered and the kind of appeals or reviews that should be available. These rules are explained below in section C of this module.

(e) Dispute settlement

Part V of the Agreement deals with dispute prevention and settlement. Transparency arrangements regarding IP laws and their administration are an important part of dispute prevention. The Agreement makes disputes between members about the respect of obligations contained in it, whether in the field of substantive standards or in the field of enforcement, subject to the WTO's dispute settlement procedures. Dispute prevention and settlement are discussed in Module IX. Table IX.1 summarizes WTO disputes dealing with the TRIPS Agreement.

(f) Transitional and institutional matters

Part VI of the Agreement contains provisions on transition periods, transfer of technology and technical cooperation. Part VII deals with institutional arrangements

⁷ Unless otherwise indicated, in this Guide, 'Paris Convention' refers to the Paris Convention for the Protection of Industrial Property (the Stockholm Act of 14 July 1967); 'Berne Convention' refers to the Berne Convention for the Protection of Literary and Artistic Works (the Paris Act of 24 July 1971); 'Rome Convention' refers to the International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations, adopted at Rome on 26 October 1961; and the 'IPIC Treaty' to the Treaty on Intellectual Property in Respect of Integrated Circuits, adopted at Washington on 26 May 1989.

and certain cross-cutting matters, such as the protection of existing subject matter. These two parts are covered below in section D of this module.

B General provisions and basic principles

1 Objectives and principles

The general goals of the TRIPS Agreement are set out in its Preamble, and include reducing distortions and impediments to international trade, promoting effective and adequate protection of IPRs, and ensuring that measures and procedures to enforce IPRs do not themselves become barriers to legitimate trade. The Preamble is largely drawn from the Uruguay Round mandates given to the TRIPS negotiators in the 1986 Punta del Este Declaration (reproduced in section A.2 of this module) and in the April 1988 mid-term review decision (relevant extract in footnote 3).

The general goals contained in the Preamble of the Agreement should be read in conjunction with Article 7, entitled 'Objectives'. Article 7 reflects the search for a balanced approach to IP protection in the societal interest, taking into account the interests of both producers and users. IP protection is expected to contribute not only to the promotion of technological innovation, but also to the transfer and dissemination of technology in a way that benefits both its producers and users and that respects a balance of rights and obligations, with the overall goal of promoting social and economic welfare.

Article 8, entitled 'Principles', recognizes the rights of members to adopt measures for public health and other public interest reasons and to prevent the abuse of IPRs, provided that such measures are consistent with the provisions of the TRIPS Agreement.

The Preamble and Articles 7 and 8 express a range of general goals, objectives and principles of the Agreement. As recognized by WTO dispute settlement panels, they are to be borne in mind when the substantive rules of the Agreement are being examined. The 2001 Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration) provides that '[i]n 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'.9

2 Minimum standards agreement

As discussed above, the TRIPS Agreement sets out minimum standards of protection to be provided by each member. Article 1.1 makes it clear that members may, but are not obliged to, implement in their law more extensive protection than required by the

⁸ See Panel Reports, Australia - Tobacco Plain Packaging; and Canada - Pharmaceutical Patents.

⁹ WT/MIN(01)/DEC/2, para. 5(a), reproduced in Annex 6 to this Guide. See Module X below.

Agreement, provided that such protection does not contravene its provisions. For example, members may provide for longer terms of protection than that mandated by the TRIPS Agreement, but they are not required to do so; however, they cannot do this in a way that conflicts with TRIPS provisions. For instance, in light of the principle of non-discrimination, longer protection could not be made available only to nationals of one country.

Article 1.1 further clarifies that members are free to determine the appropriate method of implementing the provisions of the TRIPS Agreement within their own legal system and practice.

Given the long history of international cooperation on IP matters, members' laws in this area are often fairly similar. However, to establish how the law applies in any concrete practical situation, the applicable domestic law will have to be consulted.

3 Beneficiaries

As in the main pre-existing IP conventions, the basic obligation on each member is to accord the treatment in regard to the protection of IP provided for under the Agreement to right holders and users of other members. Article 1.3 defines who these persons are. They are referred to as 'nationals' but include persons, natural or legal, who have a close attachment to a member without necessarily having the nationality of that member. The criteria for determining which persons must thus benefit from the treatment provided for under the Agreement are those laid down for this purpose in the pre-existing IP conventions of WIPO referred to in the Agreement, applied of course with respect to all WTO members whether or not they are party to those conventions. The following clarifies who the beneficiaries are for industrial property rights and for copyright and related rights, as the rules differ slightly between these categories.

(a) Industrial property

Pursuant to Articles 2 and 3 of the Paris Convention, protection is granted in the case of industrial property to natural or legal persons who:

- · are nationals of a member:
- are domiciled in a member; or
- have real and effective industrial or commercial establishments in a member.

Pursuant to Article 5 of the IPIC Treaty, similar criteria for determining eligible beneficiaries are applied in relation to layout-designs of integrated circuits.

(b) Copyright

Pursuant to Articles 3 and 4 of the Berne Convention, protection is granted to authors of literary or artistic works who:

- · are nationals of a member;
- have their habitual residence in a member;
- have their works first (or simultaneously) published in a member;
- are authors of cinematographic works the maker of which has his headquarters or habitual residence in a member; or
- are authors of works of architecture erected in a member or of other artistic works incorporated in a building or other structure located in a member.

(c) Performers

Pursuant to Article 4 of the Rome Convention, protection is granted to performers whose:

- performance takes place in another member;
- performance is incorporated in a phonogram as defined below; or
- performance is covered by a broadcast as defined below.

(d) Producers of phonograms

Pursuant to Article 5 of the Rome Convention, protection is granted to producers of phonograms:

- if the producer is a national of another member;
- if the first fixation of sound (i.e. recording) was made in another member; or
- if the phonogram was first published in another member.

In accordance with the provisions of Article 5(3) of the Rome Convention, as incorporated into the TRIPS Agreement, a member may declare that it does not apply either the criterion of fixation or that of publication. The criterion of nationality, however, may not be excluded.

(e) Broadcasting organizations

Pursuant to Article 6 of the Rome Convention, protection is granted to broadcasting organizations:

- whose headquarters are situated in another member; or
- if the broadcast was transmitted from a transmitter in another member.

In accordance with the provisions of Article 6(2) of the Rome Convention, as incorporated into the TRIPS Agreement, a member may declare that it will protect broadcasts only if both relevant conditions are met, i.e. that the headquarters of the broadcasting organization are situated in another member and that the broadcast was transmitted from a transmitter situated in the same member.

4 National treatment and most-favoured-nation treatment

A key principle in the WTO is that of non-discrimination. It applies to trade in goods, trade in services and IPRs. It has two components: national treatment, and most-favoured-nation (MFN) treatment. As regards IPRs, the fundamental rules on national and MFN treatment of foreign nationals can be found in Articles 3 to 5 of the TRIPS Agreement. These rules are common to all categories of IP covered by the Agreement. These obligations cover not only the substantive standards of protection but also matters affecting the availability, acquisition, scope, maintenance and enforcement of IPRs as well as those matters affecting the use of IPRs specifically addressed in the Agreement. While the national treatment clause forbids discrimination between a member's own nationals and the nationals of other members, the MFN treatment clause forbids discrimination between the nationals of other members.

Article 3 on national treatment requires each member to accord to the nationals of other members treatment no less favourable than that it accords to its own nationals with regard to the protection of IP. With respect to the national treatment obligation, the exceptions allowed under the four pre-existing WIPO treaties (Paris, Berne, Rome and IPIC) are also allowed under TRIPS.

An important exception to national treatment is the so-called 'comparison of terms' for copyright protection allowed under Article 7(8) of the Berne Convention, as incorporated into the TRIPS Agreement. If a member provides a term of protection in excess of the minimum term required by TRIPS, it does not need to protect a work for longer than the term fixed in the country of origin of that work. In other words, the additional term can be made available to foreigners on the basis of 'material reciprocity'. For example, imagine that member A provides its own nationals with a copyright term of seventy years, instead of fifty years as required by TRIPS Article 12, while member B provides for fifty years. In this case, member A need not protect works from member B for more than fifty years.

With respect to performers, producers of phonograms (sound recordings such as CDs) and broadcasting organizations, the national treatment obligation applies only with respect to rights provided under the TRIPS Agreement. Therefore, the obligation is confined to the protection provided in the Agreement and does not cover other rights that holders of related rights may have under domestic laws or other international agreements.

Exceptions can be allowed to the national treatment principle for judicial and administrative procedures – for instance, foreign applicants for IP protection may be required to provide an address for service or a local agent in that jurisdiction. But Article 3.2 requires that such exceptions be necessary to secure compliance with laws and regulations which are consistent with the TRIPS Agreement and that such practices not be applied so as to constitute a disguised restriction on trade.

While the pre-existing multilateral IP conventions also provide for national treatment, they do not contain obligations on MFN treatment. In these conventions, national treatment is an across-the-board obligation with relatively minor exceptions. Given that the same treatment has to be given to nationals of other convention members as to a member's own nationals, it would normally follow that the same treatment would be given to the nationals of each of the other members. This leaves little scope for discrimination between the nationals of other members of those conventions. However, some TRIPS negotiators proposed building an MFN provision into the Agreement, given that some countries had agreed to give, as a result of bilateral negotiations, more favourable protection to IPRs of the nationals of one or more of their trading partners than they gave to their own nationals. As a result, MFN treatment was incorporated into the Agreement.

Article 4 on MFN treatment requires that, with regard to the protection of IP, any advantage, favour, privilege or immunity granted by a member to the nationals of any other member shall be accorded immediately and unconditionally to the nationals of all other members. For example, imagine that member A decides to recognize and enforce the patents granted in member B from a certain date in the past irrespective of whether the inventions covered meet the novelty criterion. In this case, member A must extend the same advantage to nationals of other members.

Where exceptions to national treatment allow material reciprocity, a consequential exception to MFN treatment is permitted under Article 4(b) and 4(c). Limited exceptions to MFN are also allowed under Article 4(a) concerning international agreements on judicial assistance or law enforcement of a general nature.

Furthermore, Article 4(d) exempts from this obligation advantages deriving from international agreements related to the protection of IP that entered into force prior to the entry into force of the WTO Agreement, i.e. before 1 January 1995. This is subject to the conditions that such agreements are notified to the TRIPS Council and do not constitute an arbitrary or unjustifiable discrimination against nationals of other

members. There is no such exemption for advantages deriving from international agreements that entail higher standards than required by the TRIPS Agreement that enter into force after 1 January 1995 – this means that any such higher standards must be available to nationals of all WTO members.

In addition, Article 5 of the TRIPS Agreement provides that national and MFN treatment obligations do not apply to procedures provided in multilateral agreements concluded under the auspices of WIPO relating to the acquisition or maintenance of IPRs. This Article recognizes that certain WIPO agreements, such as the Patent Cooperation Treaty, the Madrid Agreement Concerning the International Registration of Marks (Madrid Agreement) and the Protocol to that Agreement (Madrid Protocol), and the Hague Agreement Concerning the International Registration of Industrial Designs, provide for a system of international applications only open to persons that are nationals or residents of signatory countries or have a real and effective industrial or commercial establishment in those countries. The exception in this Article only applies in respect of procedures relating to the acquisition and maintenance of rights, not to the substantive standards of protection themselves. The exception contained in Article 5 is not limited to pre-existing WIPO agreements.

5 Exhaustion

The term 'exhaustion' refers to the generally accepted principle in IP law that a right owner's exclusive right to control the distribution of a protected item lapses after the first act of distribution. In many countries, once the item has been put on the market by or with the consent of the right owner, the exclusive distribution right is 'exhausted' (which is why the principle is referred to in some jurisdictions as the 'first-sale doctrine') and further circulation of that item can no longer be controlled by the right holder. In simple terms, exhaustion describes the fact that once one has legitimately obtained an item incorporating protected IP, for instance a copyright-protected DVD or a patented mobile phone, one is then free to further sell, transfer or otherwise distribute it without further authorization from the right holder. This entitlement does not, of course, affect any other exclusive rights the right holder may enjoy, for example, the right to authorize activities such as reproduction or communication to the public – so the entitlement to distribute a legitimately purchased CD does not in itself extend to an entitlement to make reproductions or to give public performances of the recorded music.

A key issue for international trade is that of 'parallel importation', or the right to import an IP-protected good once it has been legitimately put on the market in a foreign country. IPRs are granted, exercised and enforced distinctly within national territories, with separate application in each different jurisdiction. While it is generally accepted that IPRs are exhausted within the jurisdiction where the first sale took place, are such rights exhausted when the first sale has taken place outside the jurisdiction in question, and the protected goods then find their way into foreign markets? The answer to this depends on the choice taken in each jurisdiction, and concerning each

category of IP, as to whether a regime of national or international exhaustion should apply, and therefore whether or not parallel importation is permitted.

National exhaustion means that right owners' distribution rights are only considered exhausted once they put the protected item on the market in that jurisdiction. Distribution rights would not be considered exhausted with regard to protected items that were only put on the market in another country, so that right holders can still control the sale or import of such items into the first country. For example, in a country with a national exhaustion regime, for copyright and related rights right holders can prevent the importation into that country of DVDs that they have sold in other countries. Thus, parallel imports of products first sold on other markets are illegal in a country with a national exhaustion regime.

In contrast, if a country has an international exhaustion regime, this means that the right owner's distribution right in that country is exhausted upon first sale of the protected item, regardless of where the first act of distribution took place. Thus, right holders cannot use IPRs to prevent the importation and sale of DVDs that they have sold in another country. Accordingly, in countries with an international exhaustion regime for copyright and related rights, parallel imports are legal. A country may, in principle, adopt different exhaustion regimes for different categories of IPRs.

Note that the products imported as parallel imports are not counterfeit or pirated goods, but genuine original products that have been sold in other countries with the authorization of the right holder; they do not infringe IPRs in the country of origin.

An alternative approach is taken in some free trade areas or customs unions, namely regional exhaustion: in this case, the right holder's IPRs are exhausted once the first sale takes place anywhere within the specified region.

It is generally understood that national exhaustion favours market segmentation as well as differential pricing, product differentiation and differing release dates, whereas international exhaustion facilitates parallel importation of the same product sold at lower prices in other countries.

During the Uruguay Round negotiations, members negotiated a text that left them considerable discretion as to how to regulate the question of exhaustion. Article 6 provides that, for the purposes of dispute settlement under the TRIPS Agreement, nothing in the Agreement shall be used to address the issue of the exhaustion of intellectual property rights, provided that the national and MFN treatment obligations are complied with. This proviso was clarified in the 2001 Doha Ministerial Declaration on the TRIPS Agreement and Public Health. 10 It confirmed that the effect of the TRIPS provisions relevant to exhaustion of IPRs was to leave each member free to establish its own regime for exhaustion without challenge, subject to the MFN and national

¹⁰ WT/MIN(01)/DEC/2, reproduced in Annex 6 to this Guide.

treatment provisions of Articles 3 and 4. This Declaration is discussed further in Module X.

C Procedures for the acquisition and maintenance of IP rights

The TRIPS Agreement does not deal in detail with procedural questions concerning the acquisition and maintenance of IPRs. However, Part IV contains general rules on these matters. The essential goal is to ensure that unnecessary procedural difficulties in acquiring or maintaining IPRs are not employed to impair the protection required by the Agreement. Certain more specific rules are to be found in the sections of Part II dealing with individual categories of IPRs and in the provisions of the Paris Convention and the IPIC Treaty, which are incorporated by reference into the Agreement.

Part IV consists of a single article, Article 62. It allows members to require, as a condition for the acquisition or maintenance of rights related to trademarks, Gls, industrial designs, patents and layout-designs, compliance with reasonable procedures and formalities (paragraph 1).

Where the acquisition of an IPR is subject to the right being granted or registered, the procedures must permit the granting or registration of the right within a reasonable period of time so as to avoid unwarranted curtailment of the period of protection (paragraph 2).

Paragraph 4 of Article 62 requires that procedures concerning the acquisition or maintenance of IPRs and, where a member's law provides for such procedures, administrative revocation and *inter partes* procedures such as opposition, revocation and cancellation, must be governed by the general principles concerning decisions and review set out in paragraphs 2 and 3 of Article 41 of the Agreement. These general principles require that procedures be fair and equitable. They are discussed further in Module VIII.

Final administrative decisions in such procedures must generally be subject to review by a judicial or quasi-judicial authority (paragraph 5 of Article 62).

D Transitional arrangements and other matters

1 Transition periods

The TRIPS Agreement gave all original members of the WTO transition periods so that they could meet their obligations under it. The transition periods, which depend on the level of development of the country concerned, are contained in Articles 65 and 66. Except for LDC members, these transition periods have already expired.

(a) Developed countries and non-discrimination (all members)

Developed country members have had to comply with all of the provisions of the TRIPS Agreement since 1 January 1996. Moreover, all members, including those availing themselves of the longer transition periods, have had to comply with the national and MFN treatment obligations since 1 January 1996 (Article 65.1).

(b) Developing countries and economies in transition

For developing countries that were already WTO members, the general transition period was five years, i.e. until 1 January 2000 (Article 65.2). The same transition period was available for countries in transition from a centrally planned into a market economy, provided they met certain conditions (Article 65.3).

The TRIPS Agreement provided special transition rules in the situation where a developing country did not provide product patent protection in a given area of technology on 1 January 2000. This provision was especially relevant to pharmaceutical and agricultural chemical inventions. According to Article 65.4, a developing country could delay the application of the TRIPS obligations on product patents to such areas of technology until 1 January 2005.

However, in the situation where patent protection was not provided for pharmaceutical and agricultural chemical products commensurate with the TRIPS provisions on scope of patentable subject matter as of 1 January 1995, some additional transitional arrangements apply. In accordance with the 'mailbox' provision contained in Article 70.8, the country concerned is required to provide a means by which patent applications for such inventions can be filed. These applications do not need to be examined for their patentability until the country starts applying product patent protection in that area. However, when that time comes, the application has to be examined by reference to the prior art that had been disclosed when the application was first filed (i.e. the invention has to be assessed whether it was 'new' as of that earliest date). If the application is successful, product patent protection would then have to be granted for the remainder of the patent term counted from the filing date of the application.

If a product that is the subject of such a mailbox patent application in a member obtains marketing approval before the decision on the grant of the patent is taken, there is an obligation under Article 70.9 to grant exclusive marketing rights for a period of up to five years or until the patent is granted or rejected, whichever comes first. This is subject to a number of conditions: subsequent to the entry into force of the WTO Agreement, a patent application must have been filed, a patent granted and marketing approval obtained in another member for the product in question.

These provisions were addressed in reports adopted by the DSB in *India – Patents (US)* (DS50) and *India – Patents (EC)* (DS79).

(c) Least-developed countries

The TRIPS Agreement contains a number of specific provisions for LDCs, reflecting the recognition in the Preamble of their 'special needs ... 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'. For the purposes of determining the LDC status of a member, the WTO uses the UN list of LDCs.¹¹

Article 66.1 originally provided LDC members a transition period until 1 January 2006, with an extension upon a duly motivated request.

Pursuant to the Doha Declaration,¹² the TRIPS Council extended in 2002 the transition period for LDCs for certain obligations with respect to pharmaceutical products until 1 January 2016, or until they cease to be an LDC, whichever comes first. In 2015, it further extended this period until 1 January 2033.¹³ Supplementing these extensions, the General Council waived for the same period the obligations of LDCs under Article 70.9 concerning so-called exclusive marketing rights for pharmaceutical products. In 2015, the General Council also waived for LDC members the obligation under Article 70.8 to provide for the possibility of filing 'mailbox' applications, also until 1 January 2033.¹⁴

By decisions taken in 2005, 2013 and 2021, 15 upon successive requests of LDCs, the TRIPS Council extended the transition period for LDCs for the application of all provisions of the TRIPS Agreement, except for Articles 3 to 5 on non-discrimination, until 1 July 2034 or until they cease to be LDCs, whichever comes first. The 2005 decision also set up a process to help them implement TRIPS within their national IP regimes. The Council called on LDCs to identify their priority needs for technical and financial cooperation, which developed countries are to help to effectively address. It also called for the WTO to enhance its cooperation with WIPO and other relevant international organizations. Furthermore, the 2005 decision provided that LDC members will ensure that any changes in their laws, regulations and practice made during the additional transition period do not result in a lesser degree of consistency with the provisions of the TRIPS Agreement. In the 2013 and 2021 decisions, LDC members expressed their determination to preserve and continue progress towards implementing the Agreement. The 2013 and 2021 decisions also state that nothing in the decision shall prevent LDCs from making full use of the flexibilities provided by the Agreement. All three decisions are without prejudice to the extension with respect to pharmaceutical products referenced earlier and to the right of LDC members to seek further extensions. TRIPS flexibilities in the public health context are covered in detail in Module X. Technical cooperation for LDCs is further discussed in Module XI.

¹¹ See UN Department of Economic and Social Affairs, 'Least-Developed Countries (LDCs)', available at: www.un.org/development/desa/dpad/least-developed-country-category.html.

¹² WT/MIN(01)/DEC/2, reproduced in Annex 6 to this Guide.

¹³ IP/C/25 (2002) and IP/C/73 (2015). IP/C/73 is reproduced in Annex 10 of this Guide.

¹⁴ WT/L/478 (2002) and WT/L/971 (2015).

 $_{15}$ $_{\underline{\text{IP/C/40}}}$ (2005), $_{\underline{\text{IP/C/64}}}$ (2013) and $_{\underline{\text{IP/C/88}}}$ (2021). $_{\underline{\text{IP/C/88}}}$ is reproduced in Annex 9 of this Guide.

(d) Acceding members

Any transition periods for acceding members are set out in their protocol of accession. Apart from LDCs that join the WTO, newly acceded members have generally agreed to apply all relevant provisions of the TRIPS Agreement as of the date they become a WTO member.

2 Protection of existing subject matter

(a) Application of the rules

The transition arrangements also address (in Article 70) the treatment of subject matter existing at the time that a member starts applying the provisions of the Agreement (e.g. already existing works, inventions or distinctive signs). Article 70.2 confirms that TRIPS obligations generally apply to subject-matter existing on the date of the application of the Agreement for the member in question (i.e. at the end of the relevant transition period) which is protected in that member on that date, or which is still capable of meeting the criteria for protection (e.g. undisclosed information or distinctive signs not yet protected as trademarks). The interpretation of Article 70.2 was addressed in reports adopted by the DSB in Canada – Patent Term (DS170).

(b) Additional requirements in respect of pre-existing works and phonograms

In respect of copyright and the rights of producers of phonograms (sound recordings) and performers in existing phonograms, there is an additional requirement to comply with Article 18 of the Berne Convention, not only in respect of the rights of authors but also in respect of the rights of performers and producers of phonograms in phonograms (Articles 9.1, 14.6 and 70.2 of the TRIPS Agreement). Article 18 of the Berne Convention includes the so-called 'rule of retroactivity', according to which the Agreement applies to all works which have not fallen into the public domain either in the country of origin or the country where protection is claimed through the expiry of a term of protection. The provisions of Article 18 allow some transitional flexibility where a country is, as a result, taking subject matter out of the public domain and putting it under protection, to safeguard the interests of persons who have in good faith already taken steps on the basis of the material in the public domain (for example, a film producer that has already invested in the making of a film using a work that is brought under copyright). The application of Article 18 of the Berne Convention to the rights of producers of phonograms and performers in existing phonograms was addressed in two dispute settlement complaints, in Japan - Measures Concerning Sound Recordings (DS28, 42). Both cases were settled bilaterally without panel reports.

3 Transfer of technology

Article 7 of the TRIPS Agreement recognizes that the protection and enforcement of IPRs should contribute to the transfer and dissemination of technology (see section B1 above).

Article 66.2 of the TRIPS Agreement requires developed country members to provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to LDC members in order to enable them to create a sound and viable technological base.

In 2003, pursuant to instructions given by ministers at the Doha ministerial meeting, the Council adopted a decision on 'Implementation of Article 66.2 of the TRIPS Agreement' that put in place a mechanism for ensuring the monitoring and full implementation of the obligations in question. ¹⁶ Under this Decision, developed country members shall submit annually reports on actions taken or planned in pursuance of their commitments under Article 66.2. To this end, they are to provide new detailed reports every third year and, in the intervening years, provide updates to their most recent reports. These submissions are reviewed by the Council at its end-of-year meeting each year. The review meetings are intended to provide members an opportunity to, *inter alia*, discuss the effectiveness of the incentives provided in promoting and encouraging technology transfer to LDC members in order to enable them to create a sound and viable technological base.

The precise nature of such incentives was not elaborated upon in the TRIPS Agreement. The annual reports submitted by developed countries to the TRIPS Council contain examples of available incentives. The subject of technology transfer is discussed further in Module XI.

Annual reports submitted pursuant to the decision referred to above are available on the WTO Documents Online database, <u>docs.wto.org</u>, and the e-TRIPS Gateway, <u>e-trips.wto.org</u>. Further information on how to access these reports can be found in Appendix 1 to this Guide.

Transfer of technology to LDC members is also addressed in the 2003 Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health 17 and the 2005 Protocol Amending the TRIPS Agreement. 18 Both are discussed further in Module X.

¹⁶ IP/C/28.

¹⁷ WT/L/540 and Corr.1, reproduced in Annex 7 to this Guide.

¹⁸ WT/L/641, reproduced in Annex 8 to this Guide.

4 Technical cooperation

Article 67 of the TRIPS Agreement requires developed country members to provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country members. According to this provision, the objective of such cooperation is to facilitate the implementation of the Agreement. The Article specifies that such assistance shall include assistance in the preparation of laws and regulations on the protection and enforcement of IPRs as well as on the prevention of their abuse, and support regarding the establishment or reinforcement of domestic offices and agencies relevant to these matters, including the training of personnel.

In order to ensure that information on available assistance is readily accessible and to facilitate the monitoring of compliance with the obligation of Article 67, developed country members present descriptions of their relevant technical and financial cooperation programmes and update them annually. For the sake of transparency, intergovernmental organizations, such as WIPO and the World Health Organization (WHO), have also presented, upon the invitation of the Council, information on their activities. The information from developed country members, intergovernmental organizations and the WTO Secretariat on their technical cooperation activities in the area of TRIPS is available on the WTO Documents Online database at docs.wto.org.

The TRIPS Council has agreed that each developed country member should notify a contact point for technical cooperation on TRIPS, in particular for the exchange of information between donors and recipients of technical assistance. These notifications are also available on the WTO Documents Online database. Further information on how to access the reports and other information referred to above can be found in Appendix 1 to this Guide.

5 Security exceptions

In line with other WTO Agreements, Article 73 stipulates that the TRIPS Agreement cannot be construed to require a member to furnish information against its essential security interests, nor to prevent action which it considers necessary for the protection of such interests, subject to certain conditions, or in pursuance of obligations under the United Nations Charter for the maintenance of international peace and security.

The application of Article 73(b)(iii), which provides that '[n]othing in the Agreement shall be construed: ... (b) to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests; ... (iii) taken in time of war or other emergency in international relations; ...', was addressed by the Panel in Saudi Arabia – IPRs (DS567). This Panel applied the same analytical framework developed by the Panel in Russia – Traffic in Transit (DS512), which assessed a claim under the identically worded security exception found in GATT Article XXI(b)(iii).

The Saudi Arabia – IPRs Panel first determined whether a 'war or other emergency in international relations' in the context of Article 73 had been established, a fact which was to be determined objectively, rather than by the invoking member itself. It reasoned that an 'emergency in international relations' generally refers to a situation of armed or latent armed conflict, or other situations of heightened tension or crisis that give rise to military, defence, or law and public order interests, rather than political or economic conflicts.

The Panel's second consideration was whether the member's 'action' was 'taken in time of' war or an emergency in international relations. The Panel found that Article 73 requires such an action to have been taken during the referenced war or emergency, and that this is an objective fact amenable to objective determination.

The third step in the Panel's analysis assessed whether the invoking member had sufficiently articulated its 'essential security interests' to enable an assessment of whether there is any link between the actions at issue and the protection of its essential security interests. The Panel clarified that 'essential security interests' generally relate to the quintessential functions of the state. Although members have discretion to self-designate their 'essential security interests' they must do so in good faith.

Finally, the Panel queried whether the relevant actions were so remote from, or unrelated to, the 'emergency in international relations' as to make it implausible that the invoking member considers its actions to be necessary for the protection of its essential security interests arising out of the emergency.

E Institutional arrangements

The WTO Agreement serves as an umbrella agreement for the TRIPS Agreement and the other trade agreements annexed to it. It includes provisions on the establishment, scope, functions and structure of the WTO. It defines the WTO's relationship with other organizations, its secretariat, budget and contributions, legal status, and decision-making and amendment procedures. Additionally, it presents information on the definition of original members, accession, non-application, acceptance, entry into force and deposit, denunciation and final provisions. The subsection below focuses on the decision-making procedures as regulated in the WTO Agreement. The following subsection discusses the work of the TRIPS Council.

1 Decision-making procedures

The cross-cutting rules on decision-making and amendment procedures are contained in the WTO Agreement. It provides that the Ministerial Conference has the authority to

take decisions on all matters under any of the Multilateral Trade Agreements, ¹⁹ including the TRIPS Agreement, if so requested by a member, in accordance with the specific requirements for decision-making in the WTO Agreement and in the relevant Multilateral Trade Agreement (Article IV:1). In the intervals between meetings of the Ministerial Conference, its functions are conducted by the General Council (Article IV:2). Given this, a reference to the Ministerial Conference/General Council is used below where appropriate.

According to the general rules on decision-making, the WTO continues the practice of decision-making by consensus (Article IX:1). Where a decision cannot be arrived at by consensus, the Article provides for the possibility of deciding a matter by voting. In these circumstances, decisions concerning authoritative interpretations and waivers can be taken by specific qualified majorities that vary as indicated below. Similarly, a decision to submit a proposed amendment to the members for acceptance is to be taken by consensus, failing which there is the possibility of deciding it by qualified majority (Article X). In the absence of specific rules, decisions of the Ministerial Conference and the General Council can be taken by a majority of the votes cast but, to date, all decisions in the WTO have been agreed by consensus. The practice has been that where a body has failed to reach consensus on a matter, it has held further consultations with a view to seeking consensus.

The rules on authoritative interpretations are set out in Article IX:2 of the WTO Agreement. It provides that the Ministerial Conference and the General Council have the exclusive authority to adopt interpretations of the WTO Agreement and the Multilateral Trade Agreements; this authority must be exercised on the basis of a recommendation by the Council overseeing the functioning of the relevant agreement, i.e. in the case of the TRIPS Agreement on the basis of a recommendation by the TRIPS Council. If a decision concerning interpretation cannot be reached by consensus, the decision by the Ministerial Conference or the General Council to adopt an interpretation requires a three-fourths majority of WTO members. This procedure cannot be used in a manner that would undermine the amendment provisions set out in Article X. In other words, the validity of an authoritative interpretation that goes so far as to effectively amend a provision of a WTO Multilateral Trade Agreement could be challenged on this basis.

To date, no such formal interpretation of the TRIPS Agreement or any other Multilateral Trade Agreement has been adopted.

It should be noted that, for the purposes of resolving a specific dispute, dispute settlement panels and the Appellate Body may need to clarify the provisions of the TRIPS Agreement, but without adding to or diminishing the rights and obligations in the Agreement. The outcome of a dispute does not bind other members, although the

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¹⁹ The first three annexes to the WTO Agreement, including the TRIPS Agreement, are binding on all WTO members, and are termed the 'Multilateral Trade Agreements'. They are distinct from the agreements and legal instruments found in Annex 4, termed the 'Plurilateral Trade Agreements', which are only binding on those members who have accepted them. See Article II of the WTO Agreement.

clarifications made in dispute settlement are widely referred to for guidance on understanding the relevant provisions of the TRIPS Agreement. For discussion of the dispute settlement system, see Module IX.

Paragraphs 3 and 4 of Article IX of the WTO Agreement provide the Ministerial Conference/General Council with authority to waive an obligation imposed on a member by the WTO Agreement or any of the Multilateral Trade Agreements, including the TRIPS Agreement. It may exercise this authority 'in exceptional circumstances'. A request for a waiver must be submitted initially to the Council overseeing the relevant agreement; thus a request for a waiver concerning the TRIPS Agreement must be submitted initially to the TRIPS Council. After the relevant Council has considered a draft waiver, it forwards it to the Ministerial Conference/General Council for consideration pursuant to the practice of decision-making by consensus. If the latter does not reach consensus, any decision to grant a waiver requires a three-fourths majority of the members. The usual practice is that once the relevant sectoral council has approved a draft waiver by consensus, the General Council adopts it by consensus without further substantive discussion. Any waiver granted for a period of more than one year is to be reviewed by the Ministerial Conference not later than one year after it is granted, and thereafter annually until the waiver terminates. In each review, the Ministerial Conference/General Council is to examine whether the exceptional circumstances justifying the waiver still exist and whether the terms and conditions attached to the waiver have been met. The Ministerial Conference/General Council, on the basis of the annual review, may extend, modify or terminate the waiver.

Of around 250 waivers agreed upon by the end of 2018, only three concerned the TRIPS Agreement. Two of them supplement the TRIPS Council decisions to extend LDC transition periods for certain obligations with respect to pharmaceutical products. The first one waives obligations concerning so-called exclusive marketing rights in Article 70.9. The second waives the 'mailbox' provision found in Article 70.8. The third one anticipated the amendment to TRIPS to enable the special compulsory licensing system for pharmaceutical patent standards. It waives, in certain circumstances, certain conditions in Article 31 associated with compulsory licences for medicines. Following the entry into force of the amendment in 2017, this waiver now only needs to apply to the minority of members yet to accept the amendment.²⁰

Article X of the WTO Agreement lays down the procedure for amending the Multilateral Trade Agreements, including the TRIPS Agreement. The TRIPS Council can initiate the procedure for amending the TRIPS Agreement by submitting a proposal to the Ministerial Conference. Any member also may submit an amendment proposal. The Ministerial Conference itself (or the General Council meeting in that capacity) then decides whether to submit the proposed amendment to WTO members for acceptance. As mentioned above, the Ministerial Conference has followed the practice of decision-making by consensus, although Article X:1 foresees the possibility of voting if

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 $^{^{20}}$ For further information, see section D1 of this module on transition periods and discussions in Module X on the 'special compulsory licensing system', formerly known as the 'Paragraph 6 System'.

consensus cannot be reached. Once members have decided to submit an amendment for acceptance, each member must separately notify its formal acceptance of an agreed amendment. The amendment enters into force once two thirds of members have done so. If the amendment alters the rights and obligations of members, then it only enters into force for those members that have notified their acceptance; otherwise, it comes into effect for all members after two thirds have accepted it.

The process for amending the WTO Multilateral Trade Agreements has to date been used only once in the context of the TRIPS Agreement – the amendment that made the waiver decision providing the special compulsory licensing system referred to above a permanent part of the Agreement (see Module X). Following a recommendation by the TRIPS Council, the decision on the amendment was taken by the General Council acting with the authority of the Ministerial Conference. The Protocol Amending the TRIPS Agreement entered into force, for those members that had accepted it, on 23 January 2017, following acceptance by two thirds of the WTO membership.

A specific amendment scenario is set out in Article 71.2 of the TRIPS Agreement – it refers to amendments 'merely serving the purpose of adjusting to higher levels of protection of intellectual property rights achieved, and in force, in other multilateral agreements and accepted under those agreements by all Members of the WTO'. The TRIPS Council may refer consensus proposals for such amendments to the Ministerial Conference, which may adopt the amendment without any further acceptance process. This provision has not been used so far.

2 The work of the TRIPS Council

The TRIPS Council itself was created by the WTO Agreement to 'oversee the functioning' of the TRIPS Agreement, and is the main forum for work on the Agreement. Article 68 is the main provision on the Council's role, but it should be read together with the provisions of the WTO Agreement concerning the structure and operation of the WTO as well as the TRIPS provisions on transparency and review.

In its regular sessions, the TRIPS Council mostly serves as a forum for managing transparency of domestic implementation of the Agreement and for discussion between member governments on key issues. The substantive discussions are often facilitated by the collection of information about the comparative approaches taken by members in their national laws and policies through the notification process and through more specific surveys and questionnaires. Some of the main functions and working methods of the TRIPS Council in regular session are described below and in Appendix 1 to this Guide.

Currently, the TRIPS Council also meets in special sessions ('special sessions' refers to negotiating sessions of WTO bodies). The Trade Negotiations Committee was set up by the Doha Ministerial Declaration,²¹ which in turn assigned it to create subsidiary

²¹ WT/MIN(01)/DEC/1.

negotiating bodies to handle negotiations for different topics, among them the special sessions of the TRIPS Council. These special sessions serve as a forum for negotiations on the establishment of a multilateral system for notification and registration of GIs for wines and spirits, as mandated by the Doha Ministerial Declaration and Article 23.4 of the TRIPS Agreement (see Module XI).

The regular and special sessions of the TRIPS Council are both open to all WTO member governments, to observer governments (including those seeking accession to the WTO), and to other accredited or *ad hoc* observers. They are convened under separate chairs, but their meetings are often held back-to-back for practical reasons.

Beyond the TRIPS Council, other mechanisms can be used to promote dialogue among WTO members, such as the consultations on TRIPS implementation issues that have been convened directly by the Director-General of the WTO, in line with a mandate given by the Hong Kong Ministerial Declaration (see Module XI).

In addition, the Trade Policy Review Mechanism undertakes regular reviews of the trade policies of WTO members, and this process regularly looks at IP policies as one of a wide range of policy fields covered. The Secretariat regularly reports to the TRIPS Council on the many and diverse IP issues raised in the latest trade policy reviews.

(a) Notifications

The TRIPS Agreement obliges members to make certain notifications to the TRIPS Council. These notifications facilitate the Council's work of monitoring the operation of the Agreement and promote the transparency of members' laws and policies on IP protection. In addition, members wishing to avail themselves of certain flexibilities provided in the Agreement that relate to the substantive obligations have to notify the Council.

Article 63.2 requires members to notify the laws and regulations by which they give effect to the Agreement's provisions. The Article specifies that the purpose is to assist the TRIPS Council in its review of the operation of the Agreement. The Council has agreed that laws and regulations should be notified without delay as of the time that the corresponding substantive TRIPS obligation has effect. Any subsequent amendments should also be notified without delay. Given the difficulty of examining laws and legal procedures relevant to many of the enforcement obligations in the TRIPS Agreement – especially since much relevant material is often found in general civil and criminal law, not in IP legislation – members have undertaken, in addition to notifying legislative texts, to provide information on how they are meeting these obligations by responding to a Checklist of Issues on Enforcement (IP/C/5).

As seen in section B3 above, Articles 1.3 and 3.1 allow members to avail themselves of certain options in regard to the definition of beneficiary persons and national treatment, provided that notifications are made to the TRIPS Council.

As seen in section B4 above, Article 4 on MFN treatment provides that, with regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other members. There are certain exceptions to this obligation. According to subparagraph (d) of that Article, exempted from this obligation is any advantage, favour, privilege or immunity accorded by a member deriving from international agreements related to the protection of IP which entered into force prior to the entry into force of the WTO Agreement, provided that such agreements are notified to the TRIPS Council and do not constitute an arbitrary or unjustifiable discrimination against nationals of other members.

Article 69 of the Agreement requires members to establish and notify contact points in their administrations for the purpose of cooperation with each other aimed at the elimination of trade in infringing goods.

A number of notification provisions of the Berne and Rome Conventions are incorporated by reference into the TRIPS Agreement but without being explicitly referred to in it. A member wishing to make such notifications has to make them to the TRIPS Council, even if the member in question had already made a notification under the Berne or the Rome Convention in regard to the same issue.

All of the notifications referred to above are circulated in the IP/N/- series of documents, which are available on the WTO Documents Online database. The easiest way to access this documentation is through the e-TRIPS Gateway, which provides access to various notifications, reviews and reports from members, and related background materials. Notified laws and regulations are also available on the WIPO Lex search facility for national laws and treaties on intellectual property, wipolex.wipo.int.

Appendix 1 to this Guide contains a more detailed guide to TRIPS notifications and related transparency materials, as well as their access through the e-TRIPS Gateway. Notifications pursuant to Article 6ter of the Paris Convention, as incorporated into the TRIPS Agreement, will be discussed below.

(b) Review of national laws and regulations

A key mechanism for monitoring implementation of the TRIPS Agreement is the examination of each member's national legislation by other members, in particular at the end of its transition period. The notifications made pursuant to Article 63.2 discussed above form the basis for these reviews. The procedures for these reviews provide for written questions and replies prior to the review meeting, with follow-up questions and replies during the course of the meeting. At subsequent meetings of the Council, an opportunity is given to follow up on points emerging from the review session that delegations consider to have not been adequately addressed. The records of these reviews are circulated in the IP/Q/- series of documents, which are available on the WTO Documents Online database and the e-TRIPS Gateway.

(c) Forum for consultations

The TRIPS Council constitutes a forum for consultations on any problems relating to the TRIPS Agreement arising between countries, as well as for clarifying or interpreting provisions of the Agreement. Members occasionally bring such issues before the Council for the purposes of sharing information, clarification or discussion. To the extent they involve differences between members, the aim is, whenever possible, to resolve them without the need for formal recourse to dispute settlement.

(d) Forum for further negotiation or review

The WTO constitutes a forum for negotiations among its members concerning their multilateral trade relations in the area of IP, as in other areas covered by the WTO agreements. Certain specific areas of further work are called for in the text of the TRIPS Agreement. These areas include:

- the negotiation of a multilateral system of notification and registration of GIs for wines;
- the review of Article 27.3(b) (which concerns the option to exclude from patentability certain plant and animal inventions); and
- the examination of the applicability to TRIPS of non-violation complaints under the dispute settlement process.

Apart from these specific reviews that will be discussed in Module XI, Article 71.1 includes a provision for a general review of the implementation of the Agreement in the year 2000, and every two years after that date. The Council may also undertake reviews 'in the light of any relevant new developments which might warrant modification or amendment' of the Agreement. In effect, these review provisions have led to a regular item appearing on the agenda of the TRIPS Council since 2000. No proposals on issues to be taken up under this item are being pursued. The Doha Ministerial Declaration mentions the Article 71.1 review in the context of the TRIPS Council's broader work programme, and refers to work on the issues of the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by members pursuant to Article 71.1.²²

The Doha Ministerial Declaration and the Doha Declaration on the TRIPS Agreement and Public Health, both adopted in 2001, and certain subsequent ministerial declarations²³ have given specific tasks to the Council's regular and special sessions. Past and ongoing work on such matters will be discussed in subsequent modules in the context of the substantive area concerned.

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 $^{^{22}}$ WT/MIN(01)/DEC/1, para. 19.

²³ See, e.g. WT/MIN(05)/DEC and WT/MIN(17)/66-WT/L/1033.

(e) Cooperation with the World Intellectual Property Organization

To facilitate the implementation of the TRIPS Agreement, the WTO concluded with WIPO an agreement on cooperation between the two organizations, which came into force on 1 January 1996. As explicitly set out in the Preamble to the TRIPS Agreement, the WTO aims to establish a mutually supportive relationship with WIPO. The Agreement provides for cooperation in three main areas, namely (1) notification of, access to and translation of national laws and regulations; (2) implementation of procedures for the protection of national emblems; and (3) technical cooperation.

As regards notification of, access to and translation of national laws and regulations, the WTO Secretariat transmits to the WIPO Secretariat copies of the laws and regulations it has received from members under Article 63.2 of the TRIPS Agreement.²⁴ The International Bureau of WIPO places such laws and regulations in its collection and makes them available to the public through the WIPO Lex search facility. In 2010, the two organizations established a WIPO-WTO Common Portal²⁵ that allows countries to simultaneously electronically submit texts of IP laws and regulations to the two organizations. WIPO also makes available to developing countries assistance for translation of their laws and regulations.

As regards the implementation of procedures for the protection of national emblems under Article 6ter of the Paris Convention for the purposes of the TRIPS Agreement, the cooperation agreement provides that the procedures relating to communication of emblems and transmittal of objections under the TRIPS Agreement shall be administered by the WIPO Secretariat in accordance with the procedures it applies under Article 6ter of the Paris Convention. Article 6ter of the Paris Convention, as incorporated into the TRIPS Agreement, provides for the communication of emblems and of objections thereto among members. The TRIPS Council has decided that their communication through the WIPO Secretariat would be considered as communications for the purposes of the TRIPS Agreement.

As regards technical cooperation, the cooperation agreement provides that the WIPO and WTO Secretariats enhance cooperation in their legal-technical assistance and technical cooperation activities relating to the TRIPS Agreement for developing countries, so as to maximize the usefulness of those activities and ensure their mutually supportive nature. The assistance they make available to the members of their own organization are also be made available to the members of the other organization.

An example of this cooperation is the WIPO-WTO Joint Initiative on Technical Cooperation for Least-Developed Countries that was launched in 2001. It is aimed at helping LDC members of the WTO comply with their obligations under the

²⁴ Parties to the Paris and Berne Conventions are required to notify their relevant laws to the WIPO Secretariat. The Assemblies of the Paris and Berne Unions have decided that the requirements under these conventions to communicate national laws to the WIPO Secretariat can be fulfilled by communication of such laws through the WTO Secretariat.

²⁵ The WIPO-WTO Common Portal can be accessed at wipolex.wipo.int/en/info/common-portal.

TRIPS Agreement and make best use of the IP system for their economic, social and cultural development. It is open to other LDCs as well. The 2005 TRIPS Council Decision on the extension of LDCs' transition period discussed above calls upon the WTO to seek to enhance its cooperation with WIPO and other relevant international organizations. The two organizations also run a number of annual joint technical cooperation activities, notably the Colloquium for University Teachers of IP and the Advanced Course on IP for government officials. The organizations collaborate on the production of a scholarly journal, the WIPO WTO Colloquium Papers, which provides a peer-reviewed academic publication for emerging scholars principally from the developing world.²⁶

²⁶ The WIPO WTO Colloquium Papers are available at www.wto.org/colloquiumpapers.