Chapter X

Intellectual Property, TRIPS and Development

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The recognition of intellectual property rights is integral to innovation systems and assumes even greater significance when products and services are traded in global markets. The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement) which was adopted at the conclusion of the Uruguay Round established for the first time a formal link between the regulation of the world trading system and intellectual property rights in internationally traded goods and services. TRIPS establishes minimum standards for the protection and enforcement of intellectual property which are binding on all WTO members. For developing and least-developed countries, the implementation of their TRIPS obligations presents particular challenges. While the precise relationship between intellectual property and development remains contentious, it is acknowledged that development is not necessarily promoted merely by the introduction of intellectual property systems; rather, intellectual property protection must form part of a wider development strategy. The question for developing and least-developed countries is how to implement TRIPS in a manner that also serves their social and economic development needs and objectives. This chapter provides an overview of the international regulation of intellectual property, through numerous multilateral, regional and bilateral agreements. It considers the minimum standards prescribed by TRIPS and the strengthening of intellectual property protection and enforcement obligations in subsequent regional and bilateral free trade agreements and multilateral agreements. Various general and specific flexibilities provided by TRIPS are described and the use of these by developing and least-developed countries to design intellectual property systems that promote their development is examined. Increasingly, the need to achieve a better alignment between the development needs of developing and least-developed countries and intellectual property protection is being recognised, as demonstrated by proposed amendments to TRIPS to provide greater flexibility for public health measures and the adoption of a Development Agenda by the World Intellectual Property Organisation (WIPO).

The law of intellectual property has a pivotal role in providing both incentive and security for those engaging and investing in the innovative process.¹

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Intellectual property is crucial to the promotion of innovation. It provides an incentive to innovate as well as security for investment in innovation. The industries of the 21st century-information technology, biotechnology, pharmaceuticals, communications, education and entertainment - are all knowledge-based. The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement) 2, adopted in 1994 at the conclusion of the Uruguay round of trade negotiations, requires all WTO member countries to provide for the protection and enforcement of intellectual property rights. Having forged a link for the first time between intellectual property rights and the international trading system, the adoption of TRIPS means that any country that aims to participate fully in the global economy needs to understand the role of intellectual property and align its intellectual property laws and practices with the international minimum standards prescribed by TRIPS. However, for developing and least-developed countries, the implementation of intellectual property systems and enforcement mechanisms raises questions and challenges. Does recognition and enforcement of intellectual property serve their development needs and objectives? Does TRIPS encourage or hinder the transfer of technologies to developing and least-developed countries, particularly those that meet urgent needs in areas such public health, food security, water and energy? What is the effect of TRIPS on developing countries’ access to knowledge and information? Is there scope for flexibility in implementation of TRIPS in pursuit of development strategies?

A. INTRODUCTION TO INTELLECTUAL PROPERTY AND TRIPS

1.1 The Concept of Intellectual Property

The range of matters that are subject to intellectual property protection is diverse and extensive. Examples of things which can be protected by intellectual property include novels, works of art, photographs, musical scores, sound recordings, films, computer software and hardware, web sites, designs for mass-produced goods, bio-engineered living organisms, new pharmaceuticals and plant varieties, trade secrets, know-how, invented characters and brand names. The various forms of intellectual property rights – patents, copyright, registered designs, trade marks, confidential information, and so on - developed independently of each other, serve different purposes and are governed by different legal rules. There is, however, a common thread running through the intellectual property systems that justifies grouping them together and studying them as a whole. In a general sense, intellectual property is concerned with protecting the creative and organisational efforts involved in developing new products, processes, designs and materials. This is reflected in the legal definition of intellectual property, which focuses on the rights or bundles of rights given for the protection of creative or organisational effort. Since the concept of property refers to the relationship between a person and a thing (whether tangible or intangible), the rights which are granted in respect of creative effort can be classified as property — or proprietary — rights. Intellectual property is personal property which can be owned and dealt with in the same way as other forms of property, including by selling and licensing. The various intellectual property rights are not mutually exclusive and it will often be necessary to rely on two or more systems concurrently to effectively protect the same subject matter. In many cases, the rights come into play sequentially with one right taking over from another at different stages of a product’s life-cycle. Most intellectual property rights are created by statute, although some are still based rights recognised in common law.

A central theme running through the entire field of intellectual property is the need to strike a balance between “on the one hand, the incentive to innovate and, on the other, the diffusion of the social benefit of the innovation”. Intellectual property systems are concerned not only with providing incentive and reward to authors and inventors, but also aim to promote the dissemination and use of new ideas, information and technology. If the appropriate balance is achieved, the flow of new and innovative ideas and products will be optimised. On the other hand, protection that is either too broad or inadequate will not be conducive to optimal levels of innovation. The attempt to balance the interests of innovators and the broader community is evident in the exceptions and exclusions provided in the various intellectual property regimes.

1.2 Rationales for Intellectual Property Protection

The existence of intellectual property rights is usually justified by reference to one or more of the following grounds:

*Natural rights*
One of the most basic justifications for intellectual property is that a person who puts intellectual effort into creating something should have a natural right to own and control what he creates: “he who sows shall also reap”. Such an entitlement is recognised in Art 27(2) of the *Universal Declaration of Human Rights* which states: “Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.”

*Encourage and reward innovation and creation*
Intellectual property rights serve as an incentive for the investment of time and capital in the research and development required to produce inventive and creative works. By providing the owners with exclusive property rights they are entitled to the benefit of the stream of revenue generated by exploitation of their intellectual property.

*Encourage dissemination of information and ideas*
The existence of intellectual property laws encourages the disclosure and dissemination of information and widens the store of knowledge available in the community. This justification is commonly given for patents and copyright. The specifications of patented inventions are published by patent offices around the world and form a valuable source of advanced technical information, much of which is not published elsewhere.

*Economic efficiency*
Economic theorists justify the recognition of property rights in creative endeavour on the basis that it leads to more efficient use of resources.

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Consumer protection
Some intellectual property rights offer protection for consumers by enabling them to make informed choices between goods and services from different sources.

Technology transfer
Intellectual property systems facilitate the dissemination of technology so that it can be used by parties other than the owner, using mechanisms such as licensing and joint ventures. Protection of intellectual property supports foreign direct investment, enabling technology to be transferred to other countries where it is used by the owner (e.g., to manufacture patented equipment or pharmaceuticals) or by their local subsidiary or licensee.

1.3 The International Framework of Intellectual Property

Understanding TRIPS and the operation of domestic intellectual property systems requires an appreciation of the complex international legal framework underpinning them. There are numerous international treaties and agreements relating to intellectual property, some of which pre-date TRIPS while others have been entered into subsequent to the completion of the Uruguay Round.

The need for reciprocity of protection becomes apparent as soon as goods incorporating intellectual property, whether they take the form of books, machinery or trademarked products, are traded across national boundaries. This need is all the more striking when the goods moving across borders are not tangible items, but are materials in digital form which are made available or transmitted on the internet. Unless foreign countries have adequate intellectual property laws in place and effective means of enforcing those rights, any exported goods are likely to be reproduced and distributed without authorisation and without any recourse by the right-owner. By setting minimum standards of protection and adopting the national standard of treatment, the international agreements offer a means of ensuring that intellectual property owners can benefit from the exploitation of their products in foreign markets.

The importance of international collaboration and cooperation on intellectual property matters has long been recognised and there are numerous international conventions dealing with a wide range of substantive and procedural aspects of intellectual property protection and enforcement. The long-standing nature of international cooperation relating to intellectual property is demonstrated by the fact that the two pre-eminent treaties in the field were entered into well over a century ago. The Paris Convention for the Protection of Industrial Property (1883) establishes the basic framework for member countries’ laws on patents, trade marks, designs, indications of origin and unfair competition. The Berne Convention for the Protection of Literary and Artistic Works (1886) was the first major agreement of international cooperation in relation to copyright. The main purpose of the Berne Convention is to protect the rights of authors of literary and artistic works, including musical and dramatic works, adaptations, translations, arrangements of music and other alterations of works as well as the moral rights of integrity and attribution. Both the Paris Convention and Berne Convention have been updated and amended over the years and they
remain central to the international copyright and industrial property (patents, designs, trade marks) systems.\(^5\)

Although international cooperation on protection of intellectual property rights in goods traded across borders had occurred since the 19\(^{th}\) century it was not until the finalisation of the Uruguay Round of trade negotiations that intellectual property rights were formally brought within the scope of the GATT/WTO system. From the early 1980s there was increasing concern about the rapid growth of international trade in counterfeit and pirate goods and the lack of effective intellectual property protection in developing countries. In many instances, countries had no intellectual property laws. Even in those countries which had enacted intellectual property laws, the mechanisms for enforcing intellectual property rights and the available remedies were often inadequate. Further, the existing treaties were ineffective in dealing with failure to enact minimum standards of intellectual property protection or ensuring that laws were enforced. Not surprisingly, the cost of losses from counterfeiting and piracy was growing, particularly in the areas of computer software, sound recordings, books, movies and videos, pharmaceutical drugs, electronic products, toys, agricultural chemicals and designer clothing.

It was against this background that the United States\(^6\) moved to have trade-related intellectual property included on the negotiating agenda of the Uruguay Round of GATT negotiations that commenced in 1986. The aim of the GATT intellectual property negotiations was to formulate multilateral rules for stronger and more comprehensive protection of a range of intellectual property rights and to strengthen the means of enforcement. This was achieved in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). The TRIPS Agreement forms Annex IC to the Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations (Final Act) which was finalised in Geneva in December 1993 and ratified in Marrakech in 1994. Developing and least-developed countries accepted their TRIPS obligations in return for increased access to agriculture and textiles markets in developed countries.

TRIPS is the most comprehensive multilateral treaty in the field of intellectual property, setting minimum standards for protection and enforcement across a broad range of recognised forms of intellectual property, and providing a mechanism for the enforcement of these obligations.\(^7\) By bringing intellectual property into the WTO system, the TRIPS Agreement forged a link between the regulation of international trade and intellectual property protection in a much more direct way than had previously existed.

However, the development of the international framework of intellectual property protection and enforcement did not end with the adoption of the TRIPS Agreement in 1994. Some developed countries remained dissatisfied with the level of international intellectual property protection provided under the various existing multilateral intellectual property treaties and TRIPS. The United States, in particular, continued to push for higher standards of

\(^{5}\) Their continuing relevance is reinforced by the fact that TRIPS requires all WTO members to give effect to their substantive provisions; Arts 2.1 and 9.1, TRIPS.

\(^{6}\) The United States had begun enforcing intellectual property rights by relying on the authority of the United States Trade Representative under section 301 of the United States Trade Act of 1974.

\(^{7}\) TRIPS covers seven intellectual property areas: copyright and related rights; trade marks; geographic indications; industrial designs; patents; layout designs of integrated circuits; protection of undisclosed information.

\(^{8}\) Art 1.2, TRIPS
intellectual property protection. The result is that, since the mid-1990s, there has been a major expansion in the reach of intellectual property and a shift in focus from the minimum standards of protection and enforcement required by TRIPS to the harmonisation of national and regional laws.9 TRIPS-plus intellectual property protection requirements that go beyond the TRIPS minimum standards have been introduced through bilateral and regional Free Trade Agreements (FTAs) and bilateral investment treaties (BITs) as well as multilateral treaties. Post-TRIPS developments have seen patent and copyright protection extended to new kinds of subject matter, the elimination or narrowing of permitted exceptions (for example, limiting the grounds and conditions for issuing compulsory licences) and the lengthening of terms of protection. As well as extending the scope of intellectual property protection beyond that required by TRIPS, these agreements have sought to remove or limit existing exceptions and flexibilities.

There has been a proliferation of bilateral and regional FTAs that have required developing countries to adopt higher standards of intellectual property protection.10 In fact, intellectual property is dealt with in most of the FTAs entered into by developed countries. The United States has entered into FTAs with many developing countries, including Chile, Colombia, Panama, Bahrain, Peru, Jordan, Morocco, the Dominican Republic and others. The EU has followed the lead of the United States, entering into bilateral trade agreements with a number of emerging economies and developing countries such as India, South Africa11 and a series of Mediterranean countries.12 Immediately after TRIPS was accepted, the United States and other countries pushed the international community, through WIPO, to negotiate and adopt new multilateral treaties designed to strengthen copyright protection in the digital environment. This resulted in the adoption of the so-called ‘internet treaties’ in December 1996, the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty.13 Work continues on new multilateral treaties that aim to further strengthen intellectual property protection and enforcement, through initiatives such as the Anti-Counterfeiting Trade Agreement (ACTA).14

1.4 The TRIPS Agreement

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10 John Braithwaite and Peter Drahos, Global Business Regulation (Cambridge University, 2000) 40.
11 The EU utilised the bilateral trade negotiations with South Africa to gain additional IP protection (geographical indications) for various grape varieties and sherries for which it wanted special protection. See, Willem Pretorius, ‘TRIPS and Developing Countries: How Level is the Playing Field?’ in Peter Drahos and Ruth Mayne, Global Intellectual Property Rights: Knowledge, Access and Development (Palgrave Macmillan, 2002) 194.
14 Participants in the ACTA negotiations were Australia, Canada, the European Union, Japan, the Republic of Korea, Mexico, Morocco, New Zealand, Singapore, Switzerland and the United States. ACTA was signed on 1 October 2011 in Tokyo, at http://www.mofa.go.jp/policy/economy/i_property/pdfs/acta1105_en.pdf.
The TRIPS Agreement came into effect on 1 January 1995. Developed countries were required to fully implement their obligations under TRIPS by 1 January 1996. Developing countries and countries undergoing transformation from centrally-planned into a market, free-enterprise economy were given until 1 January 2000 to bring their domestic laws into conformity with TRIPS. For least-developed countries, the compliance target date was initially set as 1 January 2006, although it was open to individual members to request a further extension. In 2005, the TRIPS Council approved an extension of the implementation date for least-developed countries to 1 July 2013. Under an extension granted by the Ministerial Conference in 2001, less-developed countries are not required to provide full patent protection for pharmaceuticals until 2016. By 2011, more than 126 WTO members (of a total of 155) had given notice of their enactment of intellectual property laws.

1.5 Substantive Provisions of TRIPS

The TRIPS Agreement provides a multilateral framework of principles, rules and disciplines covering the various forms of intellectual property listed in Pt II. It does not attempt to define intellectual property, simply stating that it includes the following seven categories:

- copyright and related rights (that is, the rights of performers, producers of sound recordings and broadcasting organisations);
- trade marks including service marks;
- geographical indications including appellations of origin;
- industrial designs;
- patents including the protection of new plant varieties;
- layout designs of integrated circuits; and
- undisclosed information including trade secrets and test data.

Part I contains general principles, including the obligation on all WTO members to give effect to the provisions of the TRIPS Agreement. TRIPS describes the minimum standards which members are to apply, although they are free to introduce more extensive protection provided it does not conflict with the Agreement. The continuance of existing obligations under other major intellectual property conventions including the Paris Convention and Berne Convention is acknowledged and the application of the national treatment principle and most favoured nation treatment is affirmed.

Part II sets out the minimum standards of protection which WTO members are to provide in each of the main areas of intellectual property. For each intellectual property system, TRIPS defines the subject-matter to be protected, the rights to be conferred, permissible exceptions to those rights and the minimum duration of protection. In setting the minimum standards, TRIPS obliges WTO members to comply with the substantive provisions of the Paris and

\[\text{(Footnotes are omitted for brevity.)}\]
Berne Conventions, which are incorporated into the TRIPS Agreement. In areas where the existing Conventions were seen to be deficient, TRIPS provides for significant additional obligations which are referred to as being Berne-plus or Paris-plus provisions. For example, TRIPS builds upon the standards of the Berne Convention regarding copyright protection by additionally requiring WTO members to:

- extend copyright protection to computer programs in source or object code;
- make copyright protection available for “compilations of data or other material whether in machine readable or other form, which by reason of the selection or arrangement of their contents constitute intellectual creations”; and
- enable owners of copyright in computer programs, certain cinematographic films and sound recordings to control commercial rental of these works.

Part III deals with the procedures and remedies available in WTO member countries for the enforcement of intellectual property rights. It requires WTO members to have in place administrative and judicial enforcement procedures for the effective enforcement of intellectual property rights. Such procedures must be fair and equitable, not unnecessarily complicated or costly and should not involve unreasonable time limits or unwarranted delays. Civil judicial proceedings are to be available in relation to all the rights protected under the TRIPS Agreement and burdensome requirements concerning mandatory personal appearances are prohibited. The remedies available in civil actions should include injunctions and damages and actions should be permitted on an ex parte basis. In relation to pirated copyright and counterfeit trademark goods, customs authorities should have the power to seize goods presented for importation and criminal penalties including imprisonment and fines should be available where such infringement is occurring on a commercial scale.

1.6 Non-Discrimination Principles

A key feature of all the intellectual property conventions is that they are based on a non-discrimination principle in that they require members to accord each other national treatment. The national treatment standard forbids discrimination under domestic laws between a member’s own nationals and the nationals of other members. For example, the operation of this principle means that a copyright work produced in one Berne Convention country will qualify for protection under the laws of another country that is also a party to the Convention as if the work had originated in the latter country. Article 3.1 of TRIPS requires WTO members to accord national treatment to the nationals of other members, treating them no less favourably than their own nationals with respect to intellectual property protection.

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25 Art 2.1, TRIPS requires WTO members to comply with Arts 1-12, and Art 19 of the Paris Convention (Stockholm Act, 14 July 1967); Art 9.1, TRIPS requires WTO members to comply with Arts 1-21 of the Berne Convention (Paris Act, 24 July 1971), except for the rights conferred under Art 6bis of the Berne Convention (that is, moral rights).
26 Art 9.2, TRIPS
27 Art 10.2, TRIPS
28 Arts 11, 14(4), TRIPS
29 Art 41(1), TRIPS
30 Art 41(2), TRIPS
31 Art 42, TRIPS
32 Arts 44, 45, 50, TRIPS
33 Art 51, TRIPS
34 Art 61, TRIPS
subject to existing exceptions provided in international treaties.\textsuperscript{35} The TRIPS Agreement also incorporates the most favoured nation (MFN) principle, prohibiting discrimination among the nationals of other WTO member countries. MFN treatment means that any “advantage, favour, privilege or immunity” which is granted by a WTO member country to the nationals of another WTO country is to be “accorded immediately and unconditionally to the nationals of all other Members.”\textsuperscript{36}

### 1.7 Administration of TRIPS – the TRIPS Council

The WTO Charter establishes the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council), consisting of all WTO members, as the body responsible for administering the TRIPS Agreement and for monitoring governments’ compliance with it.\textsuperscript{37} WTO members must notify the TRIPS Council of changes to their intellectual property laws and regulations to give effect to their obligations under TRIPS so that it can review the operation of the Agreement.\textsuperscript{38}

### 1.8 Dispute Settlement under TRIPS - the WTO’s Dispute Settlement Body

Whereas the earlier multilateral intellectual property treaties (the Paris Convention and the Berne Convention) lacked a dispute settlement and enforcement mechanism, enforcement of WTO member states’ obligations under TRIPS is strengthened by enabling member countries to bring disputes to the WTO’s Dispute Settlement Body (DSB). Complaints about TRIPS compliance referred to the DSB are dealt with at a government-to-government level.

Complaints can be filed about a direct conflict between a WTO member’s intellectual property law and their obligations under TRIPS.\textsuperscript{39} Provision was also made in TRIPS for WTO member states to bring so-called “non-violation” complaints. Non-violation complaints seek to preserve the balance of benefits (such as market access) achieved during the multilateral trade negotiations so that, even in the absence of a specific breach of a TRIPS provision, a complainant may allege that a benefit that should have accrued to it has been “nullified or impaired” or the attainment of a TRIPS objective has been impeded.\textsuperscript{40}

Under Art 64.2 of TRIPS a moratorium applied to non-violation complaints which meant that there was a moratorium on bringing non-violation complaints until 2000. WTO members agreed to extend this period, pending a recommendation by the TRIPS Council on whether non-violation complaints should be allowed at all in relation to intellectual property and, if so, to what extent and how they could be brought to the DSB. The issue has not formally been resolved, but the majority of WTO members currently favour a permanent ban on non-violation complaints in TRIPS or, at least, an extension of the moratorium. In practice, the moratorium is simply extended from one Ministerial Conference to the next. At the eighth Ministerial Conference in November 2011, the TRIPS Council was requested to continue its examination of the “scope and modalities for complaints” of the kind envisaged by Art XXIII


\textsuperscript{36} Art 4, TRIPS. Note that this is subject to an exception for any “advantage, favour, privilege or immunity” granted under in the circumstances described in Art 4 (a) – (d).

\textsuperscript{37} Art 68, TRIPS

\textsuperscript{38} Art 63.2, TRIPS.

\textsuperscript{39} Art 64.1, TRIPS.

\textsuperscript{40} Art 64.2, TRIPS.
(1) (b) and (c) of GATT 1994 and to make recommendations at the ninth WTO Ministerial Conference in December 2013. Until then, WTO members have agreed not to initiate non-violation complaints under TRIPS.\textsuperscript{41}

Where a dispute cannot be resolved by consultation between the parties within 60 days of the complaint being filed, the DSB establishes a panel of experts to consider and determine the dispute. Panels typically consist of three experts, chosen by the parties to the dispute. The panel has six months to hear the matter and to provide its report to the DSB which can either accept or reject the report by consensus. Unless rejected by a consensus within 60 days, the report becomes the DSB’s ruling or recommendation. Either party can appeal the panel’s report, based on issues of law. An appeal is heard by three members of the permanent seven-member Appellate Body which can uphold, modify or reverse the panel’s legal findings and conclusions. Appeals must be finalised within 90 days and the DSB must accept or reject the report within 30 days. An appeal report can only be rejected by consensus of the DSB.

1.9 Intellectual Property Disputes in WTO’s Dispute Settlement Body

Around 30 disputes involving intellectual property obligations under TRIPS have been referred to the DSB. There have been three findings of non-compliance by developing countries.

Some examples of leading disputes involving developing countries are:

- **India Patent Protection for Pharmaceutical and Agricultural Chemical Products (1996)\textsuperscript{42}**

In this complaint brought by the United States against India in July 1996 (in which the European Union participated as a third party), the United States claimed that India’s patent law did not protect pharmaceutical and agricultural chemical products and was in violation of Arts 27, 65 and 70 of TRIPS. In particular, India was criticised for failing to provide a means for the filing of patent applications for pharmaceutical and agricultural chemical products - the so-called “patent mail box” - as required by Art 70.8 of TRIPS, and for failing to establish a system for granting exclusive marketing rights to such products, as required by Art 70.9 of TRIPS.

The report of the Panel, circulated on 5 September 1997, found that India was in violation of its obligations under Arts 70.8, 70.9 of TRIPS because:

\[\text{it has failed to establish a mechanism that adequately preserves novelty and priority in respect of applications for product patents in respect of pharmaceutical and agricultural chemical inventions during the transitional period to which it is entitled under the Agreement, and to publish and notify adequately information about such a mechanism; and that India has not}\]


\textsuperscript{42} India – Patent Protection for Pharmaceutical and Agricultural Chemical Products, Dispute DS50; see <http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds50_e.htm>. Note also a similar case brought by the United States in 1996 against Pakistan: Pakistan – Patent Protection for Pharmaceutical and Agricultural Chemical Products, DS36; see <http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds36_e.htm>. This dispute was settled by agreement between the parties, as notified to the DSB meeting on 25 February 1997.
complied with its obligations [under] the TRIPS Agreement, because it has failed to establish a system for the grant of exclusive marketing rights. 

India appealed against some aspects of the Panel decision, but the WTO Appellate Body upheld these findings of the Panel, in a report circulated on 19 December 1997. The reports of the Panel and Appellate Body were adopted by the DSB on 16 January 1998.

- **China - Measures Affecting the Protection and Enforcement of IP (2007)**

In April 2007 the United States filed a complaint against China, contending that it failed to protect and enforcement intellectual property rights in accordance with TRIPS. The United States alleged that China’s Copyright Law and customs measures affecting distribution and market access for publications, movies and music did not meet the requirements of Arts 9.1, 59 and 61 of TRIPS. Art 4 of China’s Copyright Law entirely denied copyright protection to works that had not been authorised for publication or dissemination in China, while China’s Customs Regulations permitted goods that had been confiscated by customs authorities to be auctioned after simply removing the trade mark.

A WTO panel was composed in December 2007, after the parties were unable to resolve the dispute through consultations. The Panel’s report, circulated on 26 January 2009, found that the Copyright Law was inconsistent with China’s obligations under Art 5(1) of the Berne Convention, as incorporated by Art 9.1 of TRIPS, and Art 41.1 of TRIPS. The Panel concluded that, to the extent that the Copyright Law and the customs measures are inconsistent with the TRIPS Agreement, they nullify or impair benefits accruing to the United States under that Agreement. It recommended that China should bring its Copyright Law and customs measures into conformity with its obligations under the TRIPS Agreement.

Following adoption of the Panel’s report by the DSB in March 2009, in early 2010 China amended its Customs Regulations and Copyright Law in an effort to comply with the

47 The first sentence of Art 4 of the Chinese Copyright Law stated that “[w]orks the publication and/or dissemination of which are prohibited by law shall not be protected by this Law”.
48 In particular, the first sentence of Art 4 of the Copyright Law.
49 Art 9.1, TRIPS states: “Members shall comply with Articles 1 through 21 of the Berne Convention (1971) and the Appendix thereto.
50 Art 41.1, TRIPS states: “Members shall ensure that enforcement procedures as specified in this Part [Part III] are available under their law so as to permit effective action against any act of infringement of intellectual property rights covered by this Agreement, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements. These procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.”
51 Panel Report, China Measures Affecting the Protection and Enforcement of Intellectual Property Rights, WTDS362/R (26 January 2009), 8.3-8.5. This was only the second time that a TRIPS dispute involving a developing country had resulted in the release of a Panel report.
finding. The amended Art 27 of the Customs Regulations states that “the customs may lawfully auction [the goods] after the infringement features have been eliminated, but for imported goods with counterfeited trade marks, except for special circumstances, such goods shall not be permitted to be traded only by clearing off the trade marks”. The amendment made to Art 4 of the Chinese Copyright Law is, arguably less effective. Although deleting the first sentence of Art 4 which was found to be inconsistent with TRIPS, the amendments insert a new sentence, stating: “The publication and dissemination of works shall be subject to the administration and supervision of the state”.

- India and Brazil – Seizure of Generic Drugs in Transit (2010)

On 11 May 2010, India filed a complaint against the European Union and the Netherlands, complaining about the repeated seizure of generic drugs originating in India while they were transiting through ports and airports in the Netherlands en route to third country destinations. India is a major manufacturer of generic drugs, accounting in 2006 for 70% of generic antiretroviral drugs used in the treatment of HIV/AIDS, compared with 7% from South Africa, 6% from the United Kingdom and 4% from the United States.

The reason for the seizures was alleged patent infringement. India contended that as well as being inconsistent with general obligations of the European Union and the Netherlands under Arts V and X of GATT 1994, the measures taken violated various TRIPS provisions, namely, Art 28 (read with Art 2), Arts 41 and 42 and Art 31 (read with the provisions of the Decision on TRIPS and Public Health (2003)).

A corresponding complaint was filed by Brazil the following day (12 May 2010), complaining of repeated seizures on patent infringement grounds of generic drugs originating in India but transiting through ports and airports in the Netherlands to Brazil and other destinations. Brazil alleged that the actions by the European Union and the Netherlands are inconsistent with their obligations under Arts V and X of GATT 1994, Art XVI:4 of the WTO Agreement and various TRIPS provisions.

Both of these disputes are currently in consultations. Canada, China, Ecuador, Japan and Turkey have joined the consultations in respect of India’s complaint (DS408), while Canada, China, Ecuador, India, Japan and Turkey have joined the consultations on Brazil’s complaint DS409).

B. TRIPS AND DEVELOPING COUNTRIES

2.1 Intellectual Property and Development

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52 WTO, European Union and a Member State – Seizure of generic drugs in transit, Dispute DS408, filed 11 May 2010, at http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds408_e.htm
54 WTO, European Union and a Member State – Seizure of generic drugs in transit, Dispute DS409, filed 12 May 2010, at http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds409_e.htm
Of the WTO’s membership of 155 countries, around two-thirds are developing countries and, of these, 31 fall within the category of least-developed countries as designated by the United Nations. Neither the WTO nor the United Nations define “developed” or “developing”, leaving it to member countries to categorise themselves as they consider appropriate. The United Nations Economic and Social Council’s committee for development policy identifies least-developed countries by applying three criteria: low income; human capital status; and economic vulnerability.

“Development” is a contested term among scholars, organizations and development experts. Nevertheless, it has been acknowledged in many international conventions and forums as one of the most important and pressing challenges facing the international community. In a general sense, the concept is understood to mean improving the lives of people socially and economically. It encapsulates the improvement of individuals’ lives through providing greater education, skills development, income and employment.

The relationship between intellectual property rights and economic development continues to be controversial. Whereas some see development as being promoted through the introduction of intellectual property systems, others question whether this is the case.

According to some theories of development, recognition and enforcement of intellectual property rights is essential to the evolution of states from “under-developed” to “developed”. This view was prevalent during the colonial era among European countries which required their territories in Asia, Africa and Latin America to adopt intellectual property laws to promote their social and economic development.

While debates continue

55 On 17 December 2011, the WTO Ministerial Conference announced that Samoa and Montenegro will accede to the WTO in 2012; see <http://www.wto.org/english/news_e/news11_e/ace_wsm_17dec11_e.htm>
56 See WTO, at <http://www.wto.org/english/thewto_e/whatis_e/tif_e/dev1_e.htm>
57 These include: the United Nations Millennium Summit in 2000, the United Nations Declaration on the Right to Development of 1986, the United Nations Millennium Development Goals of 2001, the São Paulo Consensus of 2004, the Plan of Implementation agreed at the World Summit on Sustainable Development (WSSD), the Declaration of Principles of the first phase of the World Summit on the Information Society (WSIS), the Doha Declaration of 2005, the Programme of Action for the Least Developed Countries (LDCs) for the Decade 2001-2010, the Monterey Consensus, and the Johannesburg Declaration on Sustainable Development.
about the contribution of intellectual property rights to the process of development, the fact is that TRIPS mandates the minimum standards of intellectual property protection and enforcement that are to be recognised by both developed and developing countries. With little scope for deviation from the standards required by TRIPS, the current issue for the international community is how those standards can be adopted in developing and least-developed countries in a manner that promotes their social and economic development. This requires knowledge and use of the flexibilities retained in the TRIPS Agreement to ensure that intellectual property systems are designed to meet their needs as well as the integration of a development agenda into the international intellectual property system.63

2.2 Accommodating TRIPS to Development Needs and Objectives

Following the adoption of TRIPS in 1994, developing countries continued to express concerns about the consequences of its implementation for them. They argued that TRIPS could result in increases in the cost of pharmaceuticals and educational materials, legitimise the “biopiracy” of their genetic resources and traditional knowledge, and hinder the transfer to them of technologies essential to their development.64

Since the beginning of the Doha trade negotiations round in 2001 - styled “the development round” – increased attention has been given to the need to integrate the “development dimension” into international policy making on intellectual property. During the years between the adoption of TRIPS and the commencement of the Doha Round, international attention came to be increasingly focused on the realities of implementation of TRIPS obligations in developing and least-developed countries and the need to achieve a greater coherence between TRIPS requirements and developmental objectives. The 2001 Doha Ministerial Declaration65 highlighted the importance of placing the needs and interests of developing countries “at the heart of the Work Programme” for the trade negotiation round66 and instructed the TRIPS Council to “take fully into account the development dimension” in its activities.67

2.3 Balancing of Interests and General Flexibilities

While TRIPS is binding on all WTO members, in recognition of their different circumstances and stages of development, it contains both general and specific provisions which introduce a degree of flexibility. Article 1.1 of TRIPS states that while all WTO members must give effect to the Agreement, they remain “free to determine the appropriate method of implementing the provisions of [the] Agreement within their own legal system and practice”. Clearly, the flexibilities provided in the Agreement can be utilised by individual WTO member countries to implement their TRIPS obligations in a manner consistent with their own social and economic development strategies.

63 Susan K. Sell, “Everything Old is New Again: The Development Agenda Then and Now” (2011) 3 WIPO Journal 17, 23.
65 WTO, Doha Ministerial Declaration (adopted 14 November 2001), WT/MIN(01)/DEC/W/1, 20 November 2001; at <http://www.wto.org/english/tratop_e/minist_e/min01_e/mindecl_e.htm>
66 Ibid, at para 2
67 Ibid, at para 19
Article 7 of TRIPS, setting out the objectives of the Agreement, draws attention to the balancing of interests that is central to intellectual property systems: recognising and conferring legally enforceable property rights while also fostering ongoing creativity and innovation. This balancing is acknowledged in Art 7 which makes it clear that the protection and enforcement of intellectual property rights should:

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

The special needs of least-developed country WTO members are acknowledged in the TRIPS Preamble, requiring that they be accorded “maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological basis”.68

Article 8 of TRIPS sets out principles guiding the implementation of the Agreement:

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

Article 27.1 requires TRIPS member countries to provide patent protection for “any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application”. However, TRIPS member countries are also afforded a degree of flexibility in determining the scope of patentable inventions in their jurisdiction. Under Art 27.2, TRIPS members may exclude from patentability certain inventions the commercial exploitation of which conflicts with the need to “protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment”. Art 27.3 specifically permits the exclusion from patentability of

- (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
- (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

Article 30 allows TRIPS members to provide for limited exceptions to the rights granted to patent owners, subject to the proviso that “such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the interests of third parties.”

A provision which introduces a significant potential for flexibility is Art 31 which enables any TRIPS member country to enact laws to permit compulsory licensing of patents. Under a compulsory licence, the government permits another party to use the patented product or

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68 Preamble, TRIPS
process without the authorisation of the patent owner, subject to certain conditions. Compulsory licences must be non-exclusive (for example, the patent owner can continue to exercise the patent) and subject to payment of “adequate remuneration” to the patent owner “in the circumstances of each case, taking into account the economic value of the authorisation”. A compulsory licence can only be issued following the failure of attempts to negotiate a voluntary licence with the patent owner on reasonable commercial terms.

2.4 Specific Flexibilities for Developing and Least-Developed Countries

In addition to these general provisions that introduce flexibility into the implementation of TRIPS, it contains specific provisions that address the position of developing and least-developed countries:

2.4.1 Extension of period for compliance with TRIPS

The TRIPS Agreement came into effect on 1 January 1995. While it applies to all WTO member countries, it provided different transition periods for countries to implement its provisions, according to their level of development. Developed countries were given a transition period of 1 year following the entry into force of the WTO Agreement, which meant that they were to fully implement their TRIPS obligations by 1 January 1996. Articles 65 and 66.1 of TRIPS extended the periods within which developing and least-developed countries were to comply with the Agreement. Developing countries and countries undergoing transformation from centrally-planned to a market, free-enterprise economy were given a further four years, until 1 January 2000, to bring their domestic laws into conformity with TRIPS. For least-developed countries, in view of their “special needs and requirements...their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base” the compliance date was initially set as 1 January 2006, although it was open to individual members to request a further extension. In 2005, WTO members approved an extension of the implementation date for least-developed countries to 1 July 2013. In the 2001 Doha Declaration on the TRIPS Agreement and Public Health, least-developed countries were exempted from implementing the obligations under sections 5 and 7 of Part II of TRIPS with respect to pharmaceutical and agrichemical products until 1 January 2016. In December 2011, the eighth WTO Ministerial Conference invited the TRIPS Council to consider a request from least-developed country members for a further extension of the transition period under Art 66.1.

2.4.2 Incentives for technology transfer to least-developed countries

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69 Art 65.1, TRIPS
70 Art 65.2 and 65.3, TRIPS.
71 Art 66.1, TRIPS
72 WTO, Decision on the Extension of the Transition Period under Article 66.1 for Least-Developed Country Members, adopted by the TRIPS Council, on 29 November 2005, IP/C/40; at http://www.wto.org/english/news_e/pres05_e/pr424_e.htm
A frequently expressed concern about the implementation of TRIPS has been that it may result in developing countries having to pay higher prices for imported (sometimes essential) technologies, thereby hindering their own economic and social development. Article 66.2 of TRIPS establishes an obligation on developed countries to provide incentives to enterprises and institutions within their jurisdiction designed to promote and encourage “technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base”. WTO members are not required to carry out the technology transfer themselves but rather, are to provide incentives to their enterprises and institutions to encourage technology to be transferred to least-developed countries.

Concerns that Art 66.2 was not being implemented effectively were raised at the Doha Ministerial Conference in November 2001. In response, the Ministers established a working group to examine the relationship between trade and technology transfer and agreed that the TRIPS Council would put in place a mechanism for ensuring the monitoring and full implementation of the obligations. The mandatory nature of the obligation under Art 66.2 was reaffirmed in 2001 in the Doha Decision on Implementation-Related Issues and Concerns and the Declaration on the TRIPS Agreement and Public Health. In 2003 the TRIPS Council adopted a decision requiring developed country WTO members to report annually on actions taken or planned under Art 66.2. A new detailed report is to be provided every three years, with updates submitted in the intervening years. The 2003 decision details the information to be provided by developed countries about their implementation of Art 66.2:

- an overview of their incentives regime to meet their obligations under Art 66.2;
- identification of specific incentives and the agency making it available;
- eligible enterprises or institutions in the developed WTO member country; and
- any information on the functioning in practice of these incentives, such as the type of technology transferred and the terms of transfer, the mode of technology transfer and any least-developed countries to which technology has been transferred.

The TRIPS Council’s decisions on TRIPS and Public Health in 2003 and 2005 reiterated the commitment to giving effect to Art 66.2 to encourage WTO members to engage in

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75 Art 66.2, TRIPS. For commentary on this provision, see Suerie Moon, Meaningful Technology Transfer to the LDCs: A Proposal for a Monitoring Mechanism for TRIPS Article 66.2, International Centre for Trade and Sustainable Development (ICTSD), Policy Brief No. 9, April 2011, at http://ictsd.org/i/publications/106434/
76 Concerns about technology transfer were again raised by Argentina and Brazil in the 2004 proposal for the establishment of a WIPO Development Agenda which stated that “higher standards of intellectual property protection have failed to foster the transfer of technology through foreign direct investment and licensing”: WIPO, Proposal by Argentina and Brazil for the Establishment of a Development Agenda for WIPO, 27 August 2007, WO/GA/31/11, Annex, p 3, at <http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=31737>
78 WTO, Declaration on the TRIPS Agreement and Public Health (adopted 14 November 2001), WT/MIN(01)/DEC/2, 20 November 2001
technology transfer and capacity building in the pharmaceutical sector to overcome the problems faced by countries lacking pharmaceutical manufacturing capacities.

Nevertheless, concerns continue to be expressed about the effectiveness of Art 66.2. It is contended that Art 66.2 has had little impact and that the reporting system fails to monitor its implementation in a meaningful way. To illustrate, in the ninth annual review of developed country WTO members’ reports on implementation of Art 66.2 in October 2011, the TRIPS Council received reports from only 17 of a total of 69 high income countries and 30 OECD countries.

2.4.3 Provision of technical assistance to developing and least-developed countries

While developing and least-developed countries agreed to implement their intellectual property obligations under TRIPS, it was clear from the time the Agreement was negotiated that many would require technical assistance to do so from developed economies with well-established intellectual property systems. Article 67 of TRIPS acknowledges the need for technical cooperation and assistance, requiring developed country WTO members to provide, on request and upon agreed terms and conditions:

- technical and financial cooperation in favour of developing and least-developed country Members. Such cooperation shall include assistance in the preparation of laws and regulations on the protection and enforcement of intellectual property rights as well as on the prevention of their abuse, and shall include support regarding the establishment or reinforcement of domestic offices and agencies relevant to these matters, including the training of personnel.

The 2005 decision of the TRIPS Council extending the transition period for least-developed countries to 2013 also established a process for providing assistance to least-developed countries to implement TRIPS in their national intellectual property systems. The TRIPS Council called on least-developed countries to provide to the TRIPS Council (by 1 January 2008) as much information as possible on their individual priority needs for technical and financial cooperation in order to assist them to take steps to implement the TRIPS Agreement. Developed countries are to provide technical and financial cooperation in favour of least-developed WTO countries in order to effectively address their identified needs. To assist in this process, the WTO undertook to seek to enhance its cooperation with WIPO and other relevant international organisations.

2.5 Intellectual Property and Public health

An individual’s right to “medical care” to support their health and well-being was recognised as a fundamental right in the Universal Declaration of Human Rights adopted by the United

82 Suerie Moon, Does TRIPS Art. 66.2 Encourage Technology Transfer to LDCs?, p 1, at <http://www.iprsonline.org/New%202009/Policy%20Briefs/policy-brief-2.pdf> p 1
84 Art 67, TRIPS
86 The section is headed “Enhanced technical cooperation for least-developed country members”.
Nations General Assembly in 1948. Before the adoption of TRIPS in 1994, patent protection for pharmaceutical products was not compulsory. More than 50 countries did not grant patents for pharmaceutical product inventions while yet others excluded pharmaceutical processes from patenting. Following the adoption of TRIPS, concerns were raised about the impact of TRIPS patent protection obligations on public health and, specifically, whether patenting requirements have the effect of restricting access to essential medicines and health technologies required for the treatment of diseases such as HIV/AIDS, tuberculosis and malaria.

Under TRIPS, WTO member states must provide patent protection for inventions “in all fields of technology”, including pharmaceutical products and processes. WTO member countries are required (under Art 27.1) to grant patents for:

- any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.

Subject to permitted exceptions, patents are to be available “without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced”.

However, TRIPS provides a degree of flexibility for developing countries in the implementation their obligations regarding protection and enforcement of patents, through a range of general and specific provisions which they can use to design patent systems that support their public health needs and objectives.

Certain inventions can be excluded from patentability entirely. A WTO member may exclude inventions from patentability if their commercial exploitation should be prevented to protect “ordre public or morality, including to protection animal or plant life or health or to avoid serious prejudice to the environment”. Further, a WTO member may exclude certain kinds of inventions from the scope of the patent system in their jurisdiction: “diagnostic, therapeutic and surgical methods for the treatment of humans or animals”; and “plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes”.

Another important ground of flexibility is found in Art 31 which allows WTO members to introduce compulsory licensing provisions into their laws, so that the government or a third party is permitted to use the patent without the authorisation of the patent owner. Article 31 does not specify or limit the reasons that can be used to justify the issuance of a compulsory licence; rather, it sets out a range of conditions must be satisfied (for example, use under a compulsory licence is to be non-exclusive; the person seeking the licence must have first attempted, without success, to obtain a voluntary licence from the rights owner on reasonable commercial terms; and adequate remuneration is to be paid to the right holder, taking into

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89 As provided in Arts 65.4, 70.8 and 27.3, TRIPS

90 Art 27.2, TRIPS

91 Art 27.3, TRIPS

92 Art 31, TRIPS
account the economic value of the authorisation). A limiting factor on the operation of the compulsory licensing provisions was the requirement in Art 31(f) of TRIPS that use of the patented technology under a compulsory licence must be “predominantly for the supply of the domestic market of the [WTO] Member authorizing such use”.  

While it was open to developing and least-developed countries to rely on the flexibility provided by these provisions to ensure access to essential medicines, many countries would not do so because of uncertainty about how they would be interpreted. Clarification of the interpretation and intention of these provisions came at the Doha Ministerial Conference, in the form of the Doha Ministerial Declaration (“Ministerial Declaration”) and the Doha Declaration on TRIPS and Public Health (“Doha Declaration”), both of which were made on 14 November 2001.

The Ministerial Declaration recognised the importance of supporting public health in developing countries, stating:

> We stress the importance we attach to [the] implementation and interpretation of the Agreement on Trade-Related Aspects of IP Rights (TRIPS Agreement) in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines and, in this connection, are adopting a separate declaration.

The Doha Declaration acknowledged the public health problems affecting many developing and least-developed countries and that TRIPS was part of the “wider national and international action to address these problems”. It recognised the importance of intellectual property for the development of new medicines but also that patenting may affect prices of pharmaceuticals. The Doha Declaration accepted that TRIPS “does not, and should not, prevent [WTO] members from taking measures to protect public health” and affirmed their right to implement the TRIPS obligations in a manner consistent with the objective of protecting public health and promoting access to medicines. The right of WTO members to use – to the maximum extent - the flexibilities provided in TRIPS, for this purpose, was expressly reaffirmed. Attention was drawn to the measures in TRIPS that provide flexibility for WTO members in implementing their obligations: the right to grant

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93 Art 31(f), TRIPS  
97 Ministerial Declaration, para 17  
98 Doha Declaration, paras 1 and 2  
99 Doha Declaration, para 3  
100 Doha Declaration, para 4  
101 Ibid. Following the Doha Declaration, in 2003 Malaysia issued a “government use” licence for the importation of generic antiretrovirals (ARVs) from India. In 2007, Rwanda announced that it was importing generic HIV medicines from a Canadian generic pharmaceutical manufacturer; a compulsory licence was issued in Canada under the Canadian Access to Medicines regime authorising the export of the pharmaceutical. In 2004, Mozambique, Zambia and Indonesia issued compulsory licences for local production of ARVs; in 2007, Brazil issued a compulsory licence for the manufacture of efavirenz, an important ARV. In 2006-2008 Thailand issued compulsory licences for a range of pharmaceuticals used to treat various conditions, including HIV/AIDS, heart disease, breast cancer, lung cancer and ovarian cancer.
compulsory licences and the freedom to determine the basis on which such licences are granted; the right to declare a national emergency, including in circumstances of public health crises; and the exhaustion of intellectual property rights.\(^\text{102}\)

The difficulties flowing from the limited applicability of the compulsory licensing provisions in Art 31 was recognised, particularly the requirement in Art 31(f) that use under a compulsory licence must be predominantly for the supply of the domestic market in the country where the use is authorised. The restriction to domestic use meant that pharmaceuticals could not be manufactured under a compulsory licence specifically for export to another country where they would be used. However, developing and least-developed countries typically have insufficient or no capacity to manufacture drugs such as the antiretroviral treatments for HIV/AIDS, nor can they afford to pay market prices for them.

Paragraph 6 of the Doha Declaration acknowledged that many WTO member countries would be unable to make use of the compulsory licensing flexibility under Art 31 in its existing form to obtain access to affordable medicines, and directed the TRIPS Council to “find an expeditious solution to the problem” and report back by the end of 2002.

At the WTO Ministerial Conference in Cancun Mexico, on 30 August 2003, the TRIPS Council decided to give effect to paragraph 6 of the Doha Declaration by permitting countries that lack a domestic capacity to manufacture pharmaceuticals to legitimately import cheaper generic products from the countries where they are manufactured. The WTO Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health\(^\text{103}\) (known as the “2003 waiver” or the “Paragraph 6 solution”) requires WTO members wishing to take advantage of the waivers permitted under the Declaration to notify the Council for TRIPS of their intention to use the system as an importer or to grant a compulsory licence to export pharmaceutical products to countries that cannot produce them for themselves. An importing country’s notification must name the product and expected quantity required and confirm that the country (unless it is a least-developed country) has insufficient or no manufacturing capacities in the pharmaceutical sector for the product in question. Where a WTO member country is granting a compulsory licence for export, it must notify the TRIPS Council, providing details of the licensee, the product for which the licence has been granted, the quantity of the product to be manufactured under the licence, the country to which the product is to be supplied and the duration of the licence.

At the December 2005 meeting of the WTO General Council, the 2003 waiver was formalised as a Protocol\(^\text{104}\) which will, when it enters into force, amend TRIPS by inserting a new Art 31bis (to follow Art 31) and an Annex (following Art 73). Under Art 31bis, WTO members may grant compulsory licences to manufacturers authorising them to produce patented pharmaceuticals for export to “eligible importing member”, subject to the detailed conditions set out in paragraph 2 of the Annex: An “eligible importing member” is defined as any least-developed country or any other WTO member that has notified the TRIPS Council of its intention to use the system in Art 31bis and the Annex as an importer.\(^\text{105}\) The Protocol will take effect as a formal amendment to TRIPS upon acceptance by two-thirds of

\(^\text{102}\) Doha Declaration, para 5
\(^\text{105}\) Ibid, Annex, paragraph 1
WTO members. However, as it has taken longer than initially foreseen for sufficient countries to accept the Protocol (42 as of the end of 2011), the period for acceptances has been progressively extended until 31 December 2013 or such later date as is decided by the Ministerial Conference.\footnote{WTO, TRIPS Council, Amendment of the TRIPS Agreement – Proposal for a Decision on a Third Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement, IP/C/58, 2 November 2011, at <http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm>.


When the two-thirds acceptance threshold is reached, the amendment will take effect in those members that have accepted it and replace the 2003 waiver; for other countries, the 2003 waiver will continue to apply until they accept the amendment.

C. WIPO, INTELLECTUAL PROPERTY AND DEVELOPMENT

3. WIPO and Development


109 See WIPO at http://www.wipo.int/members/en/ Vanuatu becomes the 185\textsuperscript{th} member of WIPO upon its accession in March 2012.


Since its formation in 1974, WIPO has recognised its obligation toward developing countries, stating in 1975 that:

one of the main objectives of WIPO is to assist developing countries in their development. WIPO assists developing countries in promoting their industrialization, their commerce and their cultural, scientific and technological development through the modernization of their industrial property and copyright systems and in meeting some of their needs in scientific documentation and the transfer of technology and technical know-how.\footnote{Christopher May, ‘The Pre-History and Establishment of the WIPO’ (2009) (1) The WIPO Journal 20 at p 25, see <http://www.wipo.int/export/sites/www/about-wipo/en/wipo_journal/pdf/wipo_journal_1_1.pdf>; see also WIPO, WIPO’s Legal and Technical Assistance to Developing Countries for the Implications of the TRIPS Agreement <http://www.wipo.int/edocs/mdocs/mdocs/en/pcipd_1/pcipd_1_3.pdf>.}

Indeed, WIPO’s role in “promoting and facilitating the transfer of technology to developing countries” to accelerate their social and economic development is expressly recognised in the Agreement between the United Nations and the World Intellectual Property Organisation
From early on, WIPO distinguished itself as an institution crucial to the coordinated efforts, led by the United Nations, to address the problems encountered by developing countries and to integrate them into the international economic system. The WIPO Secretariat actively promoted a pro-intellectual property discourse by educating governments and stakeholders in developing countries about intellectual property and its importance for development and creativity. It emphasized the importance of stronger intellectual property protection and promoted an intellectual property culture to support modernisation and innovation, as well as to encourage flows of foreign direct investment and technology transfer to developing countries. The clear message provided to developing countries by WIPO was that participation in the international intellectual property system would lead to development, while failure to participate risked jeopardising their advancement.

The TRIPS preamble calls for “a mutually supportive relationship between the WTO and the World Intellectual Property Organisation .... as well as other relevant international organisations”. In 1995 the TRIPS Council and WIPO signed a Cooperation Agreement under which the WTO and WIPO undertook to provide legal-technical assistance and technical cooperation to developing countries to enable them to comply with their obligations under TRIPS. Technical assistance may include preparation of their intellectual property laws, development of administrative mechanisms and training of government officials in the management, use and enforcement of intellectual property systems.

3.2 Towards the WIPO Development Agenda

Ongoing efforts by developing countries to integrate development with the global trade and intellectual property systems resulted, in 2004, to a group of developing countries presenting...
a comprehensive proposal to establish a WIPO Development Agenda. The proposal submitted to the WIPO General Assembly on 4 October 2004 by delegates from Brazil and Argentina (and subsequently supported by another 12 countries), requested WIPO to adopt a development-oriented approach to intellectual property and to reconsider its work in relation to developing countries. It stated that WIPO’s role is not limited to “the promotion of intellectual property protection”. Rather, as part of the United Nations system, WIPO’s activities must be guided by the United Nations’ broad development goals – notably the Millennium Development Goals – and such goals should be fully incorporated into WIPO’s activities.

The proposal asserted:

Intellectual property protection is intended as an instrument to promote technological innovation, as well as the transfer and dissemination of technology. Intellectual property protection cannot be seen as an end in itself, nor can the harmonization of intellectual property laws leading to higher protection standards in all countries, irrespective of their levels of development.

The role of intellectual property and its impact on development must be carefully assessed on a case-by-case basis. IP protection is a policy instrument the operation of which may, in actual practice, produce benefits as well as costs, which may vary in accordance with a country’s level of development. Action is therefore needed to ensure, in all countries, that the costs do not outweigh the benefits of IP protection.

Referring to the 1995 WIPO-WTO Cooperation Agreement, the proposal called for technical cooperation relating to intellectual property to be expanded and qualitatively improved. It urged WIPO to provide technical legislative assistance to ensure that national intellectual property laws are tailored to meet each country’s level of development and are responsive to the specific needs and problems of individual societies. Further, it called for technical assistance to “be directed towards assisting developing countries to make full use of the flexibilities in existing intellectual property agreements, in particular to promote important public policy objectives.”

The proposal concluded:

120 For an account of the historical background to these developments, including discussion of the demands in the 1970s by newly independent former colonies for a New International Economic Order (NIEO), see Susan K. Sell, ‘Everything Old is New Again: The Development Agenda Then and Now’ (2011) 3 WIPO Journal 17.
122 Cuba, Dominican Republic, Ecuador, South Africa, Egypt, Kenya, Iran, Peru, Sierra Leone, Tanzania, and Venezuela.
125 Ibid
127 Ibid, at pp 4 - 5
A vision that promotes the absolute benefits of intellectual property protection without acknowledging public policy concerns undermines the very credibility of the IP system. Integrating the development dimension into the IP system and WIPO’s activities, on the other hand, will strengthen the credibility of the IP system and encourage its wider acceptance as an important tool for the promotion of innovation, creativity and development.\textsuperscript{128}

In 2007, WIPO member States adopted a historic decision to establish a WIPO Development Agenda to ensure that intellectual property rights are not considered in isolation, but within a broader framework of economic, social and public interests.\textsuperscript{129} In establishing the Development Agenda, the WIPO General Assembly adopted 45 recommendations\textsuperscript{130} to ensure that development considerations are integral to WIPO’s work and established a Committee on Development and Intellectual Property (CDIP).\textsuperscript{131} The role of the CDIP is to develop a work program for implementation of the 45 adopted recommendations; monitor, assess, discuss and report on their implementation; and discuss intellectual property and development-related issues.\textsuperscript{132} The CDIP was first convened in Geneva, Switzerland, in March 2008 and as of the end of 2011 had met eight times. The ninth meeting is scheduled for May 2012.\textsuperscript{133}

D. CONCLUSION

While intellectual property systems may promote foreign direct investment, technology transfer, domestic innovation, and research and development, the introduction of intellectual property laws will not, in itself, bring about economic growth. Achievement of socio-economic development objectives requires the implementation of broad-ranging strategies that address matters such as the need for efficient and effective governance, political stability, human capital, infrastructure and the rule of law.\textsuperscript{134} Nevertheless, intellectual property

\textsuperscript{129} See generally WIPO at http://www.wipo.int/ip-development/en/agenda/
\textsuperscript{130} The 45 recommendations adopted (from a total of 111 proposed) fall into six clusters: (a) technical assistance and capacity building; (b) norm-setting, flexibilities, public policy and public domain; (c) technology transfer, information and communication technologies and access to knowledge; (d) assessment, Evaluation and impact studies; (e) institutional matters including mandate and governance; and (f) other issues; see further, WIPO at <http://www.wipo.int/ip-development/en/agenda/recommendations.html>
\textsuperscript{131} For further on the activities of the Committee on Development and Intellectual Property (CDIP), see http://www.wipo.int/ip-development/en/agenda/cdip/
\textsuperscript{132} The CDIP’s mandate, as established by the General Assembly, is set out in the General Report, document A/43/16, 12 November 2007, at p 136; see <http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=88952>
\textsuperscript{133} For further information on the CDIP’s activities, see <http://www.wipo.int/ip-development/en/agenda/cdip/>
protection is an important part of an economic development strategy and bringing domestic intellectual property laws into alignment with the minimum standards described in TRIPS is considered essential if countries are to “reach the frontiers of [the knowledge economy], [and] convert their economies’ intangible, nonrivalrous outputs into tradeable knowledge goods”.  

During the last decade, it has increasingly been recognised that the implementation of intellectual property systems in developing and least-developed countries must occur in the context of their socio-economic circumstances and in a manner that is consistent with their broader development objectives and initiatives. By understanding and effectively using the general and specific flexibilities, limitations and exceptions that are integral to TRIPS, developing and least-developed countries can design intellectual property systems that both satisfy their TRIPS obligations and achieve an appropriate balance between the interests of innovators and users. Specifically, TRIPS flexibilities can – and should be - used to ensure access to pharmaceuticals and other technologies required for public health. As Blakeney and Mengistie observe:

A clear IPR [intellectual property rights] policy and strategy ... coupled with a programme of building the necessary implementing capacity, will enable the exploitation of any flexibilities in the TRIPS and the use of IPRs as a tool for development.136

Existing flexibilities and safeguards should be preserved as far as possible in new multilateral, regional and bilateral arrangements that build upon the TRIPS minimum standards. A cautious approach needs to be adopted towards the acceptance of new TRIPS-plus provisions which negate or dilute existing flexibilities (for example, the elimination or reduction of transitional periods, extension of patent terms and restrictions on compulsory licensing) which may have direct impact on public health, pharmaceutical production and access to medicines.137 Moreover, as shown by the 2005 proposals to amend TRIPS to permit measures to be taken based on public health considerations and the adoption of the WIPO Development Agenda in 2007, the relationship between the operation of intellectual property systems and development must be addressed in a systemic way by the international community, to ensure that recognition and enforcement of intellectual property rights does in fact contribute to the advancement of developing and least-developed countries.138
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Conference papers

United Nations, WTO, WIPO and other Documents


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