

United Nations Conference on Trade and Development

# **Intellectual Property in the World Trade Organization**

**Turning it into Developing  
Countries' Real Property**



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## Preface

As the focal point of the United Nations for the integrated treatment of trade and development and interrelated issues, and in accordance with the Accra Accord adopted at the twelfth session of UNCTAD in 2008, the UNCTAD secretariat supports member States in assuring development gains from international trade, the trading system and trade negotiations, with a view to their beneficial and fuller integration into the world economy and to the achievement of the United Nations Millennium Development Goals (MDGs). Through intergovernmental deliberations and consensus-building, policy research and analysis, and technical cooperation and capacity-building support, UNCTAD's work on trade negotiations and commercial diplomacy aims at enhancing human, institutional and regulatory capacities of developing countries to analyze, formulate and implement appropriate trade policies and strategies in multilateral, interregional and regional trade negotiations.

This paper is part of a series on "Assuring Development Gains from the International Trading System and Trade Negotiations". The targeted readership is government officials involved in trade negotiations, trade and trade-related policymakers, and other stakeholders involved in trade negotiations and policymaking, including non-governmental organizations (NGOs), private sector representatives and the research community.

The objective of the series is to improve understanding and appreciation of key and emerging trade policy and negotiating issues facing developing countries in international trade, the trading system and trade negotiations. The series seeks to do so by providing a balanced, objective and sound analysis of technical issues involved, drawing implications for development and poverty reduction objectives, and assessing policy options and approaches to international trade negotiations in goods, services and trade-related issues. It also seeks to contribute to the international policy debate on innovative ideas and practical solutions to realize a development dimension for the international trading system with a view to the achievement of the Millennium Development Goals. Authors are invited to express their personal opinions and the papers do not necessarily reflect the views of the UNCTAD secretariat.

The series is produced by a team led by Mina Mashayekhi, Head, Trade Negotiations and Commercial Diplomacy Branch, DITC.

## **Abstract**

The paper examines the development implications of the World Trade Organization (WTO) Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) and aims to offer suggestions on how to reduce the agreement's development deficit and increase its development friendliness. The paper provides a historic overview of the TRIPS negotiations, the agreement itself and the development deficits therein. It also presents the broader context surrounding intellectual property (IP) issues, namely, on the one hand, the increasing trend towards higher IP standards and on the other hand, the growing insight on the need to rebalance existing IP rules. It also analyses selected aspects of the TRIPS Agreement, highlighting their development implications.

## **Acknowledgements**

The paper was prepared by Mohan Kumar, who is currently Deputy Chief of Mission, the Embassy of India in Paris. With over 28 years of experience in India's Foreign Service, he was India's lead negotiator on intellectual property rights-related issues during the Uruguay Round and in a run-up to the launching of the Doha Round in 2001. He played an active role in the negotiations that led to the adoption of the Declaration on TRIPS and Public Health. The author is grateful to Lakshmi Puri, Mina Mashayekhi, Dimo Calovski, Sophia Twarog, Christoph Spenneman and Michael Adam for comments. Updating was done by Rajan Dhanjee and Elisabeth Tuerk.

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# I. Introduction

While technology has become the most important determinant of economic development, the technological gap between developed and developing countries is widening. Protecting intellectual property (IP) can be one means of promoting and encouraging technological development and innovation, thereby benefiting the public at large through the activities of inventors and creators. However, so far, understanding about the extent and manner in which the current IP system truly promotes innovation is still limited. In fact, protecting IP can also have important costs, including for (a) public health; (b) food security and agriculture; (c) biodiversity, traditional knowledge (TK) and folklore; (d) access to educational, technical and scientific information; and, more broadly, (e) possible costs resulting from the economic effects of creating a monopoly on knowledge. These costs can constitute impediments to the achievement of the Millennium Development Goals (MDGs), with public health and the elimination of poverty as prime goals amongst them.

In light of today's technological advances, intellectual property rights (IPRs) regimes for technology- and research-intensive sectors – e.g. information and computer technologies (ICTs) – may also have wider implications and are confronted with an ever-changing environment. For example, ICTs have contributed to democratizing technologies with important developments taking place relating to free and open-source software (FOSS), which has become a key component of the global technological ecosystem, and the current debate on information technology and development policy.<sup>1</sup>

Consideration would also need to be given to the interface between intellectual property rights (IPRs) and competition policy, which in most legal systems, is somewhat complex. Competition rules aim at ensuring free competition and may thus help to control abusive exercise of IPRs, which may give rise to – or reinforce – monopoly situations.

The costs (and benefits) of IP vary considerably between countries, particularly depending on the level of (technological) development of the economy in question. History reveals that countries have carefully managed their IP systems in light of their particular developmental needs, as they arose over time. Economies in East Asia, for example, have strategically used weaker forms of IP protection, thereby helping local firms in early stages to build technological capabilities or allowing reverse engineering and imitation. Developed countries have shown similar patterns of behaviour in the process of their industrial and economic development. For example, numerous countries had – at times – exempted various kinds of invention in certain sectors of industry from patent protection. Major industrial countries such as Italy, Japan and Switzerland serve as examples: they adopted pharmaceuticals patent protection only when their per capita income had reached about \$20,000.<sup>2</sup> Finally, for some countries, notably those at a very low level of technological and economic development, the protection of IPRs (including abiding by international rules on protection) may not generate any positive implications.

These differences suggest that there is need for flexibility allowing each country to design the IP system that best suits its particular developmental needs, and to carefully weigh the costs and benefits of IPRs in each specific circumstance.

In sum, the challenge is to identify the optimum level of IPRs protection, where IPRs can make a maximum contribution to spurring innovation, while avoiding that excessive

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<sup>1</sup> UNCTAD (2004). Free and open source software: policy and development implications. Background paper by the UNCTAD secretariat. TD/B/COM.3/EM.21/2, 17 August.

<sup>2</sup> Birdsall, Rodrik and Subramanian (2005). How to help poor countries. *Foreign Affairs*. July/August.

protection of IPRs has the opposite consequence, effectively inhibiting, rather than spurring innovation. Similar to other areas of trade policy, a proper assessment – including risk assessment – analysing the likely implications of adopting a certain policy choice can help address this challenge.

Properly addressing this challenge also implies that countries have the ability to make such choices, and are not unduly constrained by international rules mandating specific policy directions. As eloquently expressed by the international community in the 2004 São Paulo Consensus,<sup>3</sup> “it is for each Government to evaluate the trade-off between the benefits of accepting international rules and commitments and the constraints posed by the loss of policy space. It is particularly important for developing countries, bearing in mind developmental goals and objectives, that all countries take into account the need for appropriate balance between national policy space and international disciplines and commitments.” The challenge for the international community and for each country is to determine the proper balance between, on the one hand, the optimum national policy space required for measures aimed at promoting technological and productive capacities and at using technology for public interest (such as meeting universal access to health care, medicines, and education), and international commitments embodied in TRIPS and other multilateral and regional agreements.

Similarly, there is need to ensure that international rule-making – be it in the context of trade, investment or IPR/ technology agreements at the multilateral, regional or bilateral levels – does not foreclose the necessary flexibility for implementing policies according to each country’s developmental priorities and conditions. Keeping space for a country’s development policies is also a key component of a successful strategy towards achieving the MDGs. While this is an issue important for all of the world community, it is maybe most relevant in the context of LDCs, as well as for certain developing countries.

In addition, flexibility for policy choices has to be complemented with effective transfer and dissemination of technology at fair and reasonable cost to developing countries. This could be *one* of the key elements of a coherent strategy for promoting national and regional systems of innovation, aimed at accelerating the pace of economic and social development. In that context, it is important to recall that IPRs alone cannot deliver development. Rather, IPRs have to be part of a more coherent, broader strategy towards development.

To date, for many countries, it remains a challenge to design such a coherent strategy. Most importantly, this is because the relationship between IPRs, innovation, economic growth and development is complex, dependent on the particular circumstances. As the understanding about linkages between IPRs, innovation, economic growth and development remains inadequate, there is an urgent need for research on the developmental aspects of IPRs protection, as well as a careful assessment of each country’s situation.

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<sup>3</sup> The São Paulo Consensus emerged from the Eleventh UNCTAD Conference, held in São Paulo from 13-18 June 2004. See UNCTAD (2004). São Paulo Consensus. TD/410. 25 June. Available at [www.unctad.org](http://www.unctad.org).



### Box 1. The UNCTAD-XI São Paulo Consensus

The ‘São Paulo Consensus’ is, in several respects, a seminal declaration full of potential implications for the international trading system. It offers a comprehensive analysis of the complex interface between trade and development in the midst of forces unleashed by globalization. More crucially, it offers both a “policy analysis” and a “policy response” aimed at assuring development gains from the international trading system and trade negotiations.

The document’s most important reference to IPRs is contained in paragraph 101: “UNCTAD should undertake analysis, including at the regional level, of the development dimension of intellectual property and trade-related aspects of intellectual property rights (TRIPS), including improvements in the transfer of technology to developing countries, the development dimensions and implications of the establishment and enforcement of intellectual property rights, as well as protection of traditional knowledge, genetic resources and folklore and fair and equitable sharing, without prejudice to the work undertaken in other fora.”

*Source:* UNCTAD, based on São Paulo Consensus.

The TRIPS Agreement has been a major step in international rule-making as regards the protection of IPRs. It sets minimum standards for the protection of IPRs, touching on many different issues, including those related to technology transfer and innovation, to public health or to biodiversity-related issues. While the TRIPS Agreement prescribes certain basic standards, it also grants certain flexibilities, e.g. as regards the criteria of patentability, the so-called “second uses”, the patentability of plants and animals, and more broadly as regards the phased application of the agreement.

There are, however, concerns, mainly related to the limited and – in part arbitrary – nature of these flexibilities. Apart from least developed country (LDC)-specific rules, the current, stringent timelines for full application of the agreement do not allow that the date of obligatory TRIPS compliance is dependent upon and sensitive to a country’s level of development. This appears contrary to the above notion of flexibility in terms of applying IP protection standards that beneficially correspond to the level of technological and economic development of a country. Unlike industrialized countries, which had adopted certain IP protection standards at a relatively advanced stage of economic development, TRIPS obliges developing countries to adopt pharmaceutical patents at income levels of \$500 per capita for the poorest and \$2,000 to \$4,000 for the middle-income countries. As argued in a 2005 essay by Birdsall, Rodrik and Subramanian, “forcing developing countries to abide by TRIPS is about 50 to 100 years premature”.<sup>4</sup>

The stringent timelines raise even more questions, given that today there is still no clear understanding about which of the IP protection standards is appropriate for the various levels of development countries are experiencing. Similarly, there are concerns that bilateral and regional rule-making is undermining the very flexibilities the TRIPS Agreement might grant. Thus, the challenge is to determine ways and means to ensure that development benefits will flow from this multifaceted framework of rules and policies.

This paper aims to assist those facing this challenge. It aims to examine the development implications of the World Trade Organization (WTO) TRIPS Agreement and to offer suggestions on how to reduce the agreement’s development deficit and increase its

<sup>4</sup> Birdsall, Rodrik and Subramanian (2005). How to help poor countries. *Foreign Affairs* July/August.

development friendliness. In so doing, it also contributes to an implementation of the São Paulo Consensus. The paper combines these objectives with the goal of offering an easy reading introduction into the TRIPS Agreement. Along these lines, chapter I provides a short, historic overview of the TRIPS negotiations, the agreement itself and the development deficits therein. Chapter II places today's TRIPS Agreement into its broader context, namely, on the one hand, the increasing trend towards higher IP standards and on the other hand, the growing insight on the need to rebalance existing IP rules. Chapter III, the main part of the paper, reviews selected aspects of the TRIPS Agreement, highlighting the development implications of the rules contained therein. Finally, chapter IV offers some concluding remarks.

## II. History and its implications for the TRIPS Agreement's development deficit

### 1. History and key features of the WTO TRIPS Agreement

In international trade negotiations, the mandate of what is to be negotiated is of great importance to the eventual outcome of any such negotiations. The case of the Punta del Este mandate<sup>5</sup>, which led to the WTO TRIPS Agreement, provides an interesting example. Looking back, the Punta del Este mandate makes interesting reading: it refers to negotiations aiming to clarify General Agreement on Tariffs and Trade (GATT) provisions and to the elaboration, as appropriate, of new rules and disciplines. More specifically, the mandate talks of negotiations aiming to develop a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods. Thus, many developing country negotiators believed (rather naively, in hindsight) that the goal of the mandate consisted essentially of establishing a multilateral framework dealing with international trade in counterfeit goods.

Ultimately, however, this mandate was interpreted and operationalized by the more influential developed countries (led by the United States), resulting in a full-fledged agreement on intellectual property rights dealing with standards and disciplines.<sup>6</sup> Suffice it to say that the resultant TRIPS Agreement was so comprehensive as to render unnecessary a multilateral framework of rules and disciplines dealing with international trade in counterfeit goods – something that was explicitly mentioned as a central aspect of the Punta del Este mandate on the subject.

What can developing countries learn from this experience? First, the particular language in the negotiating mandate is critical to the outcome. Almost anything in the mandate can be used by a group of countries to pursue their own trade agenda. Second, and as a consequence, developing countries must pay every attention and actively engage in negotiations over the wording of the mandate. Because TRIPS was not the focus of attention in Punta del Este in 1986 (and ironically enough, “services” was), the language in the mandate slipped by without much scrutiny.<sup>7</sup> A third lesson to be learnt relates to the development content of the mandate. As there was not much input from developing countries in this regard, the Punta del Este TRIPS mandate contains virtually no mention of issues such as development, public health and transfer of technology. This was to cost the developing countries dear, as can be seen when looking at the key features of the TRIPS Agreement. This reveals certain deficiencies, both in terms of regaining sufficient policy space and in terms of negotiating a quid pro quo for surrendering policy space.<sup>8</sup>

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<sup>5</sup> See Ministerial Declaration of the GATT contracting parties launching the Uruguay Round in Punta del Este in 1986.

<sup>6</sup> For a thorough description of the Uruguay Round Negotiations leading to the TRIPS Agreement, including the dynamics between developed and developing countries, see Zutshi, B.K. (1998). *Bringing TRIPS into the Multilateral Trading System. The Uruguay Round and Beyond, Essays in Honour of Arthur Dunkel*, Bhagwati and Hirsch Ed., New York and Geneva; Adede AO (2001). The political economy of the TRIPS Agreement: origins and history of negotiations. Paper prepared for the Multi-Stakeholders Dialogue at the Aberdare Country Club in Kenya, 30-31 July; and Bronckers M (1994). The impact of TRIPS: intellectual property protection in developing countries. *31 Common Market Law Review*, 1246.

<sup>7</sup> Retroactively, developing countries should have questioned the meaning of “clarification of GATT provisions and elaboration of new rules and disciplines”.

<sup>8</sup> For example, the TRIPS Agreement only contains best endeavour provisions on training of trainers and support for innovation and infrastructure, instead of mandatory obligations to that effect.

**Box 2. The WTO TRIPS Agreement – key features**

What the TRIPS Agreement does, at the most basic level, is to oblige all WTO members to extend the fundamental principles governing international trade, namely, National Treatment (article 3) and MFN (Most Favoured Nation) Treatment (article 4) to IPRs. According to the national treatment principle, nationals of any country are to be treated in the same way as (e.g. not less favourably than) nationals of the country where protection is granted (with a few exceptions). Similarly, according to the MFN principle, a country has the obligation to extend to any WTO member the advantages it grants to any other WTO members (again with some exceptions).

The TRIPS Agreement establishes obligations for a series of IPRs. As regards copyrights, it establishes a minimum term of protection for literary and artistic works of 50 years (from publication or from creation).<sup>9</sup> Regarding trademarks, the agreement prescribes a minimum term of protection and sets out (in some detail) what is a protectable subject matter. The same goes for industrial designs. On integrated circuits, the agreement essentially prescribes compliance with the basic obligations of the Washington Treaty.

Geographical indications<sup>10</sup> are a novel feature in the TRIPS Agreement and, again, minimum standards of protection are established. Patents were probably the most controversial of all subjects and consumed the maximum time in the negotiations. While the agreement establishes criteria for patentability (e.g. novelty, inventive step and industrial application), it does not contain any definition of these terms, meaning that the standard for these criteria is left for each individual member to decide. Other key issues included (a) what are patentable subject matters and what can be excluded from patentability; (b) the issue of product versus process patents; and (c) compulsory licence (use without the authorization of the patent rights holder). All of these aspects have key developmental implications.

The TRIPS Agreement is also the only WTO agreement that contains specific provisions relating to “enforcement of IPRs”, including details about civil and administrative procedures and remedies. One may question whether this negates the principle contained in article 1 of the TRIPS Agreement which states, “Members shall be free to determine the appropriate method of implementing the provisions of this Agreement”. There are also general provisions relating to amendment and reservations in the TRIPS Agreement that are unique to it and are not seen in other WTO agreements.

Finally, note has to be taken of articles 8 and 9 of TRIPS, which set out objectives and principles of the agreement. Both of these provisions are of key developmental importance.<sup>11</sup>

*Source:* UNCTAD, based on the TRIPS Agreement.

In addition to the mandate, the negotiations resulting in the TRIPS Agreement have some characteristics which allow for important lessons to be learnt. First, for a majority of developing countries (leaving aside a handful) the technical expertise necessary to handle the negotiations was simply not available. Second, and perhaps flowing from the first, the developing countries were reactive in their approach, rather than proactively setting the agenda. In sum, similar to several other areas of Uruguay Round Negotiations, the extent of developing country participation in this particular area was far from optimal, leading to concern that the outcome of the negotiations was one-sided.

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<sup>9</sup> Enforcement is strengthened through an obligation to institute criminal proceedings and prescribing penalties against copyright piracy on a commercial scale.

<sup>10</sup> For an explanation on geographical indications, please see section IV.5 of this paper.

<sup>11</sup> For further details regarding articles 8 and 9 of the TRIPS, Agreement please see section IV.2 of this paper.

At the time of its conclusion, the WTO TRIPS Agreement was the most far-reaching international treaty ever negotiated in the area of IPRs. The fact that it was embodied in WTO, rather than in the World Intellectual Property Organization (WIPO), makes it an agreement with binding commitments and obligations. Indeed, the possibility to resort to WTO's integrated and binding system for the settlement of disputes (permitting cross-retaliation in trade in goods and services) was the main reason why the developed countries (led by the United States) wanted IPRs to come under the purview of WTO. In terms of substance, the TRIPS Agreement establishes minimum and universal standards (relating to patents, copyrights, trademarks, industrial designs, geographical indications, integrated circuits and undisclosed information (trade secrets)), many of which are linked to additional obligations emanating from the Paris, Berne, Rome and Washington Conventions in their respective fields.

The fact that obligations are defined with regard to other international treaties, which often did not comprise the same membership as the WTO, is an interesting feature of the TRIPS Agreement. Accordingly, a country may or may not be party to the Paris Convention for the protection of Intellectual Property (1967) or the Berne Convention for the Protection of Literary and Artistic Works (1971), but countries that became members of WTO automatically were bound by the TRIPS Agreement and therefore by the provisions of the Paris and the Berne Conventions as embodied in TRIPS. Since a number of developing countries were not party to all the Conventions of IPRs, the result of the TRIPS Agreement was that they had to amend their legislation to bring themselves into conformity with the respective obligations emanating from other IP treaties, embodied in WTO. Importantly, the standards adopted in the WTO TRIPS Agreement mirrored those prevalent in the developed countries such as the United States. Therefore, even though the standards prescribed in the TRIPS Agreement are "minimum", they may nevertheless be quite high for the countries concerned. Thus, the TRIPS Agreement is quite rigorous in prescribing, for the first time, certain common basic standards for a broad array of countries.

Developing countries' agreement to TRIPS has to be placed in the context of the overall dynamics at the end of the Uruguay Round, when developing countries had hoped to achieve a balance between gains arising from bringing agriculture into the remit of WTO and difficulties arising from other areas, notably services and intellectual property rights. Subsequently, however, numerous studies pointed to the gains for developed and costs for developing countries. This induced developing countries to direct their efforts towards "rebalancing" the Uruguay Round package, including through the so-called "implementation issues".

## **2. The TRIPS Agreement and development deficits**

Many observers and commentators (in both developing and developed countries) consider the TRIPS Agreement to be unbalanced, exhibiting certain "development deficits".<sup>12</sup> There are several aspects of how these deficits manifest themselves. For example, the WTO TRIPS Agreement, quite unlike the GATT, the General Agreement on Trade in Services (GATS) or other WTO Agreements lacks substantive provisions relating to special & differential treatment (S&D). The only S&D available in the WTO TRIPS Agreement is the

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<sup>12</sup> See Abbott FM (1998). Editorial: The enduring enigma of TRIPS: A challenge for the World Economic System. *Journal of International Economic Law*. Vol. 1, Issue 4: 497–521; or Abbott FM (1997). *The TRIPS Agreement: A guide for the South*. South Center, Geneva, November; Correa C (1998). *Implementing the TRIPs Agreement. General context and implications for developing countries*. Third World Network, Penang; Correa C (2000). *Intellectual property rights, the WTO and developing countries. The TRIPS Agreement and policy options*. ZED-TWN, London.

extra transitional period available to developing and least developed countries, which, for a variety of reasons, many countries were unable to use to the full.

A second way in which the agreement's development deficit manifests itself is more systemic, showing that the TRIPS Agreement operates in a manner different from some of the other key WTO Agreements. Most specifically, the provisions of MFN and national treatment, important as they are in any WTO agreement, are nevertheless subject to general exceptions (in both the GATT and the GATS agreements). In fact, many other WTO agreements have a separate article dealing with "general exceptions", e.g. for public health or other legitimate policy objectives. In the TRIPS Agreement, however, there are no general exceptions. Instead, the TRIPS Agreement only provides for "limited exceptions".

The fact that there are no general exceptions in the TRIPS Agreement reduces the policy space available for WTO members to meet universally-agreed and unexceptionable public interest objectives including in the areas of protecting human, animal or plant life or health. Thus, the very same provisions relating to MFN and national treatment have much more force in TRIPS than they do in other WTO agreements. This absence of general exceptions is difficult to understand, especially in view of the mandate at Punta del Este which talked of negotiations aimed at "clarifying GATT provisions" (and GATT did, indeed, have a clear provision (article XX) dealing with general exceptions).<sup>13</sup> It is arguable that, if there were a general exception, the TRIPS Agreement would not pose any impediment, real or imagined, to governments wishing to protect, for example, public health. Together with the fact that the TRIPS Agreement has concrete provisions to safeguard the rights of the producers of technological knowledge rather than its users, this lack of public interest exceptions raises concerns about development deficits.

The third manifestation of the agreement's possible development deficits relates to its somewhat rare approach within the multilateral trading regime. For instance, the then-new concept of protecting IPRs somehow did not fit with the traditional GATT paradigm of promoting free trade and fostering competition. In fact, IPRs can become barriers to trade and result in restricting rather than fostering competition. For a lot of developing countries, therefore, IPRs did simply not belong in WTO, and even today, TRIPS is considered *sui generis* amongst the WTO agreements. Finally, the TRIPS Agreement has a unique provision in article 72 specifying, "Reservations may not be entered in respect of any of the provisions of this Agreement without the consent of the other Members". Interestingly, this approach does not appear in any other WTO agreement, all of which turns TRIPS into what some call a *sui generis* WTO agreement.

Fourth, there are differences in the strength of the agreement's provisions, which in turn give rise to development challenges. Having provisions relating to patents that are strictly worded for the benefit of the patent holders and having less strictly worded language for issues such as public health, transfer of technology and socio-development objectives turns TRIPS into a lopsided agreement, with mandatory provisions protecting IPRs right holders, and best endeavour provisions befitting public interest aspects of IPRs and broader development objectives.

The difference between article 27 on the one side, and articles 7 and 8 on the other serves as an example. Article 27, in its first paragraph, makes it clear that "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the

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<sup>13</sup> Along these lines, it is even more difficult to understand why the TRIPS Agreement lacks any specific provision establishing that the TRIPS obligations are subject to the general exceptions of the GATT.

field of technology and whether products are imported or locally produced”.<sup>14</sup> On the other hand, provisions such as articles 7 and 8, dealing with crucial issues such as transfer of technology, social and economic welfare, public health and nutrition, public interest, etc., are couched in “best endeavour language”. According to article 8, such measures are also subject to the proviso that they be consistent with the provisions of the TRIPS Agreement. Thus, the TRIPS Agreement's development deficits arise mainly from the fact that it focuses on governments respecting the rights of patent holders – in part at some cost for other public policy objectives.

However, as such, prescribing certain basic standards of IPR protection to safeguard the legitimate interests of the producers of technological knowledge would not in itself result in a development deficit. Rather, the “development deficit” occurs because the potential users of the technological knowledge are unable to exploit it for development, either because the knowledge itself is inaccessible, or is so expensive with conditions of access difficult meet, that it limits policy options for users. Along these lines, the problem has taken on a North–South dimension because most, if not all, of the producers of technological knowledge are located in the developed world. Conversely, the majority of the potential users of technological knowledge are located in the developing world. Since in today's globalized economy, knowledge and technology are accepted as the basic instrument for development, the “development deficit” in the TRIPS Agreement has huge implications going far beyond mere protection of IPRs.

Finally, and related to the above, the agreement's development deficit is linked to the main objectives TRIPS is supposed to achieve. In principle, IPRs should work to the mutual advantage of both the producers and the users of technological knowledge. IPRs and their protection should promote social and economic welfare, assist the users of technological knowledge and facilitate the transfer and dissemination of technology. Accordingly, there should have been clear and enforceable provisions in the TRIPS Agreement with regard to the rights of the users of technological knowledge and the unconditional right of governments to pursue legitimate public policy objectives.

Numerous documents and studies from North and South eloquently describe such development deficits. In a seminal 2005 essay, Birdsall, Rodrik and Subramanian referred to the TRIPS Agreement as the “most egregious example” of how the developed world uses international trade agreements to impose costly and onerous obligations on poor countries.<sup>15</sup> Also, the report of the United Kingdom Commission on Intellectual Property Rights and Development<sup>16</sup> points out the challenges the TRIPS poses for development. However, it also – and quite rightly – identified some development-friendly provisions, including aspects of TRIPS which do, indeed, accommodate some policy space concerns.

These include, amongst others (a) the recognition that IPRs should contribute to the “transfer and dissemination of technology” (article 7); (b) the statement that measures may need to be taken to prevent the abuse of IPRs (Article 8); (c) the fact that TRIPS mainly sets criteria for patentability, but does not prescribe how these criteria are to be defined; (d) the fact that TRIPS allows countries to exclude from patentability plants and animals and essentially biological processes for producing them; (e) the fact that TRIPS allows countries to choose an “effective *sui generis*” plant variety protection system; (f) the fact that TRIPS

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<sup>14</sup> It has to be noted that at that point in time, most, if not all, developing countries were simply not used to granting patent protection on the lines indicated above. Moreover, the language does not grant much flexibility.

<sup>15</sup> Birdsall, Rodrik and Subramanian (2005). How to help poor countries. *Foreign Affairs*. July/August.

<sup>16</sup> Commission on Intellectual Property Rights (2002). Integrating intellectual property rights and development policy. London, November. [http://www.iprcommission.org/graphic/documents/final\\_report.htm](http://www.iprcommission.org/graphic/documents/final_report.htm).

allows countries to design their regimes for exhaustion; (g) the permission to exclude diagnostic, therapeutic and surgical methods and new uses of known products from patentability (article 82); (h) the fact that there is a recognition of governments' possibility to use or allow other third parties to use a patented invention without the consent of the patentee; (i) the fact that TRIPS does not require the imposition of data exclusivity, as such, on test data (but only protection against unfair commercial use); (j) the recognition that there might be a need for measures to prevent anticompetitive practices in contractual licences (article 40); (k) the obligation of developed countries to provide incentives to their enterprises and institutions to promote technology transfer to LDCs (article 66.2)<sup>17</sup>; (l) the provision that the TRIPS Council may grant extensions to the transition period for LDCs (article 66.1); or (m) the obligation for developed countries to provide technical and financial assistance to developing countries to facilitate its implementation (article 67).

The challenge is thus to see how the TRIPS Agreement – and respective implementation and negotiation efforts – can capitalize on the agreement's potentials, and truly realize pro-development objectives. In chapter IV, the paper will consider specific provisions of the TRIPS Agreement along with concrete suggestions for overcoming the “development deficits” and making the TRIPS Agreement a vehicle for achieving economic and social welfare. Before that, however, chapter III will describe the broader context, in which the TRIPS Agreement operates today.

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<sup>17</sup> Interestingly, these provisions in TRIPS reflect language from the draft International Code of Conduct on Technology Transfer, on which negotiations between developed and developing countries failed in the 1980s.



### III. The broader context: main trends in international IPR policies

#### 1. Introduction

To understand (with a view to remedying) the development deficit of TRIPS and to build on the agreement's positive features, it is important to view the agreement in its broader context. The following chapter will address two of the many aspects that shape the broader circumstances within which IP rules and regulations, both at the national and international levels, develop today. These two – and at a first glance, possibly contradictory – aspects are (a) a tightening of IP standards through bilateral, regional and multilateral agreements on the one hand; and (b) an increasing recognition of the need to rebalance IP rules and rule-making towards a more flexible and development-oriented framework of rules and regulations on the other. The linkage between the two raises the broader question of how effectively these TRIPS flexibilities can be used in light of the parallel development of tightening IPR standards.

#### 2. Tightening and strengthening IP rules through bilateral and regional rule-making

The past few years have seen an increasing establishment of bilateral and regional trade agreements, with strong rules for the protection of IPRs. In fact, in many cases, the main elements of recent United States and European Commission free trade agreements (FTAs) go beyond multilateral standards on IPRs,<sup>18</sup> a phenomenon characterized as “TRIPS-plus”. “TRIPS-plus” standards or commitments may be (a) implementation of a more extensive standards of protection than provided in the TRIPS Agreement (for instance a longer term or duration of protection for trademarks or copyright etc.); (b) forfeiting of flexibilities or safeguards available in the TRIPS Agreement (e.g. with regard to compulsory licensing, exhaustion, plant variety protection etc.); and finally, (c) enlargement of the scope of IPRs by inclusion of a new area such as protection of publicly available databases.

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<sup>18</sup> For a thorough analysis of IP standards in recent regional and bilateral United States FTAs, see Fink C (2005). Tightening TRIPS: The Intellectual Property Provisions of Recent United States Free Trade Agreements. Trade note for the World Bank, February, <http://www.worldbank.org/trade>; Roffe P (2004). Bilateral agreements and a TRIPS-plus world: the Chile–USA Free Trade Agreement. *TRIPS Issues Paper 4*. Quaker International Affairs Programme, Ottawa; Commission on Intellectual Property Rights (2002). Integrating Intellectual Property Rights and Development Policy. London, November, [http://www.iprcommission.org/graphic/documents/final\\_report.htm](http://www.iprcommission.org/graphic/documents/final_report.htm); Intellectual property and development: overview of developments in multilateral, plurilateral and bilateral fora. In *South Center and CIEL IP Quarterly Update*, Fourth Quarter 2004, [http://www.ciel.org/Publications/IP\\_Update\\_4Q04.pdf](http://www.ciel.org/Publications/IP_Update_4Q04.pdf); Abbott FM (2005). Toward a new era of objective assessment in the field of TRIPS and variable geometry for the preservation of multilateralism. *Journal of International Economic Law*. Vol. 8, No. 1.

**Table 1. Selected examples of TRIPS-plus provisions<sup>19</sup>**

	<b>TRIPS</b>	<b>Bilateral agreements</b>
General provisions	Members may, but shall not be obliged to, implement in their law more extensive protection (1)	The Parties shall grant protection of intellectual property rights in accordance with the <b>highest international standards</b> (EU-Morocco (39))
Copyrights	The term of protection shall be no less than 50 years (12)	The term of protection shall be no less than <b>75 years</b> (United States-Cambodia); life of author plus 70 years (CAFTA, United States-Singapore; United States Morocco, United States-Bahrain)
Trademarks	Initial registration shall be for a term of no less than 7 years. (18)	Initial registration shall be for a term of no less than <b>10 years</b> (TA United States-Viet Nam (chap. 2) (6))
Industrial designs	The duration of protection available shall amount to at least 10 years (26)	The duration of protection available shall amount to at least <b>15 years</b> (EFTA-Morocco FTA, annex 5)
Signals transmitted by satellite		<b>Shall ratify</b> the convention related to signals transmitted by satellite (FTA United States-Singapore, (16.1))
Patents	Members may exclude plants and animals from patentability (27)  Term of protection no less than 20 years (33)  Each member has the freedom to determine the grounds upon which licences are granted (Doha Declaration)	Must undertake efforts to develop legislation that makes available patent protection for <b>plants</b> (FTA United States-Chile, 17.9)  Additional protection of up to 5 years for pharmaceutical and plant products (FTA EFTA-Macedonia, annex V (3))  Compulsory licences <b>only to</b> remedy an adjudicated violation of competition laws, to address a declared national emergency, and to enable compliance with national air pollutant standards (TA United States-Romania annex I)
Test data protection for pharmaceutical products	Obligation to protect undisclosed test or other data against unfair commercial use (article 39.3). Generally, reliance on original test data is not prohibited by the Agreement.	5 years of data exclusivity CAFTA and United States-Chile, in United States-Bahrain and United States-Morocco, additional 3-year data exclusivity triggered by "new clinical information"
Breeders' rights	Members shall provide for the protection of plant varieties by an effective <i>sui generis</i> system (27)	Must join <b>UPOV 1991</b> (Association EU-Tunisia annex 7(1))

<sup>19</sup> Without any attempt at comprehensiveness, this table aims to give a quick overview of most prevalent TRIPS-plus provisions. The table is adapted from Morin JF (2003). The global governance of trade, environment and sustainable development. Presentation made at the international conference on Moving Forward from Cancun, Berlin, Germany, 30–31 October.

	TRIPS	Bilateral agreements
Layout designs	The law of a member could allow the use of the subject matter without authorization (37)	Neither party may permit the compulsory licensing of layout designs of integrated circuits. (United States-Viet Nam TA, chap. 2 (8))
Licensing practices	A member may adopt measures to control or prevent licensing practices where these are anticompetitive and constitute an abuse of IPRs, provided that the measures are appropriate and consistent with the other provisions of the TRIPS Agreement	Any measure against anti-competitive practices has to be consistent with the chapter dealing with IPRs (CAFTA, Andean-United States FTA, Peru-United States FTA)

There are questions whether these developments would result in a possible trend towards harmonization of IP regimes with those of economically and technologically more advanced countries, and potential attendant implications for development. More specific concerns of developing countries in that context relate to the fear that this trend further curtails their policy space in an important area of economic development. There is the perception that “TRIPS-plus” requirements will inhibit countries from using fully the flexibilities embodied in the TRIPS Agreement. This development is even more striking as, at the time of the negotiation of the TRIPS Agreement, there was the expectation that a multilateral WTO Agreement on IP would replace the route of bilateral and regional agreements.

In fact, right from the time the Uruguay Round negotiations were launched (as well as before), developed countries (mainly the United States and the European Union (EU)) have used bilateral and regional agreements to get developing countries to adopt higher standards of IPRs.<sup>20</sup> In the case of the United States, the bilateral route was epitomized by section 301 of the United States Trade Act, which was used to address what was termed “foreign unfair trading practices”, including “unfair practices on intellectual property rights”. The regional route adopted by the United States prior to the entry into force of the TRIPS Agreement is best symbolized by the North American Free Trade Agreement (NAFTA). In fact, a plain comparison of the IPR provisions in NAFTA, as opposed to TRIPS, demonstrates that NAFTA sets much higher standards than does TRIPS. Not only does NAFTA lack transition periods, but it also obliges signatories to conform, amongst others, to higher standards in patents, copyrights and plant variety protection. As a result, not only Mexico but also Canada had to put in place new domestic legislations for IPR protection. Another example is the Caribbean Basin Initiative (CBI, enacted in 1983, much before TRIPS), which, in return for preferential market access to the United States markets obliged the Caribbean countries to meet adequate and effective protection of IPRs.

This begs the question about the rationales for Northern countries to comprehensively work towards ever higher IP standards. One is an economic reason and related to the fact that an overwhelming majority of IP rights holders are from the developed world, notably the United States, Switzerland, Japan and the EU. For developed countries, it therefore made economic and commercial sense to aim at ensuring a rental income for them as high as

<sup>20</sup> For a discussion of the United States practice prior to the Uruguay Round see, Zutshi BK (1998). Bringing TRIPS into the Multilateral Trading System. In *The Uruguay Round and Beyond, Essays in Honour of Arthur Dunkel*. Bhagwati and Hirsch Ed., New York and Geneva, 1998. For a discussion of more recent trends in United States FTAs see Fink C (2005). Tightening TRIPS: The Intellectual Property Provisions of Recent United States Free Trade Agreements. Trade note for the World Bank, February. <http://www.worldbank.org/trade>.

possible. In addition, before the WTO TRIPS Agreement, these attempts to force developing countries into higher standards of IP protection also had a strategic purpose, namely to make the negotiations on the TRIPS Agreement easier (since a coalition of developing countries was originally opposed to it). The idea was to use a simple dynamic between different negotiating forums and outcomes. Once a country had accepted higher standards of IP protection in either a bilateral or regional agreement, it became difficult to oppose the same in the multilateral context.

In the developing world, in turn, it was hoped that, through the adoption of the TRIPS Agreement, this route of bilateral and regional agreements would be replaced by the multilateral forum of WTO. With that in mind, a number of developing countries agreed, albeit reluctantly, on the WTO TRIPS Agreement. Since then, however, there have been persistent attempts by many Northern countries to get as many developing countries as possible to conform to "TRIPS-plus standards". In fact, 10 years after TRIPS came into force, it is now clear that attempts by Northern countries to secure TRIPS plus standards worldwide have persisted - if not expanded.

Some would argue that the major trading partners may be "competing" with each other in a race towards an ever-tighter network of agreements with ever-stricter TRIPS-plus standards. Accordingly, the EU's FTA with Mexico could be interpreted as an EU reaction to NAFTA. Indeed, the EU's FTA with Mexico commits both countries to providing adequate and effective protection to "the highest international standards". Clearly, this is a far cry from the TRIPS Agreement, which is about compliance with minimum standards. In sum, this appears to be contradictory to the developing countries' original hopes related to the signature of the TRIPS Agreement in the first place.

It is interesting however, that – despite the flexibilities it grants – the TRIPS Agreement itself leaves open, favours or maybe even induces higher standards of protection. For example, in article 1 paragraph 1, the TRIPS Agreement itself allows WTO members to provide for "more extensive protection" than is required by the agreement. Similarly, the agreement also provides that amendments merely serving the purpose of adjusting to higher levels of protection of intellectual property rights already achieved, and in force, in other multilateral agreements and accepted under those agreements by all members of WTO benefit from a simplified process for adoption (i.e. they may be referred to the Ministerial Conference which can then adopt it without further formal acceptance process).<sup>21</sup> Negotiations in WIPO on the Patent Cooperation Treaty, on the International Union for the Protection of New Varieties of Plants (UPOV) and the respective revisions, as well as the Broadcasting Treaty, have to be viewed against the above background.

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<sup>21</sup> See article 71, paragraph 2: "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 may be referred to the Ministerial Conference for action in accordance with paragraph 6 of Article X of the WTO Agreement on the basis of a consensus proposal from the Council for TRIPS".

**Box 3. TRIPS-plus standards: European specificities and systemic implications**

One specific issue stands out when it comes to EU attempts for obtaining “TRIPS-plus” commitments from its trading partners. This concerns geographical indicators (GIs), and more specifically GI protection for wines and spirits. Undoubtedly, the EU has a competitive edge in this area (e.g. there are as many as 6,000 protected EU GIs, mostly wines and spirits).

Demands to strengthen the existing standards of GI protection have figured quite prominently in the bilateral agreements the EU negotiated with Chile, Mexico and South Africa. The typical “TRIPS-plus” obligation that the EU seeks from its partners is for the latter to forfeit the possibility of resort to article 24 exceptions in the WTO TRIPS Agreement (article 24 provides a number of exceptions that considerably limit the obligation to provide protection to wine and spirits under article 23). One of the EU requests is for its trading partner to remove prior conflicting trademarks or to grant protection even to those GIs that have become generic. Some bilateral agreements oblige the parties to accord exclusive protection to a list of designations which are not subject to any exceptions. In the case of the EU–South Africa bilateral agreement, South Africa was obliged to gradually phase out the name of a wine called “porto” within a certain period of time. Accordingly, South African producers have renamed their product “ruby” instead of “porto”.

Interestingly, the EU and United States interests in the area of GIs do not converge. The United States had no or little interest in GIs; its approach is to protect GIs through trademarks. These two different approaches are reflected in the FTAs that these major trading nations are pursuing with their trading partners. This, in turn, gives rise to inherent dangers about lack of coherence between the trade regimes, with different regimes reflecting the different approaches of these main trading nations. In sum, this imposes a cost of its own, and not just on the country concerned, but also on the multilateral trading system.

There have been some attempts by developing countries to use the trend towards higher IP standards in bilateral or regional agreements to their advantage. On the regional front, the Free Trade Area of the Americas (FTAA) comprising 34 countries<sup>22</sup> is an interesting case. The 2003 third revision of the draft chapter on IPRs was perhaps the first time a draft agreement on IPRs included the protection of traditional knowledge, access to genetic resources and protection of expressions of folklore, all of which are areas of interest to developing countries.<sup>23</sup> Most importantly, there was a direct and explicit reference to the Convention on Biological Diversity (CBD) and access to genetic resources is specified to be in accordance with the principles of CBD and relevant national legislation. Similarly, the section on technology transfer attempted to impose some obligations on producers of technological knowledge, another area of interest to developing countries. Interestingly, it provided that each party may suspend any or all obligations in this chapter if the provisions of this chapter are not effectively implemented by any of its counterparts.<sup>24</sup>

<sup>22</sup> For details about FTAA, see <http://www.ftaa-alca.org>. For details about the many other regional and bilateral trade negotiations, see [www.bilaterals.org](http://www.bilaterals.org).

<sup>23</sup> Note that there were, however, also a series of concerns with the draft, including that it would potentially result in the highest IPRs protection ever adopted in a regional trade agreement (see article 5 of the draft). There is a limited reference to the Doha Declaration on the TRIPS Agreement and Public Health and the section on patents raises serious questions for developing countries. Some argue that it sought to curtail the exceptions contained in the TRIPS Agreement.

<sup>24</sup> Vivas-Eugui D (2003). Regional and bilateral agreements and a TRIPS-plus world: The Free Trade Area of the Americas (FTAA). Quaker United Nations Office and Quaker International Affairs Programme, Geneva and Ottawa.

While the FTAA is on hold, other regional forums have seen fierce battles about “TRIPS-plus” standards, with some, albeit very limited, gains for developing countries. In the case of the United States–ANDEAN negotiations, for example, the Andean countries proposed linking the United States demands for stronger patent protection<sup>25</sup> to their own demands for provisions on biodiversity. More specifically, Andean countries were pressing for such measures as requiring prior informed consent from indigenous communities by researchers seeking access to patent genetic processes.<sup>26</sup> Ultimately, however, no such language found its way into the agreement. Instead, the United States and Peru reached a so-called “Understanding Regarding Biodiversity and Traditional Knowledge”.<sup>27</sup>

In this understanding, the parties recognize the importance of (a) Traditional Knowledge (TK) and biodiversity; (b) their potential contribution to cultural, economic and social development; and (c) the importance of informed consent from the appropriate authority prior to accessing genetic resources under the control of such authority equitably sharing benefits arising from the use of TK and genetic resources, and promotion of quality patent examination to ensure the conditions of patentability are satisfied. The parties also endeavour to seek ways to share information that may impact the patentability of inventions based on TK or genetic resources, e.g. through publicly accessible databases, and most importantly, recognize that access to genetic resources or TK and equitable benefit sharing can be adequately addressed through contracts that reflect mutually agreed terms between users and providers. This last aspect appears somewhat different from the position developing countries, including Peru, have been advocating in WTO, namely, that such a contract-based solution is not satisfactory and that the WTO TRIPS Agreement – in other words, a binding international legal regime – is *the* relevant international manner to ensure that misappropriation and biopiracy is prevented from occurring.

TRIPS-plus provisions in FTAs also give rise to complex and varied situations regarding the interface between competition policy and IPRs.<sup>28</sup> The majority of United States FTAs only deal with this interface in passing: they include competition grounds as one of the exceptions to the general principle that compulsory licenses should not be granted. Along these lines, article 20 of the United States–Jordan FTA provides that “Neither Party shall permit the use of the subject matter of a patent without the authorization of the right holder except in the following circumstances: (a) to remedy a practice determined after judicial or administrative process to be anti-competitive;..”.

On the other hand, the Chile–United States FTA gives preeminence to competition policy over IPRs, providing that nothing in the chapter dealing with IPRs “... prevents a Party from adopting measures necessary to prevent anticompetitive practices that may result from the abuse of the intellectual property rights set forth in this chapter” (article 13 , chapter 17, also referred to as “savings clause”).<sup>29</sup> By contrast, in CAFTA, IPRs are given preeminence over competition policy concerns. Here, the parties affirm, in the chapter dealing with IPRs, their existing rights and obligations under the TRIPS Agreement and the WIPO agreements to

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<sup>25</sup> The United States is seeking to include obligations to protect pharmaceutical test data for name-brand drugs, for 5 years, and 10 years for name-brand agrochemicals.

<sup>26</sup> [http://www.bilaterals.org/article.php3?id\\_article=3163](http://www.bilaterals.org/article.php3?id_article=3163).

<sup>27</sup> [http://www.ustr.gov/assets/Trade\\_Agreements/Bilateral/Peru\\_TPA/Final\\_Texts/asset\\_upload\\_file719\\_9535.pdf](http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Peru_TPA/Final_Texts/asset_upload_file719_9535.pdf), 12 April 2006. A similar understanding – yet undated – can be found on the United States Trade Representative (USTR) webpage for the United States–Colombia FTA –

[http://www.ustr.gov/assets/Trade\\_Agreements/Bilateral/Colombia\\_FTA/Draft\\_Text/asset\\_upload\\_file42\\_9406.pdf](http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Colombia_FTA/Draft_Text/asset_upload_file42_9406.pdf)

<sup>28</sup> UNCTAD has published substantial documentation on competition provisions in RTAs. See, for example, UNCTAD (2005). A presentation of types of common provisions to be found in international, particularly bilateral and regional, cooperation agreements on competition policy and their application (TD/RBP/CONF.6/3).

<sup>29</sup> For the final text: [http://www.ustr.gov/Trade\\_Agreements/Bilateral/Chile\\_FTA/Final\\_Texts/Section\\_Index.html](http://www.ustr.gov/Trade_Agreements/Bilateral/Chile_FTA/Final_Texts/Section_Index.html)

which they are party. CAFTA also includes a savings clause similar to that in the United States–Chile FTA, relating to measures to prevent anticompetitive practices resulting from the abuse of IPRs. However, there is a crucial proviso to this savings clause, namely the requirement that such measures have to be consistent with the chapter (art. 15.1.15). Thus, to the extent that CAFTA provides for IPR protection higher than set out in TRIPS, the parties cannot take measures against anticompetitive practices where such measures would be in conflict with such higher IP protection, even where such measures might be allowed under TRIPS. Similar provisions are also contained in the other United States FTAs, such as United States-ANDEAN or Peru-United States.

It should also be noted that, in general, competition policy provisions in FTAs would apply to IP-related cases and situations. However, so far, no information is available on how such provisions may have been used in IPR-related cases.

**Box 4. The IPR/competition interface in WTO – initial experiences of Argentina and the United States**

There is some limited experience about how countries addressed the interface between competition policy and the TRIPS Agreement: the United States, for example, had requested consultations with Argentina regarding a provision in the Argentine patent law. Eventually, the case was settled<sup>30</sup> through a commitment (as set out in the respective notification to WTO) by Argentina about how the country would interpret a particular decree it had adopted.

More specifically, the decree specifies that the Argentine patent office would not grant compulsory licenses as remedies in respect of practices which are considered to be anti-competitive (without further examination) under the patent law, unless a prior decision has first been made by the competition authority analyzing the practice in question and determining that there has been an abuse of a dominant position falling within the competition law.

The notification states that “on this basis”, Argentina and the United States agree that the Argentine patent law is consistent with TRIPS and that Argentina shall not grant compulsory licenses on the basis of a finding of anti-competitive practices – except in situations consistent with the provisions of the decree. However, the understanding as set out in the notification raises certain questions for the granting of compulsory licenses. For example, those practices which are deemed to be anti-competitive without further examination under the Argentine patent law include practices which might have been considered as grounds for the grant of a compulsory license – independently of their effect upon competition.<sup>31</sup>

Moreover, while the TRIPS Agreement somewhat relaxes the conditions for the granting of compulsory licenses to include remedy practices “determined after judicial or administrative process to be anti-competitive”, there is nothing in the agreement which requires such a procedure to be undertaken *before* a license can be granted on the grounds that the IP in question has been exercised in an anti-competitive manner. It might be argued that the statement as contained in the notification to WTO might work against an interpretation of the Argentine competition law which would allow an IP-related practice to be considered anti-competitive, even if it does not constitute an abuse of dominance.

<sup>30</sup> Argentina – Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals (WT/DS171) – Argentina – Certain Measures on the Protection of Patents and Test Data (WT/DS196) – Notification of Mutually Agreed Solution According to the Conditions Set Forth in the Agreement, see [www.wto.org](http://www.wto.org).

<sup>31</sup> The relevant paragraph of the Argentine patent law lists practices to be considered anti-competitive, including setting of excessive or discriminatory prices, refusal to supply the local market on reasonable commercial terms, slowing down of marketing or production activities and any other act capable of being included among the practices considered punishable by the patent law.

In sum, “TRIPS-plus” standards in regional and bilateral agreements can raise development concerns, and frequently they are accepted only as part of a broader package of negotiating results. In fact, the decision on whether or not to agree on increasing IP protection in a future FTA is not taken in isolation of broader political and economic processes. The United States–ANDEAN FTA is an example. Despite studies showing the potentially detrimental effects, which the suggested IP standards (e.g. extended data protection) would have on domestic health policies, the Peruvian leadership appeared to have convincing reasons for agreeing to such a deal: the need to ensure that unilateral United States tariff preferences in the area of agriculture will not expire, but rather be extended, expanded and enshrined in a legally-binding agreement.<sup>32</sup> In light of the ever-closer date for expiration of the preferences, the case for accepting far-reaching TRIPS-plus standards as regards data protection became increasingly convincing (particularly as this was considered the only method for prolonging (and possibly expanding) much-needed market access for agricultural exports.<sup>33</sup>

**Table 2. Changes in the United States–Peru Free Trade Agreement**  
(Based on Vivas-Eugui, 2008 (PowerPoint presentation))

	<b>Pre-existing provisions</b>	<b>New provisions</b>
Test data protection	<ul style="list-style-type: none"> <li>• For at least 5 years</li> <li>• Protection of the concurrent period – priority for additional five years in the territory of one party after first approval in another party</li> </ul>	<ul style="list-style-type: none"> <li>• Reasonable period of time –normally 5 years depending on the level of effort and expenditure</li> <li>• Protection starts after first approval, provided it is done within six month in the other party</li> </ul>
Patent extension	<ul style="list-style-type: none"> <li>• Extension of term of patent protection if unreasonable delays</li> </ul>	<ul style="list-style-type: none"> <li>• Extension may be granted with obligation to avoid unreasonable delays</li> </ul>
Linkage (drug approval & patent status)	<ul style="list-style-type: none"> <li>• Obligation to not grant marketing approval of a drug prior to the expiration of a patent without consent of patent owner</li> </ul>	<ul style="list-style-type: none"> <li>• Not included</li> </ul>
Side letters	<ul style="list-style-type: none"> <li>• Some Doha Language</li> <li>• Reference to P.6 solution</li> <li>• No reference to test data</li> </ul>	<ul style="list-style-type: none"> <li>• Reaffirmation of Doha obligations</li> <li>• Provisions on test data are subordinated to right of Parties to take measures on public health</li> <li>• Respect of WTO waivers</li> </ul>

Subsequent developments in the United States–Peru deal, however, offer further interesting lessons. Most importantly, the final United States–Peru Agreement did not contain some of the most stringent and controversial provisions. When aiming to obtain Congressional approval for the draft deal, USTR had to agree (with Congress) on certain modifications – several of which effectively represent a lowering of the IPR protection

<sup>32</sup> In addition to the need to preserve existing access, the FTA negotiations held promises about additional trade being freed.

<sup>33</sup> More specifically, during recent years, Peruvian (agricultural) exports have benefited from preferential access to the United States market. Following the 1991 Andean Trade Preferences Act (ATPA), the 2001 Andean Trade Promotion and Drug Eradication Act (ATPDEA) re-authorized ATPA and added products. These preferences were to expire by the end of December 2006. However, over time, access for the selected products had become vital for Peruvian agriculture, even more so as the recent years have seen a growing agricultural development in the area south of Lima, focusing on export agriculture and employing an increasing number of people. See Mashayekhi M, Tuerk E (2005). Achieving coherence between trade and health policies: Selected examples from Pakistan, the Philippines, Uganda, and Peru. In *Trade and Health: Seeking Common Ground*. McGill-Queens University Press (2007).



standard. These new baselines – different from what was originally envisaged by United States negotiators – were subsequently translated into the United States–Peru Agreement. This is an important precedent, possibly showing, amongst others changes in the United States priorities and the importance of lobbying efforts (including by, e.g. United States Congressmen and civil society groups). It was suggested, that this would set a new baseline, and possibly generate a new series of requests for revision of previous agreements.<sup>34</sup>

So-called TRIPS-plus standards are, however, not only developed in bilateral and regional arrangements, but rather, potential TRIPS-plus implications are also emanating from a multilateral forum, namely the United Nations’ specialized agency for IP, WIPO.<sup>35</sup>

Examples include the harmonization of substantive patent law standards, through negotiations for what is called a SPLT (substantive patent law treaty).<sup>36</sup> Amongst others, this is likely to result in upward harmonization and TRIPS-plus standards for developing countries, which will reduce their flexibility, for example, in defining patentability requirements. WIPO’s Digital Agenda serves as another example. While the WIPO Copyright Treaty (WCT) and the WIPO Performances and Phonograms Treaty (WPPT) are relatively balanced, in terms of costs and benefits for and rights and obligations of holders and users of IP rights, negotiations have taken place about possible protection of broadcasters rights outside the framework of the Rome Convention. There are fears that these negotiations may result in TRIPS-plus standards, for example, because the proposed treaty may create expansive rights for up to 50 years for broadcasters, cable and webcasters over materials that they had no hand in creating.<sup>37</sup>

Finally, TRIPS-plus standards are also part and parcel of the legal regimes that result from countries’ accession to WTO.<sup>38</sup> A recent example of the vigour with which individual countries pursue TRIPS-plus standards across a wide range of forums can be found in the bilateral deal between the United States and the Russian Federation, regarding the latter’s accession to WTO. It is reported that in the bilateral deal, which was reached in the form of side letters, the Russian Federation agreed to IPR standards that push those of WTO and the United States law to new levels, with specific focus on enforcement and data protection.<sup>39</sup>

In sum, key trends regarding TRIPS-plus in regional agreements include:

(a) Bilateral and regional trade agreements tend to result in higher TRIPS-plus standards for developing countries;

(b) While it is arguable that these TRIPS-plus commitments have been undertaken in return for market access in goods – agricultural and non-agricultural – the developmental implications of doing the former may far outweigh the short-term benefits of the latter;

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<sup>34</sup>Vivas-Eugui D (2008). Main changes in the IP chapter of the United States–Peru FTA. Mimeo, on file with the author. For a detailed description, see also Roffe P, Vivas-Eurui D and Veja G (2008). Intellectual property, public health and primary health care in FTAs and EPAs: A shift in policy? See also PowerPoint presentation given at the annual Prince Mahidol Award Conference 2008 – “Three Decades of Primary Health Care: Reviewing the Past and Defining the Future, 30 January - 1 February 2008, Bangkok, Thailand.

<sup>35</sup> For a detailed review of TRIPS-plus provisions in WIPO, see Musungu S and Dutfield G (2003). Multilateral agreements and a TRIPS-plus world: The World Intellectual Property Rights Organization (WIPO). TRIPS Issues Paper 3. Quaker United Nations Office and Quaker International Affairs Programme, Geneva and Ottawa.

<sup>36</sup> At the 2005 September General Assembly, WIPO member States discussed how developing country concerns would be reflected in the discussions, in particular regarding issues such as public interest flexibilities, genetic resources, traditional knowledge, competition, etc.

<sup>37</sup> See Musungu S and Dutfield G (2003). Multilateral agreements and a TRIPS-plus world: The World Intellectual Property Rights Organization (WIPO). TRIPS Issues Paper 3. Quaker United Nations Office and Quaker International Affairs Programme, Geneva and Ottawa.

<sup>38</sup> Abbott F and Correa C for Quakers United Nations Office (forthcoming). *Intellectual Property issues in WTO Accession Negotiations*.

<sup>39</sup> Intellectual Property Watch, Monthly Edition, Vol.3, No. 12/ Vol.4, No.1, December 2006 - January 2007.

(c) The most important outcome of adopting TRIPS-plus commitments is giving up the flexibilities and safeguards present in the TRIPS Agreement;

(d) In addition to increased costs of enforcement and higher rental transfers because of more extensive IPR standards, TRIPS-plus standards result in a serious restriction of policy space for development; and

(e) Bilateral and regional agreements relating to IPRs can create a dynamic by which there is universal upward movement in the standards of IPRs, possibly ultimately ending up in WIPO and WTO, where rental transfers can be better realized and standards enforced through a binding dispute resolution mechanism.

Regarding the possible impacts, which acceptance of such TRIPS-plus IPR standards might have on the development for developing countries a number of observers and institutions have recognized negative implications. For example, the September 2002 report of the Commission on Intellectual Property Rights<sup>40</sup> states categorically: “We believe that developed countries should discontinue the practice of using regional/bilateral agreements as a means of creating TRIPS-plus IP regimes in developing countries as a matter of course”. The report adds that developing countries should be free to choose, within the confines of TRIPS, where to pitch their IP regimes.

Similarly, a 2005 WHO report<sup>41</sup> struck an optimistic note, saying that at least some developing countries are now using the flexibilities available in the TRIPS Agreement.<sup>42</sup> The same WHO report however warned that the use of the flexibilities available in the TRIPS Agreement may be affected by bilateral / regional free trade agreements that contain TRIPS-plus provisions. TRIPS plus aspects in bilateral negotiations and FTAs were also a central aspect in the WHO's work on policy coherence between trade and health.<sup>43</sup>

Finally, suggestions have also been made regarding WIPO's and the United Nations' overall approach towards IP rule-making. Some commentators, as well as civil society groups, have flagged the need to rethink the idea of specialization in the United Nations regarding IPRs. They flagged a need for better substantive outputs, coordinated engagement of the United Nations entities on issues of innovation, development and intellectual property.<sup>44</sup>

### ***3 Increasing recognition of the need to rebalance IP rules and rule-making towards a more flexible and development-oriented framework***

Interestingly, the above trend towards ever-higher standards of IP protection is accompanied by an increasing recognition of the need to rebalance IP rules (and rule-making) towards a more flexible and development-oriented framework of rules and regulations. In part, this originates from the view that the purpose of IPRs is not the exclusive benefit or

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<sup>40</sup> Commission on Intellectual Property Rights (2002). Integrating intellectual property rights and development policy. London. September.

[http://www.iprcommission.org/graphic/documents/final\\_report.htm](http://www.iprcommission.org/graphic/documents/final_report.htm).

<sup>41</sup> “Anti-retrovirals and developing countries”, report prepared by the WHO Secretariat for meetings of the Executive Committee in January 2005.

<sup>42</sup> WHO referred to the case of Zimbabwe, which issued a compulsory licence in 2002 citing “emergency” for production of anti-retroviral drugs; the case of Malaysia, which in 2003 imported generic anti-retroviral agents from India for use in public hospitals; and the cases of Mozambique and Zambia in 2004, issuing compulsory licences for local production of anti-retroviral agents.

<sup>43</sup> See <http://www.nsi-ins.ca/english/research/progress/09.asp> and the forthcoming publication.

<sup>44</sup> Musungu S and Dutfield G (2003). Multilateral agreements and a TRIPS-plus world: The World Intellectual Property Rights Organization (WIPO). TRIPS Issues Paper 3. Quaker United Nations Office and Quaker International Affairs Programme, Geneva and Ottawa, which offers a series of further recommendations.

advantage of individuals or corporations who are the rights-holders, but rather to benefit the public community at large through the activities of inventors and creators.

The adoption of the Doha Declaration on TRIPS and Public Health<sup>45</sup> is a prime example. In fact, the declaration, which acknowledges and reaffirms the flexibilities of the TRIPS Agreement was the first ministerial level effort, since the inception of the TRIPS Agreement to “rebalance” the agreement in response to the desire of the larger WTO membership, the developing countries and the outside world. The Doha Declaration could offer a model to follow for other policy areas of key development importance. The amendment of the TRIPS Agreement at Hong Kong, China incorporated – in a modified way – the Doha Declaration on TRIPS and Public Health and shows that embedding development into the agreement is feasible – when and where required.

Another interesting development is the efforts to promote a development agenda for WIPO. In fact, in September 2004, 14 developing countries, including Brazil and Argentina, made a proposal for the “Establishment of a Development Agenda for WIPO” to the organization’s General Assembly, the organization’s main decision-making body.<sup>46</sup>

Specifically, the “Friends of Development” (FoDs)<sup>47</sup> raised four broad concerns and suggested corresponding actions. The FoDs’ submission<sup>48</sup> (a) calls for a review of the mandate and governance of WIPO; (b) seeks the promotion of pro-development norm-setting in WIPO; (c) proposes principles and guidelines for the provision and evaluation of WIPO’s technical assistance; and (d) suggests guidelines for future work on the transfer and dissemination of technology and related competition policies. Moreover, the FoDs emphasize the need to distinguish between the incorporation of a development agenda in all of WIPO’s bodies and activities and the mere improvement of technical assistance to developing country members. It calls on WIPO to accept its role as a United Nations specialized agency and adopt the United Nation’s overall commitment to development, including the principles set out by the MDGs. The proposal demands that development concerns be reflected in all of WIPO’s activities. However, these proposals met with a certain resistance from developed and even from some developing countries. For example, the United States and Mexico clearly rejected any substantive change in WIPO’s mandate. Rather they wanted to focus on general improvement of technical assistance provided by WIPO. Other countries offered a more nuanced response. The UK submission for example, clearly indicated the country’s concern about the developmental impact of WIPO’s activities. However, it still denied any reason for concrete change at this point in time.

As a result of three “intersessional intergovernmental meetings” (IIMs) to discuss the proposal’s call for wide-ranging changes to the mandate and functioning of WIPO, as well as related submissions from other members states, and the 2005 September General Assembly, WIPO countries agreed to establish a “Provisional Committee” to continue discussions on proposals to mainstream a development agenda into WIPO’s work. Two and a half years after the original proposals on the WIPO Development Agenda, a preliminary agreement was reached in a February 2007 session of the Provisional Committee. WIPO members had

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<sup>45</sup> WTO Doha Ministerial Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, 14 Nov. 2001, available at <http://www.wto.org>.

<sup>46</sup> WIPO (2004). Proposal by Argentina and Brazil for the Establishment of a Development Agenda for WIPO”, WO/GA/31/11, WIPO General Assembly, Geneva, 27 August.

<sup>47</sup> Notably, this includes Argentina, the Plurinational State of Bolivia, Brazil, Cuba, the Dominican Republic, Ecuador, Egypt, the Islamic Republic of Iran, Kenya, Peru, Sierra Leone, South Africa, the United Republic of Tanzania and the Bolivarian Republic of Venezuela.

<sup>48</sup> See WIPO (2004). Inter-sessional Intergovernmental Meeting on a Development Agenda for WIPO. Proposal to Establish a Development Agenda for WIPO: an Elaboration of Issues raised in Document WO/GA/31/11, IIM/1/4, 6 April 2005, [http://www.wipo.int/edocs/mdocs/mdocs/en/iim\\_1/iim\\_1\\_4.pdf](http://www.wipo.int/edocs/mdocs/mdocs/en/iim_1/iim_1_4.pdf).

negotiated to compress 40 proposals into 24 agreed proposals. They had addressed (a) a variety of issues related to technical assistance; (b) suggestions to reinforce the participatory and member-driven nature of WIPO rulemaking and to expand WIPO's involvement in technology transfer; (c) issues related to information and communication technologies (ICTs) (including expanded activities in addressing the digital divide) and access to knowledge; and (d) initial reforms of WIPO's mandate and governance. Member States also approved a proposal for WIPO "to approach intellectual property enforcement in the context of broader societal interests and especially development-oriented concerns, with a view 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", in accordance with article 7 of the TRIPS Agreement." It is expected that the remaining 71 proposals will present more difficulties for reaching an agreement. They were to be addressed in the next Provisional Committee on Proposals related to a Development Agenda (PCDA) in June 2007.<sup>49</sup>

These developments are complemented by certain trends at the national level, where an increasingly diverse and multifaceted discussion about what would be the most suitable IPR framework is taking place. Many of the suggestions come from the perspective of ensuring that everyone has access to ideas and knowledge, and that intellectual property laws do not become too restrictive.

For example, the Adelphi Charter on Creativity, Innovation and Intellectual Property, which has been written by an international group of artists, scientists, lawyers, politicians, economists, academics and business experts,<sup>50</sup> sets out new principles for copyrights and patents, and calls on governments to apply a new public interest test. It promotes a new, fair, user-friendly and efficient way of handing out intellectual property rights in the twenty-first century.

The changing context – the diverse and multifaceted technical and practical environment – to which IPR policies and regimes have to respond is also evident with respect to free and open source software (FOSS). In a FOSS environment, the degree to which a software tool can be utilized and expanded is limited only by the knowledge, learning ability and innovative energy of potential users and not by exclusionary copyrights or patents, exclusionary pricing policies or the economic politics of countries and corporations. Today, FOSS represents a key component of our technological environment<sup>51</sup> with FOSS use and development being fully compliant and taking advantage of traditional copyright regimes, while mutually influencing each other. On the one hand, FOSS presents a response to indications that the proprietary models may encourage excessive copyrighting and patent hoarding, in turn reducing investment in research and development (R&D) and resulting in a decline in innovation; on the other hand, enhanced efforts to decrease piracy are considered to

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<sup>49</sup> Subsequently, in October 2007, the WIPO General Assembly formally adopted the Development Agenda and a set of 45 recommendations to enhance the development dimension of WIPO's activities, in respect of (a) technical assistance and capacity-building; (b) norm-setting, flexibilities, public policy and public domain; (c) technology transfer, ICT and access to knowledge; assessment, evaluation and impact studies; and (d) institutional and other issues.

<sup>50</sup> The Adelphi Charter on Creativity, Innovation and Intellectual Property is the result of a project commissioned by the Royal Society for the Encouragement of Arts, Manufactures and Commerce, London, and is intended as a positive statement of what good intellectual property policy is. [http://www.adelphicharter.org/adelphi\\_charter\\_document.asp](http://www.adelphicharter.org/adelphi_charter_document.asp).

<sup>51</sup> UNCTAD (2004). Free and Open Source Software: Policy and Development Implications. Background paper by the UNCTAD secretariat, TD/B/COM.3/EM.21/2, 17 August.

improve conditions for increased adoption of FOSS, effectively making the level and type of copyright protection a distinct choice available to software authors and vendors. Today, the key challenge is to improve policy awareness of the entire scope of IPR options available to ICT producers. Choices range from public domain, at one extreme, to FOSS-styled public licenses, various open source licenses such as those proposed by the Creative Commons initiative ([www.creativecommons.org](http://www.creativecommons.org)), as well as traditional restrictive copyrights and patents. The ultimate choice should be made with a view to serving the interest of developing countries and of the global economy as a whole. FOSS and the key role that users can play in developing new products and the overall trajectory of technology evolution present a key development opportunity.

Initial tendencies towards a somewhat more nuanced approach towards IPRs can also be seen in the United States. While it remains to be seen whether the new Democratic majorities in the United States Senate and House of Representatives will result in any changes on United States IP policies, already prior to the electoral changes, selected individuals in the United States Administration had voiced concerns with their Government's IPR policies.

In February 2005, United States Senator Edward Kennedy made a statement at the United States Senate criticizing the Bush Administration for making use of bilateral free trade agreements to restrict developing countries' use of compulsory licences and other measures that enable access to cheaper generic drugs.<sup>52</sup> Subsequently, in autumn 2006, Senator Edward Kennedy and Representative Henry Waxman requested that the Government Accountability Office investigate the administration's trade negotiations and their negative effects on developing countries' access to medicines. Accompanying the respective written communications, Rep. Waxman referred to administration trade agreements as having "numerous provisions that threaten access to affordable medicine" and the need to "recognize that the Bush Administration's single-minded pursuit of intellectual property protections for drug companies can have potentially devastating consequences for the public health in developing countries".<sup>53</sup>

Similar trends – albeit less pronounced – also occur in the area of competition policy.<sup>54</sup> In developed countries, competition policies generally take a favourable approach towards the existence and exercise of IPRs: IPRs are only considered to give rise to significant market power when substitute technologies or products are not available (an issue to be determined on a case-by-case basis). Any market power would be justified, as it is considered to generate gains in dynamic efficiency,<sup>55</sup> outweighing any losses in static efficiency.<sup>56</sup> In order to safeguard the willingness of rights holders to grant licenses, restrictions in licensing arrangements are usually allowed (e.g. if the arrangement leads to a situation which is less anticompetitive than in the absence of such license). Competition law is enforced where market power deriving from an IPR is used to unreasonably restrain competition in a relevant market. In the past, developed countries have focused on the scope of the rights granted by an IPR: what was within the scope was valid and what was outside was invalid.

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<sup>52</sup> <http://www.govtrack.us/congress/record.xpd?id=109-s20050216-26>.

<sup>53</sup> [http://kenedy.senate.gov/newsroom/press\\_release.cfm?id=3144BF01-4B6C-494C-AAD1-478E95C27F9E](http://kenedy.senate.gov/newsroom/press_release.cfm?id=3144BF01-4B6C-494C-AAD1-478E95C27F9E).

<sup>54</sup> See UNCTAD (2002). Competition policy and the exercise of intellectual property rights. TD/B/COM.2/CLP/22/Rev.1; and the Organization for Economic Cooperation and Development (OECD), Intellectual Property Rights, DAF/COMP(2004)24.

<sup>55</sup> Gains would arise, for example, from the promotion of innovation and the optimal introduction of new products and more efficient production processes over time.

<sup>56</sup> Losses would arise, for example, from higher prices and reduced dissemination of protected products and processes.

In recent years, however, developed countries have experienced a shift towards a more open-minded and pragmatic economic analysis. This approach evaluates the purpose of any conduct undertaken by IP holders, licensors or licensees and any effect upon competition within an overall legal and economic context. Today, concerns about the use of IPRs to impede innovation (including in high-technology industries such as pharmaceuticals, informatics and biotechnology) are more pronounced.<sup>57</sup> Consequently, competition authorities in developed countries play a more prominent advocacy role, making suggestions about how to reform the IP system with a view to minimizing competition concerns. A report by the United States Federal Trade Commission (FTC), for example, highlights the risks which overprotection of patents can generate (particularly where these are likely to be found invalid or too extensive) and recommends several reforms (changes regarding e.g. the standards or procedures for patent grants, post-grant reviews and challenges to validity).<sup>58</sup> Similarly, recent years have seen a stepping up of enforcement action in IP-related cases (e.g. in the EU, Japan, the United States and – more recently – the Republic of Korea). For instance, all these jurisdictions have brought cases in respect of different practices by Microsoft.

However, there are important differences among and also within developed countries. Differences in view exist regarding (a) what are the appropriate scope and procedures for advocacy undertaken by competition authorities; (b) to what extent should economic analysis consider IPRs like any other form of property; (c) how to address refusals to license or to supply; and (d) how to deal with certain conditions in licensing arrangements and certain behaviour by dominant firms (e.g. tying restraints).<sup>59</sup> Importantly, questions have also been raised regarding the TRIPS compatibility of certain measures dealing with anti-competitive practices.

In the EU case against Microsoft, for instance, the European Commission decided that Microsoft had abused its dominant position by tying its Windows Media Player to its dominant Windows Operating System and refusing to supply “interoperability information” for developing competing software products.<sup>60</sup> The Commission accordingly ordered Microsoft to sell separate versions of Windows with and without the Media Player in the EU and to make available the interface protocol for the Media Player to other parties. The United States Department of Justice, in turn, stated that, compared with the approach applied in the Microsoft case in the United States, “this more aggressive remedy takes antitrust enforcement in the wrong direction”.<sup>61</sup> In its appeal to the European Court of Justice, Microsoft claimed *inter alia* that the Commission failed to take proper account of the obligations imposed on the EU by the TRIPS Agreement.<sup>62</sup> The appellate court has not yet pronounced on this case.

Differences also exist between the manner in which developing and developed countries approach the interface between IPRs and competition policy. Importantly, developing countries have mostly been inactive in this area – with the notable exception of

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<sup>57</sup> Concerns relate to practices such as: cartel-like restraints between firms operating in the same market; abuse of dominance through exclusionary conduct or monopoly leveraging (stopping supply of customers on one market in a separate market); certain licensing practices; mergers where both parties hold IPRs in similar markets; proprietary standards and network effects; or access to information essential for competition.

<sup>58</sup> Federal Trade Commission (FTC) (2003). *To promote innovation: The proper balance of competition and patent law and policy*. October. This report was written in the light of hearings of key stakeholders jointly organized by the FTC and the Department of Justice.

<sup>59</sup> See OECD (2004). *Roundtable on competition policy and intellectual property*, 8-9 June.

<sup>60</sup> Commission Decision of 24 March 2004, COMP/C-3/37.792, Microsoft.

<sup>61</sup> See United States Department of Justice, Antitrust Division Update: *Trinko and Microsoft*, Remarks by J. Bruce McDonald, Deputy Assistant Attorney General, 8 April 2004 – <http://www.usdoj.gov/atr/public/speeches/204227.htm>.

<sup>62</sup> Case T-201/04, Order of the President of the Court of First Instance of 22 December 2004, proceeding for interim relief. § 206.

South Africa. South Africa has applied its competition law in some IPR-related cases, particularly in the pharmaceuticals sector. In a case involving anti-retroviral drugs, for instance, the South African Competition Commission ruled that two companies had abused their dominant positions through excessive pricing and by refusing to grant generic suppliers access to an essential facility. In so doing, the companies had excluded other suppliers from the South African market. While the commission ordered that compulsory licenses be granted,<sup>63</sup> the case was eventually settled when the two companies agreed to (a) license four patented anti-retroviral drugs to generic manufacturers for distribution to all sub-Saharan African countries; (b) allow importation of the drugs for distribution in South Africa if the licensees did not have local manufacturing capability; and (c) charge royalties of no more than 5 per cent of net sales of the relevant drugs.<sup>64</sup> In another case involving a merger between two pharmaceutical companies, the Competition Tribunal approved the merger upon condition that the parties agreed to license out three products falling within therapeutic categories in which they had a high market share.<sup>65</sup> In this case, the South African authorities benefited from advice and non-confidential information from the European Commission, which had had similar problems with the EU dimension of this global merger.

In sum, however, developed countries remain considerably absent from proactively approaching the competition/IPR interface. This may be ascribed to (a) insufficient expertise regarding the complex practices in this area; (b) the desire to avoid discrepancies with the TRIPS Agreement; (c) bilateral pressures and TRIPS-plus agreements (in a few cases); and (d) reluctance to take away rights granted under national IPR laws (taking into account the relatively broad exemptions in respect of IPRS granted under some developing country competition laws). This leads to the paradoxical situation that developed countries have been relatively more active in applying measures in respect of anticompetitive use of IPRs, even though developing countries' markets would have more characteristics giving rise to competition-related challenges (e.g. their markets have fewer available substitute products or technologies, higher entry barriers, lower purchasing power and/or limited possibilities for competition through fresh innovation).

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<sup>63</sup> South African Competition Commission, press release no. 33, 2003.

<sup>64</sup> <http://www.cptech.org/ip/health/sa/settlement12092003.pdf>.

<sup>65</sup> Competition Tribunal, Merger Case Number: 58/AM/ May 2000.





## **IV. Overcoming the development deficit and enhancing the development potential in the TRIPS Agreement: selected examples**

### ***1. Introduction***

This chapter argues that – given the political will – it is perfectly possible to overcome the TRIPS Agreement’s “development deficits”. Conceptually, there are three different ways in which this could be done. First, one could properly “operationalize” certain provisions which are already available in the TRIPS Agreement (e.g. articles 7 and 8 dealing with Objectives and Principles). Second, one could ensure that the TRIPS Agreement does not limit policy options aimed at development – that TRIPS flexibility is fully available to all WTO members and if necessary, that additional flexibility be made available. Finally, the TRIPS Agreement would need to evolve in a manner which ensures that those areas where increased IPR protection is in the interest of developing countries (e.g. traditional knowledge and genetic resources) are adequately addressed and successfully taken care of through binding multilateral rules.

Along these lines, this chapter aims to provide a brief overview of certain key issues, and the respective development deficits and development potential in them, as well as some ideas of what could be, and what has been done to remedy this development deficit. This paper does not aim to be comprehensive in terms of reviewing all aspects of the TRIPS Agreement, even less all types of IPRs that are granted international protection. Rather, it aims at highlighting certain key issues relating to the TRIPS Agreement, focusing on those which are subject to particular activity in the TRIPS Council and those which appear most promising from a perspective of aiming to reduce the Agreement’s development deficit and maximizing the development gains.<sup>66</sup>

### ***2. Objectives and principles of the TRIPS Agreement***

The first, and most generic and cross-cutting, way to remedy the development deficit is to properly operationalize the TRIPS provisions on the objectives and the principles of the agreement. These are spelt out in articles 7 and 8, two articles of pivotal importance. These two provisions provide TRIPS with much-needed balance, and thereby offer a stepping stone towards remedying the “development deficit”.

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<sup>66</sup> Note that there are many important issues which the paper does not address, such as that of non-violation, or issues related to the EC’s push towards strengthening the TRIPS’ enforcement provisions.

**Box 5. Objectives and principles of the TRIPS Agreement**

Article 7: Objectives

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

Article 8: Principles

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. 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.

*Source:* TRIPS Agreement.

In their current form, however, there are several problems with the above provisions. The key problem with article 7 is that it expresses a wish, namely that TRIPS should contribute to transfer of technology and work to the mutual advantage of producers of technological knowledge and users of technological knowledge. What if it does not, however? In fact, TRIPS does not contain any specific provisions to ensure transfer of technology (other than article 66.2 for LDCs), or clear stipulations with regard to benefits for the users of technological knowledge and promotion of social and economic welfare. Moreover, the TRIPS Agreement does not prescribe remedies in the event transfer of technology is not brought about, or more broadly, in case the objectives of article 7 are not met.

Another -but related- problem arises with article 8. This provision grants WTO members the option of adopting measures necessary to protect public health etc., but only if those measures are consistent with the provisions of the TRIPS Agreement. Thus, one could argue that if there is a choice to be made by WTO members between promoting public health and adhering to the WTO TRIPS Agreement, article 8 is quite clear that governments must unconditionally choose the latter over the former.

Despite these concerns, developing countries view articles 7 and 8 as central and positive provisions. As regards article 7, for example, it is positive to have an explicit acknowledgement that the protection and enforcement of intellectual property rights should contribute to transfer of technology, to the advantage of users of technological knowledge and to social and economic welfare.<sup>67</sup> This is so, amongst other reasons, because defendants of IPRs (and the TRIPS Agreement in particular) are likely to respond to the above by saying that the TRIPS Agreement is about protection and enforcement of IPRs and not about transfer of technology, or social and economic welfare.

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<sup>67</sup> In fact, the wording in article 7 suggests that IPRs *should* strike the right balance between the different objectives. This begs the question about how to address situations where the enforcement of IPRs does not contribute to transfer of technology, where it does not work to the advantage of the user of technological knowledge, and where it does not lead to social and economic welfare. Would that imply that the respective IPRs would not need to be enforced? Or is it the case that IPRs must be enforced by WTO members regardless of the outcomes with regard to the above objectives which are of critical importance to developing countries? Would articles 7 and 8 grant developing countries flexibility in this context?

Another important breakthrough for developing countries in this regard was the Doha Declaration on the TRIPS Agreement and Public Health.<sup>68</sup> In the author's view, the Doha Declaration puts articles 7 and 8 on a pedestal in a way in which these two provisions will colour, inform and influence every other provision of the TRIPS Agreement. In paragraph 5 of that declaration, the first subparagraph (a) reads as follows: "In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles."

If every provision in the TRIPS Agreement is to be read and interpreted in the light of its objectives and principles, this provides clear guidance for WTO panels and the Appellate Body that may be called upon to judge whether measures taken by WTO members fall foul of the TRIPS Agreement or not. Nothing that has been done so far "rebalances" the WTO Agreement in such a significant manner reducing the "development deficit" in the agreement to a similar extent.

So far, there has already been one WTO dispute that involved the consideration of articles 7 and 8, the "Canada-Generics case".<sup>69</sup> However, the *Canada-Generics Panel's* ruling was issued before the Doha Declaration on the TRIPS Agreement and Public Health. If the panel were to rule today, it might have been forced to be "guided" by subparagraph (a) of paragraph 5 of the above declaration and its ruling may well have been different in some significant respects. In 2000, the Generics Panel said something to the effect that the goals and the limitations stated in articles 7 and 8.1 must obviously be "borne in mind".<sup>70</sup> To bear in mind is one thing. But, in the light of the Doha Declaration, "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". Following the Doha Declaration, it is safe to say that the Panels and the Appellate Body *will have to* take cognizance of the interpretative guidance contained therein.

#### Box 6. TRIPS and MDGs

At the 2000 World Summit, countries agreed to "create an environment – at the national and global levels alike – which is conducive to development and to the elimination of poverty"<sup>71</sup>. The MDGs most pertinent in light of the TRIPS Agreement are to eradicate extreme poverty and hunger and to combat HIV/AIDS, malaria and other diseases.

With respect to the goal of eradicating hunger, the TRIPS provision of article 27.3(b) which says that WTO members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof, does have implications for developing countries, particularly LDCs, and their goal to tackle hunger and poverty. Any system (such as the International Union for the Protection of New Varieties of Plants (UPOV), for instance) that places a premium on plant breeders' rights at the expense of consumers does have the potential to adversely affect developing countries' capacity to achieve food security and tackle hunger and poverty. Therefore, developing countries – including LDCs – would be well advised to look at a *sui generis* system that properly suits their needs.

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<sup>68</sup> See WTO Doha Ministerial Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, 14 November 2001, available on [www.wto.org](http://www.wto.org).

<sup>69</sup> See report of the panel WT/DS114/R dated on the 17 March 2000 *Canada-Patent Protection of Pharmaceutical Products*.

<sup>70</sup> Paragraph 7.26 *Canada - Generics* Panel report.

<sup>71</sup> United Nations Millennium Declaration, paragraph 12.

However, perhaps the most important Millennium Development Goal in the context of TRIPS is the one that relates to combating HIV/AIDS, malaria and other diseases. The debate on public health in WTO that ultimately led to the adoption of the Doha Declaration on TRIPS and Public Health in November 2001 brought into sharp focus the different views and perceptions on this subject.

*Source:* UNCTAD, based on United Nations General Assembly, "United Nations Millennium Declaration", A/RES/55/2, 18 September 2000.

Obviously, the Doha Declaration and what we said above applies fully to the article 8 principles as it does to the article 7 objectives. But, the central catch in article 8 lies in the words "provided that such measures are consistent with the provisions of this Agreement". This language which appears in both subparagraphs of article 8 renders the principles and purposes otherwise so clearly elaborated in article 8 of the TRIPS Agreement null and void.

Take, for example, the stipulation that WTO members may adopt measures necessary to protect public health and nutrition or to promote the public interest in sectors of vital importance to their socio-economic and technological development. Or take the acknowledgement in subparagraph 2 of article 8 that appropriate measures may be needed to prevent the abuse of IPRs by rights holders or the resort to practices, which unreasonably restrain trade or adversely affect the international transfer of technology.

It would be extraordinary if the reading of article 8 is interpreted to mean that WTO members can adopt measures to protect public health or to pursue socio-economic goals and technological development, etc., *if and only if* these measures are consistent with the provisions of the TRIPS Agreement. This might have been acceptable if the TRIPS Agreement, like the GATT and the GATS, had a separate provision serving as "general exceptions".<sup>72</sup> Since there is, however, no such provision relating to "general exceptions" in the TRIPS Agreement, the effect of article 8 as it is currently worded is to make the public health, economic and technological policies of the WTO member governments contingent on one single criterion, i.e., whether or not the policy is consistent with the provisions of the TRIPS Agreement.

While this could be viewed as unacceptable and inimical to the credibility of both the TRIPS Agreement and to WTO itself, one could argue that the TRIPS Agreement regained a modicum of credibility with the adoption by WTO members of the Doha Declaration on Public Health. Most importantly, the Doha Declaration affirms the flexibilities already contained in the TRIPS Agreement reminding everyone that the TRIPS Agreement does possess some flexibilities as to which WTO members have a "right" to resort to in some circumstances. More specifically, paragraph 5 contains a reference to the "overriding" nature of articles 7 and 8, thus elevating them to the status of "core" or "entrenched" provisions of the TRIPS Agreement.<sup>73</sup>

However, the question which remains is how to address the issues listed in article 8 other than those relating to public health. Obviously, it is the language "provided that such measures are consistent with the provisions of this Agreement" which tilts the WTO TRIPS

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<sup>72</sup> Such a provision could possibly have read as follows: "Nothing in this agreement shall be construed to prevent the adoption by a WTO Member of measures necessary to protect public health, to promote transfer of technology or socio-economic development."

<sup>73</sup> For developing countries, it was an article of faith that every provision of the TRIPS Agreement shall be read and interpreted in the light of the objectives and principles contained in articles 7 and 8 of the agreement. This was anathema to at least one key developed country. In the end, the reference to customary rules of interpretation of public international law was used to justify the "interpretative guidance".

Agreement to one side, and which therefore elicits certain criticism of a “development deficit”. To conclude, while the Doha Declaration has at least provided a way forward towards operationalizing articles 7 and 8 of the TRIPS Agreement as regards health-related issues (and thus erasing some of the “development deficit” of the agreement), much yet remains to be done as regards development aspects beyond health.

### **3. Public health, compulsory licensing and data protection**

The following reviews three areas of intellectual property standards which are closely linked to health-related issues: (a) the Doha Declaration on TRIPS and Public Health and respective follow-up actions; (b) compulsory licensing; and (c) data protection (data exclusivity). While the last two issues also have important implications that go beyond health-related issues, they have mostly been discussed in a health-related context, which is why the paper addresses them in conjunction with the more specific topic TRIPS and public health.

#### **Public health**<sup>74</sup>

As already shown through the above examples, TRIPS and public health are one of the key areas where WTO members have aimed to (and still aim to) address the agreement’s development deficit. The agreement’s main reference to public health is in paragraph 1 of article 8, which provides that WTO members may adopt measures necessary to protect public health and nutrition, provided that such measures are consistent with the provisions of the agreement (see above). Another reference is in paragraph 2 of article 27, which provides that WTO members may exclude from patentability those inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect, among other things, human life or health.

The issue of public health or human life and health loomed large during the Uruguay Round, when the TRIPS Agreement was being negotiated. Patents were the most contentious subject to be negotiated, amongst others, because at that time, several developing countries simply excluded patentability for inventions relating to pharmaceutical, food and agricultural products. The rationale was clear: these sets of products were so important for achieving public health objectives that patenting them would have either led to limited access or, in some particularly poor countries, to no access at all.

Interestingly, during the negotiations there was a proposal which excluded patent protection for inventions whose use would be injurious to public health, among other things. But, the final language in the TRIPS Agreement in paragraph 2 of article 27 clearly put patent protection ahead of public health<sup>75</sup> and the situation was made worse by the stipulation in article 8 that WTO members may adopt measures to protect public health and nutrition but only if those measures were consistent with the TRIPS Agreement.

Thus, in the end, the TRIPS Agreement effectively put an end to any “sectoral exclusions”. In paragraph 1 of Article 27 it provides that patents shall be available and patent

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<sup>74</sup> For various texts and analyses on TRIPS and public health see, Islam R (2004). The generic drug deal of the WTO from Doha to Cancun – A peripheral response to a perennial conundrum. In *Journal of World Intellectual Property*, Vol. 7 No. 5, September; Vandoren P and Van Eeckhaute J-C (2003) The WTO decision on paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health – making it work. In *Journal of World Intellectual Property*, Vol. 6 No. 6, November; Varella MD (2004). The WTO, intellectual property and AIDS – Case studies from Brazil and South Africa. In *Journal of World Intellectual Property*, Vol. 7 No. 4, July; Sun H (2003). Reshaping the TRIPS Agreement concerning public health: Two critical issues. In *Journal of World Trade*, 37 (1): 163–197.

<sup>75</sup> Since both the European Patent Convention and United States law allowed patent protection for inventions in all fields of technology, there was little doubt that this would figure in the Dunkel draft, named after Arthur Dunkel, Director-General of GATT between January 1980 and June 1993.

rights enjoyable without discrimination as to the field of technology. Considering the number of developed countries, which uninstalled the late 1970s had sectoral exceptions and the many developing countries which had sectoral exceptions until the late eighties, this was the single most important change that the TRIPS Agreement brought (not without challenge from many developing countries). Indeed, it is correct to say that in some countries the entire opposition to the TRIPS Agreement emanated from this single issue.

Even shortly after the TRIPS Agreement was agreed to and ratified by governments around the world, doubts were expressed by observers and experts on how patent protection would impact on prices of pharmaceutical products and their availability. It was while this debate, largely academic at the time, was going on that the HIV/AIDS pandemic became a critical issue in Africa. It was known that the cost of drugs for tackling AIDS was prohibitively high in the western world, which basically meant that the drugs were effectively out of reach for the vast majority of people in Africa. As this was happening, a large coalition of international NGOs started a campaign arguing that unconditional patent protection in the pharmaceutical sector would have deleterious consequences for public health.

By the middle of 2001, the African Group of countries brought the issue to the WTO TRIPS Council. While the African Group obviously had HIV/AIDS as the central focus, they were careful to add that there were other public health problems as well, and that the TRIPS Agreement in its current form was inadequate to cope with these problems and, worse still, that the TRIPS Agreement prevented WTO members from protecting and promoting public health. The African Group was joined by India, Brazil and a host of other mainly developing countries. By then, the issue had “hotted up” on the international stage (thanks to efforts by NGOs) and the issue could no longer be ignored.<sup>76</sup>

The WTO TRIPS Council began tentatively by organizing special sessions in 2001 in which countries put forward their views and ideas. The response by some major developed countries was that the TRIPS Agreement was fine and that the problems lay elsewhere. Moreover, at the end of a long process, the key countries involved were able to agree to what is now known as the “Declaration on the TRIPS Agreement and Public Health.”<sup>77</sup>

It is difficult to overestimate the importance of the Doha Declaration on the TRIPS Agreement and public health. This is the first time since the inception of the TRIPS Agreement that an effort has been made at the WTO ministerial level to rebalance the agreement in response to the desires of the larger WTO membership, the developing countries and the outside world.

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<sup>76</sup> For a discussion about NGOs and public health see Odell JS and Sell SK (2003). Reframing the issue: the WTO coalition on intellectual property and public health, 2001. Prepared for an UNCTAD Conference held on 6-7 November, Geneva; Abbott FM (2005). The WTO medicines decision: world pharmaceutical trade and the protection of public health. *AJIL*, Vol. 99, April: 356; Tuerk E (2003). The Role of NGOs in international governance – NGOs and developing country WTO members: Is there potential for alliance? In Griller S (ed.). *International Governance and non-economic concerns: new challenges for the international legal order*. Springer, Vienna/New York.

<sup>77</sup> The author was one of India's lead negotiators on TRIPS and Public Health at the WTO Doha Ministerial Conference in November 2001.

**Box 7. The Doha Declaration on TRIPS and Public Health – key features**

Paragraph 1 covers the scope of the issues addressed. While certain developed countries were keen that the declaration only deal with HIV/AIDS, negotiators from developing countries wanted the broadest possible scope (even for Africa, HIV/AIDS was one of many problems to be addressed). The final outcome is satisfactory inasmuch as the scope is “public health problems” as such, but “especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics”.

Paragraph 2 stresses the need for the TRIPS Agreement to be part of the wider national and international action to address these problems. This language originates from arguments put forward by key developed countries that TRIPS is not part of the problem and that the public health problems in developing and least developed countries lie elsewhere (lack of medical infrastructure, doctors, poverty, etc.). Finally, everyone agreed that TRIPS needed to be part of the solution, not part of the problem.

Paragraph 3 contains a statement which tries to capture the delicate balance inherent in IPRs between providing the incentive for development of new medicines on the one hand and their effect on prices on the other.

Paragraph 4 is key. In its first sentence, it states that the agreement does not and should not prevent members from taking measures to protect public health. This language originates from the fact that developing countries had argued convincingly that the TRIPS Agreement was widely seen as preventing WTO members from adopting measures to protect public health. At the same time, the key developed countries felt that the TRIPS Agreement did not prevent members from taking such measures. Thus, the first sentence of paragraph 4 contains a compromise solution.

In the second sentence of paragraph 4, ministers state that the TRIPS Agreement can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health. This is the momentous statement that “rebalances” the TRIPS Agreement and reduces the development deficit in an important way. First, it provides the clearest guidance yet to panellists and the Appellate Body as to how the TRIPS Agreement “should be interpreted” (which is of vital importance for the future public policy options of developing countries). Second, the Doha Declaration also provides guidance to governments as to how the TRIPS Agreement should be implemented. Third, the declaration accepts the developing country negotiators’ assertion that WTO members have the “right to protect public health” and that this “right” cannot be prejudiced in any way by the TRIPS Agreement. Finally, the declaration refers to a fundamental and specific public policy objective, namely, “to promote access to medicines for all”. This is enormously important because this specific objective does not figure anywhere in the TRIPS Agreement (noting that article 8 does indeed refer to the goal of “protect[ing] public health”. Through the declaration, however, all the WTO members agreed on the right of Governments to implement the TRIPS Agreement in a manner to promote access to medicines for all.

Also, paragraph 5 is a central aspect of the declaration: it recognizes the “flexibilities” in the TRIPS Agreement. It does so by reminding everyone that the TRIPS Agreement possesses some flexibilities to which WTO members have a “right” to resort to in some circumstances. More specifically, paragraph 5 contains a reference to the “overriding” nature of articles 7 and 8, thus elevating them to the status of “core” or “entrenched” provisions of the TRIPS Agreement.

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Paragraph 6 acknowledges the problems faced by those WTO members with insufficient or no manufacturing capacities in making use of compulsory licensing available in article 31 of the TRIPS Agreement, and instructs the TRIPS Council to find an expeditious solution to the problem. Given the late time the issue arose,<sup>78</sup> there was simply no time for negotiators to find a solution to what was perceived as a genuine problem.

Paragraph 7 of the Declaration applies to LDCs and reaffirms developed country members' commitment to provide incentives and to encourage the transfer of technology to LDCs (see TRIPS article 66.2). Paragraph 7 also provides that, until 1 January 2016, LDCs will not be obliged with respect to pharmaceutical products, to implement sections 5 and 7 of part II of TRIPS (product patenting), or to enforce the respective rights.

*Source:* UNCTAD, based on WTO, Doha Declaration on TRIPS and Public Health, WT/MIN(01)/DEC/2.

The declaration alone did not, however, solve the issue. In fact, many more issues remained to be addressed. Accordingly, paragraph 6 of the Doha Declaration instructs the TRIPS Council to find an expeditious solution to the problem faced by those WTO members with insufficient or no manufacturing capacities in resorting to compulsory licences.

The problem in that context was fairly straightforward: WTO members can issue compulsory licences for domestic production as well as importation. If domestic production is a choice readily available, then that is the best way to go for use of the subject matter of a patent without the authorization of the rights holder, while respecting provisions of article 31 (see below). But what if this choice is not available either, due to insufficient manufacturing capacity or, worse, no manufacturing capacity at all? The member, then resorting to importation, has to depend on sources of supply from generic producers in other countries with sufficient manufacturing capacity. In such cases, however, several problems arise: (a) countries with significant domestic industry come under an obligation to provide patent protection as of 2005; (b) there is the limitation of subparagraph (f) of article 31 which stipulates that use without the authorization of the right-holder has to be "predominantly for the supply of the domestic market". Thus, it was clear that, in order to find a solution to the problem in paragraph 6 of the Declaration, there was a need for either a waiver from some provisions of the TRIPS Agreement or an outright amendment of those provisions.

After lengthy negotiations in the TRIPS Council and elsewhere, the WTO General Council took a decision on 30 August 2003.<sup>79</sup> The decision lays down in some detail the scope of the issue as well as what is meant by "eligible importing Member" and by "exporting Member". In its operative part, the decision waives the obligations of an exporting member under article 31(f) and (h) of the TRIPS Agreement.<sup>80</sup> The August 2003 decision establishes a temporary waiver, ensuring that this condition would not apply and the exporting member can supply the amount necessary to meet the needs of the eligible importing member.<sup>81</sup>

While the temporary waiver itself had been subject to long negotiations, this was not yet the end of the story. It is a matter of regret to many participants that the implementation of the August 2003 decision ran into serious difficulties in the TRIPS Council and took on the

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<sup>78</sup> The issue arose towards the latter part of the discussions or negotiations in Geneva in the run-up to the Doha Ministerial Conference, with some informal papers being floated (by the EC, among others).

<sup>79</sup> See WTO (2003). Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. Document WT/L/540. 2 September 2.

<sup>80</sup> This is the provision which stipulates that use without the authorization of the right holder has to be predominantly for the supply of the domestic market.

<sup>81</sup> All the terms set out in paragraph 2 of the decision would have to be met by both the eligible importing member and the exporting member.



shape of developed versus developing countries. Throughout 2004 and 2005, there were intense discussions about the legal form (whether to use a footnote, an annex, or the introduction of an article 31 *bis*) and the content (full technical transposition of all the elements of the waiver or selected transposition of elements “as appropriate”; whether and how to reflect the Chairman’s statement, which developing countries perceived to contain a series of unfavourable elements) of the amendment.

The African Group, which launched the initiative in 2001, had submitted several proposals for an amendment of the TRIPS Agreement<sup>82</sup>, arguing for (a) an amendment in the TRIPS’ main text of article 31 (rather than a footnote); (b) a selected transposition of the elements (justified on the grounds that some provisions have already outlived their utility and there are some others whose purpose would otherwise be served by other provisions of the TRIPS Agreement); and (c) leaving aside the Chairman’s Statement (which the African Group viewed as not being an integral part of the 30 August decision).

The African Group’s position was supported by a wide range of developing countries including, among others, Argentina, Jamaica, Hong Kong (China), India, Brazil, Malaysia and the Philippines. Developed countries (notably the United States, supported by Switzerland, Japan, Canada, with the EC taking a position closer to the developing country positions) objected to the African Group views and several deadlines were missed with difficult negotiations over selected issues.

Finally, on 6 December 2005, right before WTO’s Hong Kong (China) Ministerial, members agreed on an amendment of the TRIPS Agreement. The amendment of the TRIPS contains three elements: (a) a new article 31 *bis* (setting out the required exception, including as it applies for countries who are members of regional trade agreements (RTAs)); (b) an annex (defining key concepts, e.g. “pharmaceutical product” and “eligible importing Member”, as well as establishing requirements for notification, and containing provisions on transfer of technology as well as an annual review mechanism); and (c) an appendix (including details for establishing whether a country has no or insufficient manufacturing capacity).

The December Decision does not refer to the Chairman’s statement. The statement was, however, read out by the then Chair of the General Council at the adoption of the amendment. In fact, members followed a previously agreed, meticulous process for the adoption.<sup>83</sup> Importantly, the process differed from the 2003 process, where individual members, subsequent to the Chairman’s statement, expressed their views (and interpretations) about the statement and the decision. The December 2005 process was a response to controversies about the legal nature of the Chairman’s statement, and aimed to ensure that any action taken would not change the previous legal status/nature of the statement. The amendment will enter into force, once it has been accepted/ratified by two thirds of the WTO members. Until then, the waiver will remain in force.<sup>84</sup>

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<sup>82</sup> IP/C/W/437: Implementation of paragraph 11 of the 30 August decision. *Communication from Nigeria*; IP/C/W/440: Legal arguments to support the African Group proposal on the implementation of paragraph 11 of the 30 August 2003 decision. *Communication from Rwanda*.

<sup>83</sup> First, no member made any statement in the TRIPS Council while agreeing on the proposal for the General Council; second, in the General Council the 11 opt-out members reiterated their intention to only use the mechanism in cases of national emergency; third, the General Council Chair read out the 2003 Chairman’s statement; and fourth, members adopted the amendment without any additional statements.

<sup>84</sup> By November 2006, three countries had ratified/accepted the amendment. El Salvador (19 September) was followed by Switzerland (13 September 2006). The United States had previously ratified it (December 2005), and 96 countries remain to go in order for the amendment to come into effect. It was noted that, if possible, the deadline for reaching that may be extended.

While in the Hong Kong (China) Declaration,<sup>85</sup> ministers “welcome the work that has taken place in the Council and the decision of the General Council of 6 December 2005 on an amendment of the TRIPS Agreement”, the amendment, as well as the process of its adoption, has spurred criticism from numerous civil society groups.

What does this now mean for TRIPS and public health and remedying the agreement's development deficit? Interestingly, at the time of the adoption of the waiver, no importing country had yet used the previous, temporary waiver. Some claim that this was due to the complex and burdensome administrative and other requirements that must be met. At the same time, however, several potential exporting countries amended their domestic legislation to make it conform to the 30 August 2004 waiver. Norway was the first country to implement the waiver domestically, followed by Canada and India, as well as the Republic of Korea, the EU and Switzerland. The United States, Switzerland and El Salvador have respectively accepted the waiver.<sup>86</sup> At the WTO's Hong Kong (China) Ministerial, the World Health Organization (WHO) congratulated WTO members for the unprecedented decision of amending the TRIPS agreement in a manner that supports countries' right to protect the health of their people, and affirmed that it would strive to provide the relevant technical advice to its member States on the effective use of the amended agreement.<sup>87</sup>

While this points to a potentially favourable development, possible challenges for the ability of countries to protect public health by using the mechanism arise from “TRIPS-plus” obligations in numerous bilateral or regional agreements.<sup>88</sup> Several recent FTAs have come under heavy criticism for the impact that the IP provisions may have on public health.<sup>89</sup> Much of this criticism focuses on United States FTAs and United States regional and bilateral negotiations. Interestingly, however, such criticism was not only coming from developing countries, but also from within the United States administration. Already earlier on United States Democratic Senators have urged the United States Government, to fully respect (including in their negotiations for other FTAs) the Doha Declaration and the flexibilities contained therein.<sup>90</sup> Calls upon developed countries to refrain from pressuring their southern trading partners into far-reaching and potentially harmful international IP obligations, also originate from United Nations institutions and their respective bodies. The Special Rapporteur on the Human Right to Health, Paul Hunt, for example, conducted a mission to Peru, and

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<sup>85</sup> Doha Work Programme, Ministerial Declaration, Sixth Session of the Ministerial Conference, WT/MIN(05)/DEC.

<sup>86</sup> [http://www.wto.org/english/tratop\\_e/trips\\_e/amendment\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm).

<sup>87</sup> Statement of WHO on International Trade and Health, at the World Trade Organization Ministerial Conference, Sixth session, Hong Kong (China) 13–18 December 2005.

<sup>88</sup> Abbott FM (2004). The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements. *Occasional Paper 14*, Quaker United Nations Office, Geneva.

<sup>89</sup> “Thai-United States FTA negotiations no impact on essential drugs”, in [www.bilaterals.org](http://www.bilaterals.org), [http://www.bilaterals.org/article.php3?id\\_article=3448](http://www.bilaterals.org/article.php3?id_article=3448), 7 January 2006; “IPR debate centers on cheap drugs”, in [www.bilaterals.org](http://www.bilaterals.org), [http://www.bilaterals.org/article.php3?id\\_article=3436](http://www.bilaterals.org/article.php3?id_article=3436), 6 January 2006. See also Ghanotakis E (2004). How the U.S. interpretation of flexibilities inherent in TRIPS affects access to medicines for developing countries. In *Journal of World Intellectual Property*, vol. 7 no. 4, July.

<sup>90</sup> In essence, Senator Kennedy argued that the American Government undermined WTO's Doha Declaration on the TRIPS Agreement and Public Health. Senator Kennedy gave examples of trade agreements signed with Australia, Jordan, Morocco, Singapore and the Central American Free Trade Agreement where, in his view, the United States had undermined the very core of the Doha Declaration. The tactics mentioned include: blocking the approval and use of generic versions of drugs, preventing new treatments of HIV/AIDS from getting to patients in the developing world, legal tactics to delay approval of generic drugs and blocking of parallel imports. Senator Kennedy called on the United States Government to respect the Doha Declaration in full – <http://www.govtrack.us/congress/record.xpd?id=109-s20050216-26>.

flagged the suggested IP provisions in the draft United States–ANDEAN FTA as one of the issues of utmost concern.<sup>91</sup>

### *Compulsory licensing*<sup>92</sup>

If patent protection for pharmaceutical and other products is characterized as one of the most contentious issues in the TRIPS negotiations, it is fair to say that article 31 (a key safeguard relating to patent use or abuse) was also “intensely negotiated”.<sup>93</sup> Article 31 is somewhat arcanelly entitled “Other Use Without Authorization of the Right Holder” but is more commonly known as compulsory licensing<sup>94</sup>.

A compulsory licence is an authorization granted by a government to a person for the use and exploitation of a patented product or process without the consent of the patent holder. Thus, a compulsory licence is a tool to restrain private rights (e.g. those of the patent holder) in favour of the public interest (e.g. the public interest in having technical knowledge more immediately accessible). Compulsory licence can also be used as a tool for governments to limit private powers that reside in the grant of patents.<sup>95</sup> Article 31 of TRIPS, however, specifies that for governments to use this tool, the law of the WTO member in question must provide for compulsory licensing.

Some point to the campaign carried out by some developed countries (possibly in line with their pharmaceutical lobbies) that provisions on compulsory licences were of no use for developing countries. This went to extent that during the 1990s, even some reputed international organizations would suggest model laws for developing countries and LDCs without any provision for compulsory licensing. Given that the very first sentence of TRIPS article 31 requires the law of a WTO member to provide for compulsory licensing, in order for them to use it, failure to establish domestic laws accordingly has significant implications. Today, there are several countries that have forfeited the right to resort to compulsory licensing. Most likely, this is mainly due to dynamics arising from developed countries and the pharmaceutical lobbies in those countries. At the same time, however, several countries – such as Argentina, Brazil and India – have issued domestic laws providing for compulsory licence. These can, in fact, serve as models to choose from.

In the light of these circumstances, it is therefore a victory for developing countries that the Doha Declaration on the TRIPS Agreement and Public Health affirms the right to grant compulsory licences. More specifically, in subparagraph (b) of paragraph 5, the declaration states that each member has the right to grant compulsory licences and the freedom to determine the grounds upon which licences are granted. Thus, while the right to grant compulsory licences was always there in the TRIPS Agreement, it is helpful for developing countries to have a clarification that they have the freedom to determine the grounds upon which licences are granted. The underlying intent in this declaration specifies

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<sup>91</sup> See report submitted by Paul Hunt, Special Rapporteur on the right of everyone to the highest attainable standard of physical and mental health, E/CN.4/2005/51/Add.3, 4 February 2005, reporting on his mission to Peru.

<sup>92</sup> For various analyses on compulsory licences in the public health context, see Vandoren P and Ravillard P (2005). A new EC initiative to allow export of medicines under compulsory licences to poor countries. In *Journal of World Intellectual Property*. Vol. 8, No. 2, March; Curci G and Vittori M (2004). Improving access to life-saving patented drugs – between compulsory licensing and differential pricing. In *Journal of World Intellectual Property*. Vol. 7, No. 5, September.

<sup>93</sup> See the section on compulsory licences on page 317 of Watal J (2001). *Intellectual Property Rights in the WTO and Developing Countries*. Kluwer Law International, The Hague.

<sup>94</sup> For a detailed negotiating history of this provision and others in the TRIPS Agreement, see the “TRIPS and Development: Resource Book” jointly produced by UNCTAD / ICSTD.

<sup>95</sup> See UNCTAD – ICTSD Project on IPRs and Sustainable Development (2005), *Resource Book on TRIPS and Development*, Cambridge University Press, New York, chapter 25.

that the exception in article 31 (Other Use without the Authorization of the Right Holder) is much broader than the exception in article 30 (Exceptions to Rights Conferred).

This distinction between articles 31 and 30 is important, given the more limited nature of the latter provision. In other words, article 30 is a much more limited sort of exception to rights conferred. For example, the exceptions provided under article 30 should not unreasonably conflict with a normal exploitation of the patent and should not unreasonably prejudice the legitimate interests of the patent owner. Article 31, in turn, does not contain any such stipulations for the granting of compulsory licences. It only establishes a series of conditions (listed from subparagraphs (a) through (l)) which must be respected.

While appearing somewhat onerous, these conditions need not be so in practice; policymakers of developing countries have significant leeway in interpreting the conditions listed in article 31 and whether they have been fulfilled.<sup>96</sup> Thus, on the issue of what constitutes a national emergency or other circumstances of extreme urgency, subparagraph (c) of paragraph 5 of the Doha Declaration rightly points out that each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency.

The Doha Declaration is also significant as regards members' freedom to determine the grounds upon which compulsory licences are granted. Article 31 excludes no grounds whatsoever and the Doha Declaration reaffirms the full freedom to determine any grounds. This is important as before Doha there was some debate about whether the failure of "local working"<sup>97</sup> was a valid reason for issuing compulsory licences.<sup>98</sup> In light of this debate, in 2000, the United States requested consultations with Brazil on the latter's law which established a "local working" requirement for the enjoyment of exclusive patent rights.<sup>99</sup> The United States considered that such a requirement was inconsistent with Brazil's obligations under articles 27 and 28 of the TRIPS Agreement. However the United States subsequently withdrew its complaint against Brazil, and thus far, there is no indication that Brazil withdrew its legislation. Rather, in a joint communication issued with the United States, Brazil merely said it would provide advance notice to the United States should it grant a compulsory licence on a patent held by a United States company.

While so far no WTO panel has ruled on the question of whether or not failure to work a patent locally can be grounds for issuing compulsory licences, a number of arguments suggest there is absolutely no justification for ruling out, a priori, failure to work locally as grounds for issuing compulsory licences. Taking a historic perspective, it is interesting that, during the Uruguay Round, there were drafts that excluded failure to work locally as grounds for issuing compulsory licences. Thus, if negotiators had intended it, the TRIPS Agreement would have explicitly forbidden failure of local working as a valid reason for issuing compulsory licences. Of course, some will argue that, while it is not forbidden, it is neither clearly allowed. As a response, one can note that neither are there other grounds clearly articulated in the TRIPS Agreement.

In light of these arguments, it is therefore positive that the Doha Declaration on the TRIPS Agreement and Public Health brings closure to this issue by reaffirming the freedom of WTO members to determine the grounds upon which compulsory licences are granted.

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<sup>96</sup> See Watal J (2001). *Intellectual Property Rights in the WTO and Developing Countries*. Kluwer Law International, The Hague.

<sup>97</sup> Local working requirements establish, for example, that exclusive patent rights can only be enjoyed if the patented subject matter is produced locally, rather than imported into the country in question.

<sup>98</sup> In fact, this was provided in the Paris Convention that predated the TRIPS Agreement.

<sup>99</sup> Request for consultations by the *United States, Brazil – Measures Affecting Patent Protection* – See WTO documents WT/DS 199/1 of June 2000. In essence, Brazil's local working requirement stipulates that a patent shall be subject to compulsory licensing if the subject matter of the patent is not "worked" in the territory of Brazil.

Moreover, in its paragraph 4, the declaration affirms that the TRIPS Agreement can and should be interpreted and implemented in a manner supportive of WTO members' rights to protect public health and, in particular, to promote access to medicines for all. It would therefore be only logical to issue compulsory licences on the grounds of failure of local working in order to protect public health and promote access to medicines for all.

There is yet another aspect that greatly influences the utility of article 31. In fact, the utility of article 31 for dealing with the issue of compulsory licences for developing and least developed countries hinges on the interpretation of article 31 vis-à-vis other provisions in the TRIPS Agreement. This is especially the case as regards article 27.1, which prohibits discrimination. In a dispute involving Canada and the EC,<sup>100</sup> the panel issued an obiter dictum which reads as follows: "The acknowledged fact that the Article 31 exception for compulsory licences and government use is understood to be subject to the non-discrimination rule of Article 27.1, without the need for any textual provision so providing, further strengthens the case for treating the non-discrimination rules as applicable to Article 30." Some argue that language still leaves a considerable degree of flexibility in the interpretation of article 27.1.<sup>101</sup> Others in turn fear that it would take away the central flexibility of article 31, which is the freedom to determine the grounds (as well as to consider the issuing) of compulsory licences on their individual merits. What is important to remember, though, is that this report was, first of all, not appealed and secondly, pre-dates the Doha Declaration.

As explained above, the Doha Declaration on the TRIPS Agreement and Public Health makes it clear that articles 7 and 8 dealing with objectives and principles are key provisions, and that 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. One can therefore expect that if the panel were to reconsider the above issues today, it would have to read article 31 in the light of articles 7 and 8, and in the light of the affirmation in paragraph 4 of the Doha Declaration on the right of WTO members to protect public health and to promote access to medicines for all. It is obvious that the panel would have to be "guided" by the Doha Declaration and not by a view that lacks any textual provision.<sup>102</sup>

To conclude, it is important (a) that those WTO members that wish to use compulsory licences provide for it in their legislation; and (b) that article 31 be interpreted and implemented in both the letter and the spirit of the Doha Declaration on the TRIPS Agreement and Public Health.

The paragraph 6 system was used for the first time – albeit not directly – in 2007, when the Rwandan Government, as the first and only country so far, notified WTO to make use of the Paragraph 6 mechanism.<sup>103</sup>

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<sup>100</sup> See WTO (2000). *Canada – Patent Protection of Pharmaceutical Products*, *Complaint by the European Communities and their member States*. WT/DS114/R, 17 March. Note that thus far, there is no WTO dispute settlement ruling that directly interprets Article 31. For a thorough analysis of the case, see Howse R (2000). The Canadian generic medicines panel: A dangerous precedent in dangerous times. In *Journal of World Intellectual Property*. July; Howse R (2000). The Canadian generic medicines panel, a dangerous precedent in dangerous times. *Bridges Monthly*. April – <http://www.iprsonline.org/ictsd/docs/HowseBridgesYear4N3April2000.pdf>.

<sup>101</sup> See UNCTAD-ICTSD Project on IPRs and Sustainable Development. *Resource Book on TRIPS and Development*. Cambridge University Press. New York, 2005: 480.

<sup>102</sup> There are other reasons, which suggest that the panel's reasoning is fundamentally flawed. For example, (a) the panel admits that there is no textual provision for interpreting article 31 of TRIPS as being subject to the non-discrimination rule of article 27.1 of TRIPS; and (b) the panel gives no real explanation as to why (and how) it arrived at the above conclusion (except to say that Canada had acknowledged it). It is important to note that neither the agreement nor the negotiating history substantiate this claim. See Howse, cited above.

<sup>103</sup> See Rwanda's Notification under paragraph 2 (a) of the decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health on 17 July 2007, IP/N/9/RWA/1

### **Data protection**

Paragraph 3 of article 39 of the TRIPS Agreement imposes an obligation upon WTO members to protect undisclosed test or other data against unfair commercial exploitation, when such data are required as a condition for obtaining approval for the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities.<sup>104</sup>

In order to obtain marketing approval, applicants planning to sell new pharmaceutical products have to undertake a number of tests on safety and related matters. Data from these tests are then submitted to the regulatory authorities, who take the decision for marketing approval. Questions about protecting such test data arise when a request for marketing approval is filed for a product which is similar to an already-approved product. The point of contention is whether “data exclusivity” prevents regulatory authorities from relying on the test data of the original product or whether regulatory authorities can rely on the test data of the original product and approve the marketing for the new applicant provided the product is similar to an already approved one.

The implications of choosing one or the other interpretation are profound. As it is very costly to produce one’s own data, a mechanism preventing regulatory authorities from relying on test data may effectively result in “pipeline protection” and has the effect of “market exclusivity”.<sup>105</sup> Moreover, it delays the entry of generics (the second or the third applicant), leading to adverse impacts on public health objectives, including access to medicines for all. Finally, test data exclusivity may also pose an additional obstacle for governments aiming to effectively use compulsory licensing.<sup>106</sup>

There are a number of questions regarding the nature and duration of test data protection, all of which have important developmental implications. As regards duration, the United States, EU and other developed countries believe that data exclusivity needs to be maintained for a period of 5 to 10 years. For developing countries, protection of test data is an obligation to protect undisclosed test or other data only against “unfair commercial use”.

A glance at what are the clear obligations of this provision shows the following. First, undisclosed test or other data must relate to a new chemical entity. While there is no definition of what is new, it would appear that this provision would not apply to new uses of known products nor to dosage forms, new forms of administration, etc., of existing drugs, since there would be no new chemical entity involved.

Second, as regards the duration of data exclusivity (and the reliance of regulatory authorities for subsequent approval for second or third applicants on such data) the bottom

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of 19 July 2007. Canada granted authorization to Apotex Inc. on 19 September 2007 to make, construct and use the patented inventions solely for the purpose directly related to the manufacture of ApoTriAvir and to sell it for export to Rwanda for a period of two years. See Canada’s notification of the TRIPS Council on 4 October 2007 available at [http://www.wto.org/english/news\\_e/news07\\_e/trips\\_health\\_notif\\_oct07\\_e.htm](http://www.wto.org/english/news_e/news07_e/trips_health_notif_oct07_e.htm), IP/N/10/CAN/1 of 8 October 2007. For more details on the facts surrounding the case, see South Centre/ CIEL Intellectual Property Quarterly Update, Third Quarter 2007 “Rwanda and Canada: Leading the Implementation of the August 2003 Decision for Import/ Export of Pharmaceuticals Produced under Compulsory License”, available at <http://www.southcentre.org/info/scielipquarterly/ipdev2007q3.pdf>. For a detailed account of trade related aspects of intellectual property and access to medicines, including the use of the paragraph 6 solution, see Spennemann C, Roffe P and Vivas-Eugui (forthcoming). Intellectual property: trade and beyond: the case of health and international standards. Institute for European Studies, Macao (China).

<sup>104</sup> For a thorough discussion about when this provision is applicable, please see the relevant section in the UNCTAD–ICTSD Project on IPRs and Sustainable Development, *Resource Book on TRIPS and Development*. Cambridge University Press, New York, 2005.

<sup>105</sup> See Watal J (2001). *Intellectual Property Rights in the WTO and Developing Countries*. Kluwer Law International, The Hague: 203.

<sup>106</sup> Fink C (2005). Tightening TRIPS: The intellectual property provisions of recent United States free trade agreements. Trade note for the World Bank. February – <http://www.worldbank.org/trade>.

line is that article 39.2 does not clearly spell out such a requirement, and thus no such obligation. Along these lines, one could argue that the question of duration does not arise because the draft text of the TRIPS Agreement at Brussels had prescribed duration of five years, during which the test data may not be relied upon by regulatory authorities, unless the person submitting the test data agrees. But in the final TRIPS Agreement, there is no such provision, suggesting that the negotiators had decided against prescribing a specific duration. Again, the question of reliance by regulators on the test data is something that is not prohibited by the agreement. All that article 39.3 says is that there is an obligation to protect undisclosed test or other data against unfair commercial use. Of course, arguments could also be made to the contrary.

The main question, therefore, hinges on what constitutes “unfair commercial use”. This is even more important as one interpretation of this provision might be that “fair commercial use” would be acceptable. Clearly, “unfair commercial use” would have to involve some dishonest or unethical steps by the second or third applicant. It is impossible to conceive that the action of regulatory authorities to rely on undisclosed test or other data submitted by the first applicant in clearing the marketing approval of the second/third applicant can be considered as “unfair commercial use”.

To sum up, there is no clear obligation flowing from article 39.3 of the TRIPS Agreement as regards the duration of data exclusivity. This suggests that regulatory authorities are free to rely on the data submitted to them by the first applicant in clearing the marketing approvals for the second or the third applicant as long as the undisclosed or other data is protected against unfair commercial use and disclosure. This interpretation of article 39.3 has implications for public health and access to medicines for all, since faster entry of the second and/or third applicants on the scene, including generics, will lead to greater competition and lowering of the prices of medicines. The potential of generics is evident as research reveals that high-cost medicines no longer protected by patents are coming under growing pressure from lower-cost generic equivalents. The analysis reveals that there is considerable scope for generics companies to further reduce the dominance of the global pharmaceutical industry by launching lower-cost copycat drugs.<sup>107</sup>

In that context, however, it is important to recall that many bilateral agreements do not offer this flexibility for expeditious market entry of generics. In fact, most of the bilateral agreements signed by the United States explicitly mandate test data exclusivity as provided for under United States law (5 years for pharmaceutical data and 10 years for agrochemical data).<sup>108</sup> Several United States bilateral agreements go even further, providing for an additional three-year data exclusivity period triggered by new clinical data, or ensuring that test data exclusivity applies automatically in all FTA jurisdictions, once a company submits test data to a drug regulatory in one territory – even outside the FTA area.<sup>109</sup>

#### **4. The protection of traditional knowledge, genetic resources and folklore**

Issues related to the protection of traditional knowledge, genetic resources and folklore are of paramount importance for developing countries. Traditional (and indigenous) knowledge (TK)<sup>110</sup> has been used for centuries by indigenous and local communities under

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<sup>107</sup> Off-patent drugs coming under growing pressure from generics, Financial Times, 20 November 2006.

<sup>108</sup> Once a company has submitted original test data, no competing manufacturer is allowed to rely on these data for a period of five years to request marketing approval for its own drug.

<sup>109</sup> Some FTAs prevent regulatory authorities from recognizing test data submitted to a drug regulatory agency in another territory. Fink C (2005). Tightening TRIPS: The intellectual property provisions of recent United States free trade agreements”, Trade note for the World Bank. February – <http://www.worldbank.org/trade>.

<sup>110</sup> For purposes of this paper, the term “traditional knowledge” also covers “folklore”.

local laws, customs and traditions. It has played and still plays an important role. With its widespread use in traditional medicines and farming, it has an impact on food security, the development of agriculture and medical treatment. There is growing recognition of TK as a valuable type of knowledge. Similarly, the important contribution of genetic resources to pharmaceutical and other products is increasingly recognized.

However, at the time of the Uruguay Round, these issues had not yet occurred centre stage. Genetic resources figured only indirectly in the TRIPS negotiations, with the debate centring on whether or not living organisms can be patented. As regards TK, the issue only arose later.

It is ironic however, that in the 1990s, after the TRIPS Agreement was finalized, a few controversial cases of granting patents involving both traditional knowledge and genetic resources brought the issues to the fore. The landmark cases of “Turmeric”, “Neem” and “Ayahuasca” are well known and set the debate rolling. In addition, already prior to the adoption of the TRIPS Agreement, countries had agreed on the Convention on Biological Diversity (CBD) of 1992, which seeks to promote the conservation of biodiversity and the equitable sharing of benefits arising out of the utilization of genetic resources. These developments provided the context in which developing countries brought issues related to the IP protection of TK, genetic resources and folklore to the WTO TRIPS Council.<sup>111</sup>

There is a feeling that there is a lack of balance in the current IPR system as enshrined in the TRIPS Agreement and various WIPO treaties. One type of IP – that generally produced and owned by entities in developed countries – is well protected. That category of IP in which developing countries have comparative advantage, namely TK, is generally considered free for all takers.

While it is hard to agree on a clear definition of what is or what is not traditional knowledge, there is, however, some consensus on why there is an imperative need to protect traditional knowledge.<sup>112</sup> The reasons range from equity considerations, conservation concerns, preservation of traditional practices and culture, prevention of misappropriation of traditional knowledge and, finally, the promotion of its use for development.<sup>113</sup> When considering the protection of traditional knowledge, two aspects merit particular consideration: (a) how to prevent misappropriation or biopiracy; and (b) how to enhance the exploitation of traditional knowledge for development.

**Misappropriation or biopiracy:** Misappropriation of traditional knowledge or biopiracy, became the focus of attention with the first grants of patents involving traditional knowledge (especially relating to genetic resources) without the consent of the possessors of the resources and the knowledge.

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<sup>111</sup> For particularly valuable reference material on these issues, see Correa C (2001). *Traditional knowledge and intellectual property – issues and options surrounding the protection of traditional knowledge*. Discussion paper commissioned by the Quaker United Nations Office, Geneva. See also “Report of the Commission on Intellectual Property Rights” which came out in September 2002 and which has a separate chapter devoted to the subject, available at: [http://www.iprcommission.org/graphic/documents/final\\_report.htm](http://www.iprcommission.org/graphic/documents/final_report.htm). See also Twarog S and Kapoor P (eds.) (2004). *Protecting and Promoting Traditional Knowledge: Systems, National Experiences and International Dimensions*. United Nations, New York and Geneva; and Twarog S (2003). *Preserving, protecting and promoting traditional knowledge: national actions and international dimensions*. In *Progressing Towards the Doha Development Agenda: Selected Papers on Trade and Development Research Issues for Asian Countries*. International Institute for Trade and Development in cooperation with the Asian Development Bank and UNCTAD. Thailand. October.

<sup>112</sup> It is now well recognized that traditional knowledge encompasses very different types of knowledge. WIPO, for example, uses the term to refer to a whole range of tradition-based works, inventions, scientific discoveries, performances, designs, marks, names and symbols, etc. resulting from intellectual activity in the industrial, scientific, literary or artistic fields – <http://www.wipo.org>.

<sup>113</sup> See Section 2 of Correa C (2001).



The first such case was the one involving turmeric<sup>114</sup> where, in 1995, two Indian nationals at the University of Mississippi Medical Centre were granted a patent on the “use of turmeric in wound healing”. This caused outrage in India and elsewhere because the use of turmeric in wound healing was known for centuries in India to all and sundry. It was impossible to see how this could amount to an “invention” qualifying it for grant of a patent. The Indian Council of Scientific and Industrial Research requested the United States Patent and Trademark Office to reexamine the patent, which they did and the patent was revoked. However, this did not happen before the Indian Council submitted documentary evidence of traditional knowledge and spent time, money and effort. Since then, there have been several other cases of biopiracy<sup>115</sup> and a series of trends are emerging and lessons can be learnt.

One is that, in most cases, the “owners” of the traditional knowledge in question were not involved – much less consulted – in the decision to grant the patent. Another emerging trend is that much of the TK in question originated in developing countries but the patents were filed in developed countries. A third emerging trend is that the patents were “wrong” patents because they did not fulfil the novelty or the inventive step criteria outlined in the TRIPS Agreement for patentability. Such “wrong patents” may happen either because the patent examiner did not have access to the knowledge or due to oversight. Criteria of novelty and innovative step are particularly not met as regards something that has been in the public domain for long and can hardly qualify as an invention.<sup>116</sup> Alternatively, patents are sometimes granted to things which are little more than discoveries. Either way, the result is prejudicial to the “owners” of traditional knowledge.

Over time, the above trends, particularly the North–South divide originating from the “ownership” of traditional knowledge, led to further aggravation of negative perceptions about the TRIPS Agreement, which was already seen as suffering from a “development deficit”. Ironically, the argument about “wrong” or “bad” patents is that the standards for granting patents in developed countries are too low and that the criteria of novelty and innovative step are not being met. Thus, the implicit argument made by developing countries is that there must be stricter standards for the criteria of novelty and innovative step, so that patents are not granted when involving misappropriation and biopiracy.

**Exploitation of traditional knowledge for development:** While misappropriation of traditional knowledge clearly must be prevented, this does not yet necessarily lead to pro-development outcomes for the “owners” of traditional knowledge.

The key to understanding the exploitation of traditional knowledge for sustainable development may be found in the Convention on Biological Diversity (CBD).<sup>117</sup> The CBD asserts the sovereign rights of nations over their national resources and their right to determine access to these resources. It further notes that access to genetic resources should be on the basis of prior informed consent (PIC) and on mutually-agreed terms. It also calls for the fair and equitable sharing of the benefits derived from the use of traditional knowledge

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<sup>114</sup> For details, see relevant chapter in Commission on Intellectual Property Rights (2002), “Integrating Intellectual Property Rights and Development Policy”, London, September – [http://www.iprcommission.org/graphic/documents/final\\_report.htm](http://www.iprcommission.org/graphic/documents/final_report.htm)

<sup>115</sup> For a description of potential cases of biopiracy, see WTO: IP/C/W/458: Analysis of Potential Cases of Biopiracy. *Communication from Peru*.

<sup>116</sup> An additional complication is that the United States patent law, for instance, does not recognize oral traditions of knowledge as prior art and insists on documentary evidence. Even in the turmeric case, it was entirely fortuitous that the Indian Council was able to get hold of an ancient Sanskrit text in addition to a paper published in 1953 in the *Journal of the Indian Medical Association*. But what if there was no written or documentary evidence? This is an issue that needs to be addressed since in the case of traditional knowledge, much of it is oral and word-of-mouth.

<sup>117</sup> For the full text of the Convention, please see: <http://www.biodiv.org/convention/articles>.

(EBS). Most importantly, the CBD states that patents and other IPRs may have an influence on the convention's implementation and governments should cooperate to ensure that such rights are supportive of and do not run counter to the CBD's objectives.<sup>118</sup> As such, the CBD offers some framework to ensure that traditional knowledge brings about development benefits. This suggests identifying some specific measures (to be taken at different levels and by various actors) which would further proper implementation of the CBD, with a view to ensuring that traditional knowledge bring about development benefits. Much research is undertaken – in different forums – on possible options for pursuing these objectives.<sup>119</sup>

One step (to be taken by “owners” of traditional knowledge) is to document it by translating the knowledge to its written word.<sup>120</sup> It has to be noted, however, that this step is particularly – if not only – suitable in situations where TK is not only clearly in the public domain, but also has entered the public domain with the fully informed consent of the owners of the TK. The case of Ayurveda medicines could serve as an example of a situation favourable to this approach. In fact, India is following this method by building a Traditional Knowledge Digital Library (TKDL). The TKDL project is initially targeting Ayurveda and the idea is to document the knowledge available in public domain in digitized format. The purpose of TKDL is to give legitimacy to existing traditional knowledge. By making it easier for patent examiners to retrieve traditional knowledge-related information, this will help to prevent the granting of “wrong” patents. Indeed, once the information is available to patent examiners in retrievable form, the onus must be on the authorities granting patents to make sure that the criteria for patentability are strictly observed. In addition, countries that include only domestic use in their definition of prior art should change the respective provisions so as extend prior art to other countries.

**Box 8. Examples of national law, including disclosure and prior informed consent**

The Indian Patent Act (second amendment adopted in 2002) provides that the patent applicant must disclose the source of origin of the biological material used in the invention. In fact, it goes one step further by allowing for opposition to the patent application to be filed on the grounds that it does not disclose or wrongly mentions the source or geographical origin of the biological material used in the invention. Indeed, the grounds for rejection of the patent application under the Indian patent law include non-disclosure or wrongful disclosure of the source of origin of biological resource or knowledge in the patent application, and prior disclosure of knowledge, oral or otherwise.

Similarly, in the case of Brazil, the grant of industrial property rights by the authorities for a process or a product obtained using components of the “genetic heritage” is dependent on the applicant fulfilling its obligation to specify the origin of the generic material and the associated traditional knowledge.

The Andean Group of countries also provided for legislation whereby applications for patents will have to be accompanied by a copy of the contract for access, if the products or processes for which a patent application is being filed were obtained or developed from genetic resources originating in one of the member countries. If applicable, the applicant shall also submit a copy of the document that certifies the licence or authorization to use the traditional knowledge of the indigenous communities of these countries.

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<sup>118</sup> For a discussion of the legal relationship between the TRIPS Agreement and the CBD, see chapter 6 of Mann H and Porter S (2003). *The State of Trade and Environmental Law 2003 – Implications for Doha and Beyond*, ed. by The International Institute for Sustainable Development and The Center for International Environmental Law, Winnipeg, Canada.

<sup>119</sup> Report of the UNCTAD-Commonwealth Secretariat Workshop on Elements of National *Sui Generis* Systems for the Preservation, Protection and Promotion of Traditional Knowledge, Innovations and Practices and Options for an International Framework, United Nations, New York and Geneva, 2005;

<sup>120</sup> Pending the documentation of traditional knowledge, countries must take into account the unwritten nature of most traditional knowledge.

The second step is to see if – as a matter of principle – patents should be refrained in cases involving genetic resources and traditional knowledge, unless the criterion of inventive step has been fully and properly met. Once the traditional knowledge has been codified and documented, it should be possible for the patent examiners to pay special attention to this aspect, without too onerous a burden.

A third step would be to establish a proper regime for disclosure. The idea is to have patent applications disclose the origin of genetic resources and traditional knowledge. In addition, the patent application shall also reflect compliance with national laws, consent of authorities concerned as well as equitable benefit sharing. It is encouraging to note that some national laws have already taken steps in this regard. What if “wrong” or “bad” patents are still granted? It may be worthwhile considering a regime where such patents, if granted, would be immediately revoked upon presentation of information, together with a provision for compensation to be worked out for the injured party. Among all the proposals made for prevention of misappropriation of traditional knowledge, the most significant one involves the establishment of a disclosure of origin obligation in the TRIPS Agreement.

In fact, for many developing countries, the WTO TRIPS Council is *the* relevant international body that needs to take steps to ensure that misappropriation and biopiracy is prevented from occurring, because it is the only body that enforces the rights of patent holders. Some developed countries (e.g. the EU, Norway and Switzerland) have responded somewhat positively, showing some willingness – in principle – to address these issues in the context of either WTO or in WIPO. Others – notably the United States and Japan – remain opposed, emphasizing that there is no conflict between the CBD and the TRIPS Agreement.

Over time, much research has been conducted about what are different options for using disclosure as a tool to avoid misappropriation and biopiracy. Valuable work has also been undertaken in intergovernmental organizations and agreements, including UNCTAD and the CBD. In the CBD, for example, in February 2004, the Conference of the Parties (CoP) mandated the Ad Hoc Open-ended Working Group on Access and Benefit-sharing to carry out negotiations on the proposed regime, and agreed on the terms of reference for such negotiations. In response to a request by the Seventh Conference of the Parties of the Convention on Biological Diversity, UNCTAD commissioned a study entitled *Analysis of Options for Implementing Disclosure of Origin Requirements in Intellectual Property Applications* (UNCTAD/DITC/TED/2005/14). Written by Carlos Correa and Joshua Sarnoff, this study calls for an international system of mandatory disclosure of origin requirements in intellectual property applications to prevent misappropriation of genetic resources and TK, promote compliance with CBD access and benefit sharing (ABS) requirements and prevent misuse of the IP system. The paper (a) outlines model provisions for such requirements, options for application-procedure triggers, and incentives for enforcement; (b) discusses the relationship with WIPO-administered treaties; and (c) addresses intellectual property issues raised by international certificates of origin. It highlights practical solutions that achieve the objectives while minimizing administrative burdens of implementation.

In the WTO TRIPS Council, developing countries have put forward a series of communications regarding TRIPS and biodiversity, to the effect that the TRIPS Council has undertaken useful work on this subject. More specifically, the TRIPS Council has grouped three (standing) agenda items into a “Triple Agenda Item” on Biodiversity, under which members regularly address the following issues: (a) the review of the provisions of article 27.3 (b); (b) the relationship between the TRIPS Agreement and the CBD; and (c) the protection of traditional knowledge and folklore. In essence, this includes work according to

paragraph 19 of the Doha Ministerial Declaration, which is one of the declaration's key references to the so-called implementation issues.<sup>121</sup>

Most of the debate has focused on whether or not to amend TRIPS to require applicants to disclose the country of origin and source of any genetic material or TK used either in research and development, or directly in the invention for which a patent is sought. The issues to be disclosed could include, amongst others, evidence of prior informed consent (PIC) of the country/community, and the manner in which the patent applicants intend to share the benefits arising from the commercialization of the invention with the country/community of origin. Other countries, however, assert that including such requirements into the TRIPS Agreement would prove ineffective, and that a contract-based and national law-based solution was needed. At some point it seemed as if members could agree on including a compromise regarding a disclosure requirement in the TRIPS Agreement, but no agreement could be reached on views on the other two issues -namely prior informed consent and equitable benefit sharing.

In the TRIPS Council's formal and informal meetings prior to WTO's 2005 Hong Kong (China) Ministerial, a group of developing countries argued that there was momentum in the discussion, and reiterated that the requirements concerning disclosure of origin and legal provenance of genetic resources of traditional knowledge should be included in the Hong Kong (China) Ministerial Declaration in the context of an amendment of the TRIPS Agreement.<sup>122</sup> In that context, India also proposed a paragraph for the Hong Kong (China) Ministerial Declaration suggesting that "negotiations shall be undertaken on the relationship between the TRIPS Agreement and the Convention on Biological Diversity", which shall cover, *inter alia*, "the details of the mandatory requirements on patent applicants to disclose...", as well as prior informed consent and benefit sharing. However, again, consensus has proved elusive. Developed country members, including the United States and Japan, made clear that further discussions are needed at the technical level, given that there were diverging perspectives among members.

Ultimately, the Hong Kong (China) Ministerial Declaration contains two paragraphs relating to TK. Paragraph 44 addresses negotiations according to paragraph 19 of the Doha Declaration (implementation issues), amongst which issues regarding the relationship between TRIPS and the CBD (as well as the protection of traditional knowledge and folklore, the review of article 27.3 (b), and the review under article 71.1). In this paragraph 44, ministers "take note of the work undertaken by the Council for TRIPS pursuant to paragraph 19 of the Doha Ministerial Declaration and agree that this work shall continue...". Another reference is contained in paragraph 39 (implementation) of the Hong Kong (China)

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<sup>121</sup> More specifically, paragraph 19 of the Doha Ministerial Declaration states: "We instruct the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this declaration, to examine, *inter alia*, 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. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension."

<sup>122</sup> See Ecuador, Colombia, Bolivia, and India supporting Peru with its Communication IP/C/W/447: article 27.3(b), Relationship between the TRIPS Agreement and the CBD and Protection of traditional knowledge and folklore. *Communication from Peru*. Also, Brazil made a strong statement calling for negotiations, referring, amongst others, to the fact that the TRIPS Council had undertaken significant technical work on the basis of the March 2004 checklist, that by now it was widely recognized that an international, mandatory, disclosure regime in the patent system would be an efficient solution for misappropriation; that in line with paragraph 12 and 19 of the Doha Declaration and the development dimension contained therein, the council should now progress from technical issues towards negotiation; and that ministers in Hong Kong, China, should make a statement to that effect.

Ministerial Declaration, where ministers “reiterate the instruction” of the 2004 July Package to the bodies concerned “to redouble their efforts to find appropriate solution as a priority to outstanding implementation-related issues”. Ministers also “take note of the work undertaken by the Director-General in this consultative process on all outstanding implementation issues... including... those related to the relationship between the TRIPS Agreement and the Convention on Biological Diversity”. Ministers further requested the Director-General to intensify his consultative process, and to do regular reporting, and the Council to “review progress and take any appropriate action no later than 31 July 2006”.

Thus, despite developing countries’ efforts to obtain a clear negotiating mandate to bring the TRIPS Agreement more in line with the CBD (amongst others, by including provisions for mandatory access and benefit sharing, prior informed consent, etc.) the language in the ministerial text mainly “takes note” of the work undertaken by the TRIPS Council. It now remains to be seen what, specifically, will be achieved in the context of implementing the above mandates.

In May 2006, Brazil, Pakistan, Peru, Thailand and the United Republic of Tanzania, supported by China and Cuba, formally submitted (to the WTO’s General Council) a proposal to amend the TRIPS Agreement (WT/GC/W/564). A key component of the proposal is to start text-based negotiations on a new article *29bis* in the TRIPS Agreement, as an addition to article 29 (the latter entitled “Conditions on Patent Applicants”). The proposed new provision would expand this obligation, requiring patent applicants to disclose both the country providing the biological resources and related traditional knowledge and the country of origin. In addition, patent applicants would have to produce evidence of compliance with requirements in the providing country on prior informed consent to access the genetic resources, as well as fair and equitable benefit sharing. According to the proposal, failure to comply with these requirements should result in consequences within the patent system, i.e. interrupting the process of the patent application or revoking the patent granted.

It is this latter point that distinguishes the developing countries’ proposal from a more recent submission by Norway, which was presented to the TRIPS Council on 14 June (WTO document IP/C/W/473). Norway, while supporting the idea of starting text-based negotiations on a new provision on disclosure of genetic resources and traditional knowledge in patent applications, is opposed to the revocation of patents in case of non-respect of the new disclosure obligation. According to the Norwegian submission, sanctions should be of administrative and/or criminal character, such as the imposition of fines. By contrast, Norway proposes the same pre-grant remedies as the above developing country submission (i.e. interruption of the patent application process).

Countries such as Brazil and India welcomed the Norwegian proposal as leading towards the right direction. Other members, in particular the United States and Japan, however, made clear that they do not agree on the need to negotiate an amendment to the TRIPS Agreement. Along these lines, Japan introduced a submission (WTO document IP/C/W/472), reiterating that any obligations to disclose genetic resources and related traditional knowledge in patent applications should be established through contracts between the providing state and the inventor. Japan suggested that the risk of patents being granted inappropriately could be reduced by means of a global database related to genetic resources and traditional knowledge, which would allow patent examiners to better verify claims of novelty and inventive steps in patent applications. Several developed countries expressed their support for the database proposal, including Canada and the United States.

It remains to be seen what the outcomes will be, which developing countries will be in favour of strengthening the TRIPS Agreement – or using the international IP regime – in the area of TK, and what biodiversity will achieve. Besides pursuing their objectives in the TRIPS Council, developing countries could also pursue their objectives through action at the national or regional level. At the national level, for example, they could aim for putting in place legislation to make the grant of intellectual property rights contingent on disclosure of origin of genetic resources and traditional knowledge, as well as compliance with relevant laws regarding prior informed consent and equitable benefit sharing. Developing countries could also aim to strengthen such approaches at the regional level.<sup>123</sup>

In sum, many countries and communities worldwide are considering on how to best address this issue at the national, regional and international levels. TK is a complex and multifaceted issue. Therefore, a holistic approach is needed, comprising simultaneous actions at national and international levels.

## **5. Geographical Indications**

Article 22 of the TRIPS Agreement addresses geographical indications (GIs). Article 22 defines GIs as indications which identify a good as originating in the territory of a member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin. Thus, for a good to qualify for a GI, there must be a link between its quality, reputation or other characteristic and its geographical origin. Protection of GIs refers to protection against the use of such a geographical indication for products not originating from the area to which the indication refers. In other words, it is the “right to exclude others” that grants protection for legitimate holders of GIs.<sup>124</sup>

There are several reasons for granting such protection. Besides obvious trade, commercial and competitive advantages, there is a need to inform consumers and not mislead them. The cross-cutting, overall intention is to exclude those, who may imitate the product, from the use of the GI.

Article 22 of the TRIPS Agreement provides basic protection to GIs of all goods.<sup>125</sup> The key obligation in article 22 is for all WTO members to provide the legal means for interested parties to prevent the misrepresentation of a good that indicates or suggests – in a manner which misleads the public – that it originates in a geographical area other than the true place of origin. In other words, for an action to be a violation of article 22 of the TRIPS Agreement, there has to be misrepresentation of the GI of a good in such a way so as to mislead the public. If, hypothetically speaking, Beaujolais wine say, produced in China is sold just as “Beaujolais wine”, it would then be a violation of article 22 because the consumer might be misled into believing that it is Beaujolais from France. But if this wine is sold as “Beaujolais, made in China”, the public has not been misled and hence it would not be a violation of article 22 of the TRIPS Agreement.

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<sup>123</sup> For an attempt to use regional trade agreements along these lines, see the experience of Peru when negotiating a free trade agreement with the United States (see chapter on TRIPS-plus in this paper).

<sup>124</sup> Protection of GIs has to be distinguished from protection of trademarks, which originate in the Anglo-American legal tradition of protecting a specific, individual producer producing a particular product. GIs in turn are typical for the European context, and they constitute a collective mark, referring to a region. Over time, Anglo-American IP laws have frequently included a chapter on “collective marks” (i.e. trademarks), into their trademark laws. Thus, as opposed to trademarks, GIs are characterized by the absence of a “particular owner”.

<sup>125</sup> For a description of the WTO regime on GIs, see Bullbrook J (2004). Geographical indications within GATT. In *Journal of World Intellectual Property Rights*. Vol. 7. No. 4, July.

However, the TRIPS Agreement contains more than article 22. In fact, article 23 complements article 22 insofar as it provides a higher level of protection for GIs for wines and spirits. To take the above Beaujolais example, if the good is sold as “Beaujolais, made in China”, it would then be a violation of article 23, even though it is not a violation of article 22. Not just that – even if the good were sold as “Beaujolais-type wine, made in China”, that too would violate article 23. This, then, is the additional (higher) GI protection that is granted to wines and spirits under article 23 of the TRIPS Agreement. In other words, when it comes to wines and spirits, WTO members have to provide legal means to prevent use of a GI identifying wines and spirits, for those wines and spirits which do not originate in the place indicated by the GI in question. And unlike in article 22, a producer cannot escape this protection by indicating the true origin of the good or using expressions such as “kind”, “type”, “style”, “imitation” or the like. In sum, under article 23 it is not necessary for a complainant to show consumer confusion or an act of unfair competition, while it is sufficient to show that the product benefiting from the protected GI does not originate in the indicated area.

In sum, a producer of Beaujolais or Champagne would, under article 23, be able to ensure that no one outside the region in France produces the wine or spirit and sells it under the name of Beaujolais or Champagne. On the other hand, the maker of either Swiss knives or the producer of Basmati Rice or of Ceylon Tea cannot prevent other producers anywhere in the world marketing the products as say, Chinese Swiss knife, American Basmati rice or British Ceylon Tea. This is because only wines and spirits are covered by article 23 of the TRIPS Agreement and products such as knives, tea, rice, etc., are not covered by this provision.

This begs two fundamental questions: (a) Why does article 23 grant higher protection? And, more importantly, (b) Why does it grant such higher protection only to wines and spirits and why not to other products? The blunt answer to the first question is simply that such higher protection was sought by the European Community (EC) and that it was almost exclusively negotiated by the EC and Switzerland on the one hand and the United States on the other.<sup>126</sup> It is widely believed that the EC secured this concession of higher protection on wines and spirits from the United States in response to some concessions granted by it in agriculture. Whatever the truth, GIs are an area where a large number of other countries simply did not participate meaningfully in the negotiations. The answer to the second question is a related one, as it is almost impossible to justify why wines and spirits alone should qualify for the higher protection and not other products. One explanation is that there was a “deal” to that effect in the Uruguay Round.

The consequence of that “deal” is that there is an imbalance in the section on GIs in the TRIPS Agreement, with the higher protection in article 23 favouring wine and spirit producers, but nothing else.

This imbalance by itself is difficult to justify. However, over time, this imbalance also contributed to the “development deficit” of the TRIPS Agreement. In fact, some (though not all) developing countries realized that their products too could gain considerably, if they secured the higher level of additional protection provided in article 23. Two classic examples in this regard are India’s Basmati Rice and Sri Lanka’s Ceylon Tea. For both these products, protection as provided in article 22 was insufficient because it did not prevent other countries from selling “Basmati Rice made in USA” or “Ceylon Tea produced in UK”.

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<sup>126</sup> See chapter on GIs in Watal J (2001). *Intellectual Property Rights in the WTO and Developing Countries*. Kluwer Law International, The Hague.

It was against this background that, some time in early 2001, a coalition of countries emerged in WTO calling themselves “Friends of GIs”. The group was open to all countries that favoured extension of additional protection for GIs (such as the one provided in article 23) to products other than wines and spirits, and included both developing and developed countries: Bulgaria, Cuba, the Czech Republic, Egypt, Iceland, India, Jamaica, Kenya, Liechtenstein, Mauritius, Nigeria, Pakistan, Slovenia, Sri Lanka, Switzerland, Turkey and the Bolivarian Republic of Venezuela. The EC was also part of the group, although it did not always co-sponsor the proposals.

There are some unique aspects about the “Friends of the GIs”, both as regards the composition of the group and as regards the issues they are raising. First, the GI issue does not exhibit the type of North–South divide, as it often occurs in the WTO or TRIPS context. There are developing countries such as India and Sri Lanka that strongly favour extending additional protection to products other than wines and spirits, while there are developing countries such as Argentina and Chile, which vehemently oppose it. Rather than having a North–South dimension, some have characterized the issue as one between the “Old World” (including “Old Europe”) on the one hand, and the “New World” on the other.<sup>127</sup> Nevertheless, despite the fact that GIs are not a North–South issue, much of the GI debate is taking place in the context of the so-called “implementation” issues.

Second, while the agreement has been criticized for its development deficits, enhanced TRIPS protection for GIs would present developmental opportunities – at least for some developing countries. In that context, it is interesting that the developing countries in the “Friends of the GIs” are asking for strengthening of TRIPS in a particular area (GIs), whereas in other areas, the debate often goes in a different direction.<sup>128</sup> Finally, the participation of developing countries in the “Friends of the GIs” is a sign that developing countries are proactively setting the agenda in TRIPS negotiations. The problem, as will be explained later, is that for every country that fervently seeks to extend additional protection of GIs to products other than wines and spirits, there is another country that violently opposes it and wants retention of the status quo.

In May 2001, the “Friends of GIs” put forward their proposal,<sup>129</sup> the purpose of which was to demonstrate:

- Why the level of protection provided by article 22 of the TRIPS Agreement for GIs is not sufficient;
- Why providing two different levels of protection for GIs as in articles 22 and 23 of the TRIPS Agreement is totally unjustified; and
- Why the extension of the protection of GIs for wines and spirits to one uniform and common level of protection for GIs is necessary in order to conform to the section on GIs in the TRIPS Agreement and to general WTO principles.

The submission by the Friends of GIs argues cogently why article 22 protection is insufficient. For instance, (a) article 22 condones free-riding on the renown of a GI; (b) it gives rise to legal uncertainty, since it is up to national courts and administration to decide

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<sup>127</sup> Cortes Martin JM (2004). The WTO TRIPS Agreement – the battle between the Old and the New World over the protection of geographical indications. In *Journal of World Intellectual Property*. Vol. 7, No. 3, May.

<sup>128</sup> Interestingly, however, developing countries’ demands as regards biodiversity related issues, also tend towards an overall strengthening of IP standards.

<sup>129</sup> See WTO (2001). Extension of the protection of geographical indications for wines and spirits to geographical indications for other products. *Proposal from Bulgaria, Cuba, the Czech Republic, Egypt, Iceland, India, Liechtenstein, Mauritius, Nigeria, Sri Lanka, Switzerland, Turkey and the Bolivarian Republic of Venezuela*, IP/C/W/247/Rev.1, 17 May.



whether or not the public is being misled; (c) article 22 also puts the burden of proof on the producer entitled to use a GI; and finally, (d) article 22 does not prevent “usurpation” of a GI by trademarks. To conclude, the proponents argue that there is no substantive justification for discriminatory treatment between GIs for wines and spirits and those of other products.<sup>130</sup>

On the other hand, there are a number of countries that do not want an extension of additional protection of GIs to products other than wines and spirits. The group being led by Australia, Chile, Mexico, Canada, the United States and Argentina comprises countries that are already producing a number of products sold under GI-type names (e.g. Gouda Cheese) while not produced in their respective countries (the Netherlands). Under the existing provision of article 22, it is perfectly possible for Argentina or Mexico to produce Gouda Cheese and market it worldwide. It is easy to see, therefore, that if cheese gets additional protection under article 23, these countries would then stand to lose commercially.

These countries make a number of valid arguments to buttress their case for retention of the status quo. First, they argue that products which have already become generic stand no chance of getting additional protection.<sup>131</sup> It is true, in fact, that quite a large number of products have either become or are in the process of becoming generic in important markets, making it impossible for them to get additional protection as GIs.

Second, they make the point that the costs of providing additional protection under article 23, for developing countries in particular, are quite high. In addition, they point out that, contrary to what counts for the EU and perhaps Switzerland, other proponents of additional extension of GIs, such as India, Sri Lanka, Cuba, Bulgaria, etc. have only a limited (sometimes only one or two) number of products of interest. As a result, the actual gains for these countries would be minimal. Finally, they say that the TRIPS Agreement is a done deal. From a negotiating strategy perspective, they do not want to see it reopened, as some fear that if this provision were opened up and strengthened, the same could happen with other provisions.

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<sup>130</sup> For a discussion on aspects related to the agriculture negotiations see Vivas-Eugui D (2001). Negotiations on geographical indications in the TRIPS Council and their effect on the WTO Agricultural Negotiations – Implications for Developing Countries and the case of Venezuela. In *The Journal of World Intellectual Property*. Vol. 4, No. 5, Geneva, September.

<sup>131</sup> Note that article 24.9 of TRIPS states that “[t]here shall be no obligation under this agreement to protect geographical indications which are not, or cease to be, protected in their country of origin, or which have fallen into disuse in that country.” As explained in chapter 3.3.9 of the UNCTAD/ICTSD Resource Book, “[t]his reflects the nature of GIs which depend on a link to a territory. If the link is broken, protection is lost. This rule presents some risk to the holders of GIs that are depending on the actions of administrative bodies in their territories, since action or inaction by those bodies may deprive the holders of rights they might have asserted based on public association of the GI with the product.” The “TRIPS and Development: Resource Book” is jointly produced by UNCTAD and ICTSD.

**Box 9. The WTO Panel ruling on EC–Geographical Indications**

On 15 March 2005, a WTO Panel issued its report in *EC–Geographical Indications*, the first case that concerns the legal regime of GIs. The ruling turned out to be a mixed one, causing both the complainants (Australia and the United States)<sup>132</sup> and the respondent (the EC) to claim victory and express their satisfaction. The Panel Report was not appealed.

The claims on the different provisions of the EC regulation on the protection of GIs for agricultural products and foodstuffs<sup>133</sup> were both numerous and technical in nature. Amongst the key issues addressed were the national treatment obligation with respect to GIs and the relationship between the protection of GIs and prior trademarks.

Although the case may not have direct relevance for the specific issues under negotiation,<sup>134</sup> it provides valuable clarifications of the relevant TRIPS provisions on GIs and helps us to better understand how they operate. The case demonstrates that current disciplines on GIs are quite specific and that, accordingly, countries have few policy choices when implementing them. On the one hand, one could argue that, since the case highlights certain implementation difficulties for a member with a very elaborate system of IP protection (such as the EC), developing countries *a fortiori* may have difficulties in this respect. On the other hand, one could also argue that the case provides guidance for how to interpret rules on GIs in a TRIPS-consistent manner, thereby enhancing legal predictability in the context of GI protection. More broadly, Switzerland and the EC also refer to GI issues in WTO's negotiations on agriculture, essentially framing them as non-trade issues.

*Source:* See WTO, Panel Reports, “European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs. WT/DS174/R, *complaint by the United States*, 15 March 2005; WTO, Panel Reports, “European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs”, WT/DS290/R, *complaint by Australia*, 15 March 2005, both adopted 20 April 2005.

Given the strength of the arguments on both sides, it is difficult to see how a common negotiating mandate can be worked out to pursue negotiations. Proponents of extending additional protection of GIs to products other than wines and spirits insist on a mandate contemplating the application of the higher level of protection for GIs in article 23 to products other than wines and spirits and on changes in article 23.4 and article 24 on a *mutatis mutandis* basis. They also argue in favour of an understanding among WTO members that – pending the launch of negotiations – GIs from developing countries will not be declared “generic” by developed countries. Finally, they would like to see an undertaking that trademarks and patents will not be granted in the case of GIs unless there is overwhelming evidence that the quality, reputation or other characteristic of the good is *not* essentially attributable to its geographical origin.

Even assuming that a negotiating mandate can be agreed upon, there are some questions that will need to be tackled during the course of these negotiations. Should the protected products cover all products other than wines and spirits? Or should a list of products be negotiated using a combination of bilateral and multilateral means, similar to the sector-specific commitments in WTO's services agreement? What about the exceptions in article 24?

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<sup>132</sup> Due to some differences in the claims made by the two complainants, the panel, at the request of the EC, chose to issue two separate reports.

<sup>133</sup> EC, Council Regulation (EEC) No. 2081/92 of 14 July 1992. This regulation does not apply to GIs for wine and spirits, which, in the TRIPS Agreement, are subject to separate disciplines.

<sup>134</sup> The two specific issues under negotiation on GIs include (a) whether the stronger protection currently prescribed only for GIs for wines and spirits should be extended also to GIs for other products; and (b) the creation of a multilateral system of notification and registration of GIs for wines.

What about terms on which there is no agreement as to whether they are generic or not? And could some terms be generic in one market but not in another? In sum, many technical issues would need to be dealt with.

Members are, however, still far from an explicit negotiating mandate on the issue. Rather, despite the fact that the main *demandeur*, the EU, has pursued a three-pronged approach to an extended protection of GIs<sup>135</sup>, the Hong Kong (China) ministerial did not result in a significant move forward. In the Hong Kong (China) Declaration, paragraph 39 (implementation issues), members merely take note of the Director-General's work (his consultative process) on all outstanding implementation issues, including the extension of the protection of geographical indications to products other than wines and spirits. The paragraph also reiterates instructions contained in the 2004 July Package and a request to the Director-General to continue his consultative process (if need be, by appointing Chairpersons of concerned WTO bodies as his "Friends" or by holding dedicated consultations), mandating a review of progress and the taking of appropriate action no later than 31 July 2016. Not much, however, has happened since then.

In the light of the fact that negotiations have yet to take place, and that once launched, they may need to overcome a broad array of technical issues, WTO members who seek additional protection of GIs to products other than wines and spirits may wish to pursue complementary policies in the meantime. Such complementary policies could be put in place at various levels of policymaking, including the national and the bilateral levels.

At the national level, there is an imperative need to put in place a legislative framework for providing additional protection for GIs to products other than wines and spirits. The point is that, unless the product (for which higher protection is sought) is appropriately protected at "home", the case for protection abroad becomes difficult. In this regard, developing countries may need technical assistance, including from organizations such as UNCTAD.

Also, the bilateral route could prove useful for countries that seek additional protection of GIs to products other than wines and spirits. This is because a multilateral agreement in WTO, even if desirable, may prove to be time-consuming and difficult to negotiate. In fact, bilateral level action, possibly on an interim basis (pending the negotiation of a multilateral agreement) is likely to prove more beneficial for several reasons. First, the country aiming to extend additional protection for GIs will not only be able to choose products of interest, but also to choose the most attractive markets on which to focus its attention. Second, action at the bilateral level might help in preventing a GI from becoming "generic" in a specific market. Third, bilateral arrangements could also help to challenge – or at least defer (if not totally prevent) usurpation of the GI either through patents or trademarks.

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<sup>135</sup> More specifically, in the TRIPS Council the EU seeks the extension of GI protection to products other than wines and spirits (a so-called "implementation" issue); and the negotiation of a multilateral register of GI for wines and spirits (a negotiation issue). In addition, the EU pursues higher protection of GIs in the agricultural context, where it seeks the establishment of a "claw-back list" (prohibiting use of "generic" names, i.e. those used by producers other than right holders in country of origin).

**Box 10. TRIPS in the WTO July 2008 mini-Ministerial<sup>136</sup>**

Select TRIPS issues also played a role in the context of the WTO's July 2008 mini-Ministerial. More specifically, discussions intensified on the three TRIPS issues of (a) the multilateral system of GIs (notification and registration) for wines and spirits; (b) extension of stronger GI protection for all products; and (c) the disclosure requirement, including the relationship between TRIPS and the Convention on Biological Diversity (CBD) (the latter two being also "implementation" issues). In spring 2008, a group of more than 100 developed and developing countries called for "parallelism" among the three issues (which used to be on separate tracks), submitted a "draft modalities text" detailing "key parameters" for negotiating legal texts and suggested that IP issues be included in the "single undertaking". This was further pursued in the mini-Ministerial, where proponents called for initiation of negotiations for the GI extension, and for an inclusion in the TRIPS Agreement of a mandatory requirement for the disclosure of origin of biological resources and/or associated traditional knowledge in patent applications. However, little progress was made and, with differences persisting across countries (including as to whether these issues form part of a single undertaking and how to ensure parallelism) efforts focused on procedural issues that could help forge agreement on these issues in the future. TRIPS issues have important poverty-, development- and MDG-related implications, including through their impact on local communities (e.g. protection of and benefit sharing for biological resources and traditional knowledge), farmers (e.g. protection of GIs for agricultural products) and the environment/sustainable development.

To sum up, negotiations for an extension of additional protection of GIs to products other than wines and spirits are likely to be arduous and acrimonious. WTO has already witnessed strong arguments on both sides – in favour and against higher protection for GIs. The *demandeurs* may wish to increase their efforts in the context of possible next steps, bearing in mind the broader developments of the Doha Work Programme. In parallel, countries that are advocates of extending additional protection of GIs to products other than wines and spirits may be better off undertaking steps at both the national and bilateral levels to safeguard their interests in products of their choice and in markets which are attractive for them.

## **6. Competition-related provisions in the TRIPS Agreement**

It is widely acknowledged that IPR-based market power has the potential to restrain competition in relevant markets. There are, for example, concerns about cartel-like restraints, exclusionary conduct and monopoly leveraging by dominant firms, refusals to license IPRs or to sell IPR-protected products, practices or mergers which may chill technological innovation and possible effects of overly-broad IPRs. Competition rules can be used to control anti-competitive practices.

However, despite the general consensus on the need to carefully manage the competition policy/IPR interface, there remain important differences on specific issues. For example, competition and IPR authorities sometimes approach the IPR/competition interface from different perspectives. Moreover, as described above, some countries or regions – particularly developing countries – have rather limited experience in this area. There is therefore a need for consultations, technical assistance and international cooperation in this area.

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<sup>136</sup> See also Abbott F (2008). Post-mortem for the Geneva Mini-Ministerial: Where does TRIPS go from here? In ICTSD, information note No. 7. August.

The TRIPS Agreement contains numerous provisions relevant for issues related to competition policy (e.g. articles 6, 8, 31, 37 and 40). Most of these provisions are of a permissive character and stay silent on several points. Article 6, for instance, contains a “savings clause” providing that nothing in the agreement shall be used to address the issue of exhaustion of IPRs – with the choice of exhaustion being a central determinant for the competitive situation in a market.<sup>137</sup> The provision makes no attempt to harmonize exhaustion-related differences among WTO members, but rather grants important flexibilities for members regarding their choice between regional or international exhaustion, which should be considered in light of the considerable differences in members’ exhaustion regimes. A member’s choice of the exhaustion regime determines whether or not parallel importation<sup>138</sup> would be allowed upon first sale on the regional or on the international market, and obviously affects the degree of competition among distributors and the extent to which a consumer can shop around for a good price (see also section IV:3 of this paper).

Similarly, the TRIPS Agreement leaves it open to members whether or not to control abuses of IPRs, and whether or not to control practices which unreasonably restrain trade or adversely affect the international transfer of technology. However, should a member choose to exercise such controls, articles 8, 31 and 40 of the agreement place restrictions upon the type of measures which may be adopted and/or how these controls may be exercised.

The most open-ended of these provisions is article 8, paragraph 2, which declares that appropriate measures may be needed to prevent the abuse of IPRs or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology (provided that they are consistent with the provisions of the agreement). This paragraph would apply to measures taken under both competition rules and other types of rules aimed at preventing abuse of IPRs or resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology. The paragraph should be read together with the provisions of article 7, as well as with paragraph 1 of article 8 itself, which permits members to 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. Taking into account that article 8 is entitled “Principles”, it appears to provide a basis for the more detailed rules set out in other provisions (e.g. articles 31, 37 and 40) (see also section IV:2 of this paper).

Article 40 is central for competition-related issues. It recalls members’ agreement that certain licensing practices or conditions pertaining to IPRs which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology. According to article 40, nothing in the agreement shall prevent members from specifying in their legislation those licensing practices or conditions that may (in particular cases) constitute an abuse of IPRs and have an adverse effect on competition in the relevant market. Moreover, a member may adopt (consistently with the other provisions of the agreement) appropriate measures to prevent or control such practices (e.g. exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing). Finally, article 40 provides for mandatory consultations between members (upon request) in respect of certain competition policy actions. The provision on mandatory consultation covers situations where the request is addressed from the country taking action to the home country of the IP holder and vice versa. The home country would have to supply relevant publicly available non-

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<sup>137</sup> “Exhaustion” in the IPR context refers to the limits on the scope of an IPR’s exclusive rights over production, sale, importation or distribution of a protected product after its first sale by or with the consent of the right-holder.

<sup>138</sup> “Parallel importation” refers to the importation and resale in a country without the consent of the IP holder of a protected product which has been legally marketed in another country.

confidential information, as well as confidential information (subject to domestic law and to agreements for safeguarding confidentiality).

Articles 8 and 40 thus accept that members may take measures in respect of certain IP-related practices provided that such measures are consistent with the agreement and appropriate. Members would of course be free in any event to take any measures consistent with the agreement. However, such explicit “permissive” clauses may help to alleviate any concerns by developing country members that they would contravene the TRIPS Agreement should they adopt and/or apply such measures.

The “permissive effect” of article 40 is somewhat narrower than that of article 8.2. For example, article 40 only applies to licensing practices or conditions and not to other IP-related transactions which may infringe competition law<sup>139</sup> (although it is true that most competition cases do involve licensing transactions). Similarly, the types of licensing practices mentioned by article 40 are only examples and the article would also apply to certain other licensing practices.<sup>140</sup> (At the same time, in practice, the provision’s silence regarding such other practices may increase the chances that they will not be considered to be abusive in individual cases.) Finally, it appears that article 40 may not apply to a licensing practice which has adverse effects on trade and impedes the transfer and dissemination of technology – unless it also restrains competition and constitutes an abuse of an IPR. The assessment of the appropriateness of the measures taken is subject to WTO dispute settlement.

So far, developing countries (with a few exceptions) have not applied their competition legislation to the exercise of IPRs, whereas developed countries have extensive legislation, case law and/or guidelines applicable to the competition/IPR interface.<sup>141</sup> There are, therefore, concerns that WTO dispute settlement might assess the appropriateness of any measures taken by a developing country in the light of the standards prevailing in developed countries, rather than in the light of the developing country’s specific needs or of the recognition in article 7 of the TRIPS that IPRs should contribute to the transfer and dissemination of technology. There might also be a risk that, in a dispute, the assessment of the appropriateness of a measure would lead to “second-guessing” of competition authorities’ findings regarding the existence or the gravity of IPR abuse or adverse effects on competition in the relevant market.

Article 31 specifies conditions to be met where the law of a member allows compulsory licenses (see section 3 above). Such conditions include (a) prior attempts to obtain a voluntary license on reasonable terms (except in cases of a national emergency, other extreme urgency or public non-commercial use); (b) authorization on a case-by-case basis; (c)

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<sup>139</sup> Such practices may include, among others, (a) the acquisition of IPRs as part of a collusive scheme among competitors to acquire market power; (b) accumulating and enforcing every important IPR in a given market with a view to monopolize; (c) the use of patents acquired by fraud or inequitable conduct to exclude competition on a relevant market; (d) certain refusals to license IPRs or to supply protected products at all or in adequate quantity; (e) unfair practices in connection with industry standards constituting IPRs, bad faith enforcement or threats of enforcement of IPRs; (f) payments to manufacturers of generic drugs not to market competing generics upon the expiry of the patents concerned; or (g) mergers where the parties concerned hold IPRs relevant to the same markets.

<sup>140</sup> These would include, among others, (a) horizontal or vertical price maintenance clauses; (b) covenants not to compete during or after the expiration of the agreement; (c) cross-licensing or patent pooling amounting to cartelization; (d) restraints on customers, territories or distribution channels (which may be linked with restrictions upon parallel imports or export prohibitions); (e) exclusive dealing; (f) tying restraints (which may amount to coercive package licensing within the meaning of Article 40); (g) obligations to use a trademark; (h) restraints on research and development; or (i) undertakings not to challenge the validity of the IPR. Most of these practices would not be prohibited outright, but would be the subject of case-by-case economic analyses by competition authorities in the context of the overall transaction.

<sup>141</sup> See UNCTAD (2002). Competition policy and the exercise of intellectual property rights. TD/B/COM.2/CLP/22/Rev.1.

limiting the use under the compulsory license to the purpose for which it is authorized; (d) non-exclusive, usually non-assignable, use of the compulsory license, predominantly for the supply of the domestic market; (e) adequate remuneration for the right-holder; or (f) the availability of judicial or other independent review. However, two of the conditions (requiring efforts to obtain authorization from the right-holder and supplying predominantly for the domestic market) do not apply where the use is permitted to remedy a practice which (after judicial or administrative processes) has been determined to be anti-competitive. Under article 37, the article 31 provisions are applicable *mutatis mutandis* in respect of the use of layout designs of integrated circuits.

Thus, while articles 31 and 37 do not set out the *grounds* upon which compulsory licenses of patents and layout designs (of integrated circuits) may be granted, the articles implicitly accept both competition and non-competition-related grounds (for the case of patents, see the further reinforcement in the Doha Declaration on the TRIPS Agreement and Public Health). Moreover, they do not contain a requirement for the measure to be “appropriate”. One could argue, therefore that, compared to conditions for remedies set out in article 40, the *conditions* for granting compulsory licenses are less prone to challenge before WTO dispute settlement.

From a development perspective, it is notable that most developing countries still lack extensive competition legislation (or stop short of properly implementing it) and the respective case law and policy guidelines. Thus, in any work undertaken with a view to advance developing countries’ interests regarding the competition/IPR interface, the primary focus might therefore be on action at the national level. For instance, developing countries might consider:

- Building their knowledge and capacity for analysing and dealing with complex IP-related practices;
- Devising IP-related competition legislation according to their specific level of development and striving to properly implement it (e.g. choosing among divergent approaches followed in more experienced jurisdictions and adapting such approaches to their individual circumstances);
- Analysing the extent to which IP/competition problems are best addressed through case-by-case ex-post competition enforcement proceedings, advocacy by competition authorities to change the IP system and/or technical changes to the standards or procedures for patent grants, post-grant review and challenges to validity;
- Working towards the establishment of a body of case law and doctrine.

In so doing, developing countries would benefit from technical assistance and from participating in consultations and case-specific cooperation with their developed country counterparts. The experience and technical expertise accumulated in national action and international cooperation could bring important benefits. For example, it could (a) provide the basis from which to evaluate developing countries’ needs and interests; (b) enhance developing countries’ status as valid interlocutors and their bargaining power in international discussions, cooperation and eventual negotiations in this area; and also (c) establish precedents helping to influence conceptions regarding the appropriate means of dealing with the competition/IP interface. For such purposes, it would be important for developing countries to maintain flexibility and policy space to determine and apply the approaches best suited to their individual circumstances – hence a need for reflection regarding TRIPS-plus agreements. Similarly regarding cross-border case-specific cooperation on competition issues,

it is expected that the number of competition cases in developing countries involving IPRs of foreign firms will increase. Correspondingly, there will also be greater need for access to information in the home countries of these firms, or in other countries where they have been granted IPRs. Most likely, there will also be more need for international assistance with enforcement and moreover, some countries' markets may be affected by remedies mandated by the competition authorities of other countries.<sup>142</sup>

UNCTAD provides an appropriate forum and technical assistance to support action by developing countries in this area. Its mandate in the area of competition policy stems from the Set of Multilaterally Agreed Equitable Principles and Rules for the Control of Restrictive Business Practices, which has the political authority and legitimacy of a unanimously adopted General Assembly resolution.<sup>143</sup> The Set's provisions regarding the types of restrictive business practices from which enterprises should refrain broadly cover IPR-related practices. Moreover, article D.4 (e) of the Set contains an explicit reference to abuse of dominance through restrictions on parallel importation of goods under trademarks of the same origin where the purpose of such restrictions is to maintain artificially high prices. The resolution adopted by the Fifth Review Conference on the Set calls upon UNCTAD to study competitor/competition policy treatment of the exercise of IPRs,<sup>144</sup> which will be undertaken under the aegis of the Intergovernmental Group of Experts on Competition Law and Policy.

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<sup>142</sup> See TD/B/COM.2/CLP/22/Rev.1.

<sup>143</sup> General Assembly resolution 35/63 of 5 December 1980.

<sup>144</sup> See Resolution Adopted By The Conference At Its Closing Plenary Meeting On 18 November 2005, The Fifth United Nations Conference to Review All Aspects of the Set of Multilaterally Agreed Equitable Principles and Rules for the Control of Restrictive Business Practices, Antalya, Turkey, 14–18 November 2005, TD/RBP/CONF.6/14.



## V. Specific development-oriented provisions

### 1. Introduction

Specific development-oriented provisions, including differential and more favourable treatment of developing countries, have been a fundamental principle of GATT and WTO. Because of the disadvantaged starting position of developing countries, the international community had agreed that these countries should be subject to somewhat different rules and disciplines in international trade (compared to those that apply to developed countries) and that the latter would implement their obligations under GATT and WTO in ways that would be favourable to development.<sup>145</sup> This approach would be even more valid in the case of TRIPS, as it is widely acknowledged that different levels of IPR protection are suitable for different stages of the development. Thus, TRIPS should contain substantial S&D provisions.

The situation is, however, somewhat different. In fact, one fundamental issue regarding the architecture of the TRIPS Agreement is that it does not contain the typical structural elements of S&D, as do other trade agreements. Instead, the TRIPS Agreement specified the same standards of patents, copyrights, trademarks, etc., irrespective of whether the country concerned was the United States, EU, India, Brazil or China, or whether it was Albania, Saint Lucia, Barbados or Bangladesh. The 150 members of WTO had to do the same, *viz.*, conform to the same set of minimum standards in the various areas of IPRs.

The only concession granted to developing countries and least developed countries are certain transition periods, one article on technical cooperation,<sup>146</sup> and some references to technological objectives, particularly to measures for inducing the transfer of technology (ToT). This chapter will review the working of the TRIPS Agreement's development-oriented provisions, as well as the issues underlying them.

### 2. Transition periods

The main provision of the transitional period, granted to both developing countries and LDCs (and going beyond the transitional period for industrialized countries) relates to product patents. Paragraph 4 of article 65, which was intensely negotiated, specifies that developing countries (including LDCs) which did not extend product patent protection to certain areas of technology on the date of entry into force of TRIPS could enjoy an additional period of five years. Effectively, this meant that from the date of entry into force of the TRIPS Agreement, developing and LDC countries could get 10 years, in other words, until 31 December 31 2004. Thus, with the exception of the LDCs (see below), all other countries should, by now, have brought their legal frameworks in compliance with their TRIPS obligations.

Considering that this transition period constituted the TRIPS Agreement's main S&D element, it appears useful to question (a) the extent to which this central S&D tool has proven

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<sup>145</sup> Moreover, in the case of GATT, for instance, it was acknowledged that developing countries would exchange tariff concessions with developed countries, but that the latter did not expect reciprocity for commitments and did not expect the developing countries to make contributions which are inconsistent with their individual development, financial and trade needs. In the case of GATS, the "positive list approach", together with language in article XIX of GATS, ensures that individual developing country members have appropriate flexibility for opening fewer sectors, liberalizing fewer types of transactions and carrying out progressive liberalization in successive rounds of negotiations.

<sup>146</sup> Article 67 of the TRIPS Agreement is devoted to technical cooperation, in order to facilitate the implementation of the agreement. The last years have seen discussions about the nature and value, as well as the developmental implications of technical assistance activities provided in the realm of IPRs. See, amongst others, Pengelly T. Technical assistance for the formulation and implementation of intellectual property policy in developing countries and transition economies. IPR Issue Paper No.11, ICTSD.

useful; (b) what was its scope; (c) how many countries availed of this transition period; (d) whether countries acceding to WTO availed of it at all; and (e) what lessons can be learnt for future negotiations.

One central consideration relates to the scope of this transition period. Most importantly, the provision in article 65.4 is limited, insofar as it deals with sensitive areas such as pharmaceuticals and agricultural chemicals.<sup>147</sup> Second, the transition period of 10 years provided in article 65.4 is illusory because of the provision in article 70 (paras. 8 and 9) which obliges these countries to provide for acceptance of product patent applications from 1 January 1995 itself and, if certain conditions are met, to grant of exclusive marketing rights (EMRs) to the patent applicant for five years or until the patent is granted or rejected (whichever period is shorter). Thus, what is granted in article 65.4 is in some sense limited by article 70.8 and 70.9.<sup>148</sup>

Another central consideration relates to the manner how article 65.4 has been implemented. In fact, while it is difficult to obtain precise numbers, it appears that just a handful of countries have fully availed themselves of the transition period, with perhaps only India going the full distance.<sup>149</sup>

Some observers of the Indian approach towards TRIPS compliance (e.g. implementing legislative changes to phase in TRIPS obligations after expiry of the respective transition periods) note that India's TRIPS compliance would provide an example of whether TRIPS allows a balance between intellectual property protection and public health needs.

Others in turn, flag the costs which full TRIPS compliance would generate for India. Initial econometric studies reveal interesting results. An early 1999 study computed that static price impacts of patent coverage in India could raise average patented drug prices by at least 26 percent (from a 1994 base).<sup>150</sup> Another econometric study estimated that of the total loss estimated for the Indian economy, only a small proportion accounts for the foregone profits of domestic (Indian) pharmaceutical firms.<sup>151</sup> A third study showed that the most significant effect of the TRIPS regime pertains to the domestic Indian population, for whom there appears to be substantial welfare losses. It argues that this welfare loss is not only generated by higher drug prices, but also by less product variety in the near future.<sup>152</sup>

This begs the question about the reasons why such a vast majority of developing countries "opted out" of the transition period in article 65.4. For some, this might boil down

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<sup>147</sup> Patents in these areas generated enormous controversy in countries such as India and popular perceptions vis-à-vis the TRIPS Agreement turned very negative. As a concession, therefore, it may be argued that the period of 10 years was to allow countries such as India to deal with the opposition and put in place legislation that would provide full patent protection to these areas from 1 January 2005.

<sup>148</sup> See Jayashree Watal: "Articles 70.8 and 70.9 override and nullify the transitional arrangements granted in Article 65.4 with respect to patent applications for pharmaceuticals and agricultural chemicals". But, at least in the case of India, the number of applications for EMRs appears to be small. Thus, out of a total of 4,732 applications received in the mailbox, only four were for EMRs and three EMRs have been granted. Still, controversy in India is far from over, with the Government passing an ordinance and many political parties demanding that the issue be discussed thoroughly in Parliament.

<sup>149</sup> By one account, only 13 countries (out of a total WTO membership of 148, a vast majority of which are developing countries), including Argentina, Bahrain, Brazil, Cuba, Egypt, India, Jamaica, Kuwait and Pakistan, availed themselves of at least part of the 10-year transition period. Brazil availed itself only until 1997 and Argentina until 2001. For the other countries, information is difficult to obtain.

<sup>150</sup> Watal J (1999). *Introducing Product Patents in the Indian Pharmaceutical Sector: Implications for Prices and Welfare*. World Competition 20: 5- 21.

<sup>151</sup> Chaudhuri, Goldberg and Jia (2003). *The Effects of Extending Intellectual Property Rights Protection to Developing Countries: A Case Study of the Indian Pharmaceutical Market*.

<sup>152</sup> *Product Patents: Implications for Pharmaceutical Industry and Consumers*, prepared by the UNCTAD India Programme under the UNCTAD-GOI-DFID project, Strategies and Preparedness for Trade and Globalization in India, forthcoming.

to bilateral considerations either in the form of questions relating to bilateral market access or in the form of Section 301 procedures. Similarly, bilateral and regional FTAs play a big role in inducing countries to adopt TRIPS-plus standards. Giving up the transition period provided in the TRIPS Agreement is the first step towards TRIPS-plus. This aspect needs to be borne in mind since even leading developing countries such as Argentina, Brazil, Chile and Thailand either curtailed their transition period or forfeited it altogether.

The situation is also instructive in the case of newly acceding countries to WTO. Not one of the many countries that acceded to WTO between 1995 and 2004 secured the transition period provided for in article 65.4 of the TRIPS Agreement. It is difficult to believe that the Republic of Moldova did not deserve the transition period provided for in the TRIPS Agreement. And yet, given the mechanics of the WTO accession process, there seems to be very little that the candidates for accession can do to fully use flexibilities and transition periods, which they would in theory have a right to resort to.<sup>153</sup> This *problématique* is particularly challenging for LDCs wishing to accede to WTO. While LDCs were until 2006 exempted from most of the TRIPS obligations and while the Guidelines for LDCs accession specified that S&D should be applicable to all acceding LDCs, and that transitional periods foreseen under specific WTO Agreements should be granted in accession negotiations,<sup>154</sup> it remains to be seen to what extent such flexibility will actually be used by future accession countries. Foreclosing the use of transition periods in WTO accession deals is one of the numerous TRIPS-plus aspects that form part of the legal regime governing a country's membership in WTO.<sup>155</sup>

What lessons can be learnt from these trends? Considering that the TRIPS Agreement evoked bitter opposition among developing countries, it is rather strange that only a handful of these countries used (in part or full), the transition period. Yet, even if provided for in the main agreement and possibly arduously negotiated in exchange for important concessions, transition periods are frequently left unused. This is even more striking in light of the fact that transition periods can be used to develop manufacturing capacities for generics or to market pharmaceuticals developed elsewhere. Bangladesh, for example, is a case of an emerging pharmaceutical industry which can make use of the exemption to attract FDI or/and to produce pharmaceuticals which are protected elsewhere.

### **3. Least developed countries**

The TRIPS Agreement also grants specific S&D to LDCs. The term least developed countries (LDCs) refers to the classification made by the United Nations for the most vulnerable countries in the world. LDCs are identified by three main criteria: (a) low national income (per capita GDP under United States \$900); (b) weak human assets (a composite index based on health, nutrition and education indicators); and (c) high economic vulnerability (again a composite index based on indicators of instability of agricultural production and exports, inadequate diversification and economic smallness). There are 50

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<sup>153</sup> The author was the Chair of the Working Party on the Accession of the Republic of Moldova to WTO.

<sup>154</sup> More specifically, the Guidelines for LDC Accession, in their section on WTO rules, state that "Special and Differential Treatment, as set out in the Multilateral Trade Agreements, Ministerial Decisions, and other relevant WTO legal instruments, shall be applicable to all acceding LDCs, from the date of entry into force of their respective Protocols of Accession; transitional periods/transitional arrangements foreseen under specific WTO Agreements, to enable acceding LDCs to effectively implement commitments and obligations, shall be granted in accession negotiations taking into account individual development, financial and trade needs", Accession of Least developed Countries, Decision of 10 December 2002, General Council, WT/L/508.

<sup>155</sup> *Intellectual Property issues in WTO Accession Negotiations*, Frederick Abbott and Prof. Carlos Correa for Quakers United Nations Office, forthcoming.

countries currently designated by the United Nations as LDCs.<sup>156</sup> As many as 32 LDCs are now full-fledged members of WTO, comprising a significant part of the total WTO membership.

It is important to remember that LDCs played a small role, if any, in the negotiations leading up to the WTO TRIPS Agreement. Amongst others, this is one of the reasons why there are not too many provisions that deal specifically with LDCs. In fact, the TRIPS Agreement's main reference to LDCs can be found in article 66, which deals with two specific issues: a longer transitional period for LDCs and an obligation on the part of developed countries to transfer technology to LDCs.

This was an (albeit limited) response to the obvious difficulties faced by the LDCs, with such difficulties being considerably broad in implications – e.g. directly affecting the achievement of the MDGs. These difficulties were also recognized in the September 2002 report of the Commission on Intellectual Property Rights, which recommends that LDCs should be granted a transition period at least until 2016 to implement TRIPS obligations. For the time after 2016, the commission recommends introducing criteria based on indicators of economic and technological development for deciding the basis of further extension of transition period.

**Box 11. Assisting LDCs – calls to action**

It is widely recognized that LDCs face special challenges related to IPRs and development. Several international documents call upon developed countries to provide assistance in that context.

For example, developed countries are to help LDCs achieve the MDG of eradicating hunger and combating HIV/AIDS, malaria, tuberculosis and other diseases by participating actively in developing a global partnership for development (itself a Millennium Development Goal). This could be done through, inter alia, (a) cooperation with pharmaceutical companies for providing access to affordable essential drugs; (b) cooperation with multinational seed companies to ensure food security and sustainable land use; and (c) financial assistance and technical cooperation to the LDCs.

Similarly, the preamble of the TRIPS Agreement recognizes the special needs of the LDCs as regards maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base.

The additional transition period granted to LDCs is mainly governed by paragraph 1 of article 66. In addition, the Doha Declaration on the TRIPS Agreement and Public Health provides (in paragraph 7), that with respect to pharmaceutical products, LDCs will have until 1 January 2016 to implement TRIPS obligations. In fact, paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health clearly provided that the LDCs will not be obliged, with respect to pharmaceutical products, to implement or apply sections 5 and 7 of part II of the TRIPS Agreement (these pertain to patentable subject matter, rights of patent holders, conditions on patent applicants, exceptions to patent holders' rights, compulsory licensing, terms of protection, process patents and protection of undisclosed information) or to enforce rights provided for under these sections until 1 January 2016.

Following the adoption of the Doha Declaration on the TRIPS Agreement and Public Health in November 2001, the TRIPS Council (in June 2002) approved a decision by consensus extending until 2016 the transition period during which LDCs do not have to

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<sup>156</sup> <http://www.un.org/special-rep/ohrls/lde/list.htm>.

provide patent protection for pharmaceuticals. In fact, the TRIPS Council went one step further and also approved a waiver that would exempt LDCs from having to provide exclusive marketing rights (flowing from the “mail box provision”) for pharmaceuticals.

However, article 66 paragraph 1 also contains an interesting feature. While in principle, article 66 only grants a 10-year transition period, it also grants the possibility for LDCs to submit a duly motivated request for extension of this transition period. In autumn 2005, the LDCs (as a group) made use of this provision and Zambia introduced the joint duly motivated request by the LDCs for a 10-year extension of the transitional period.<sup>157</sup>

Numerous developing countries clearly supported the joint LDC request for extension, with arguments including (a) capacity problems (in terms of LDCs’ institutional, human and financial capacities); (b) figures about the cost of implementation of TRIPS for developing countries; and (c) there was no proof that IPRs had played an important role for investment decisions and arguments about the lack of systematic evidence that IPRs had induced ToT. Developed countries were cautious in responding to the joint duly motivated request, with the main arguments being that the language of TRIPS’ article 66 requires looking at the request on a “member-by-member” basis (because each member has a different status), and that IPRs are a necessary (albeit not sufficient) ingredient for sound investment and technology transfer. The overall perception, however, was that the LDCs’ request by Zambia was an opportunity for WTO to show that it was not insensitive to development.

Thus, shortly afterwards, on 29 November, WTO members adopted a decision to grant LDCs an additional 7.5 years until they are obliged to provide protection for trademarks, copyrights, patents and other intellectual property rights under the TRIPS Agreement.<sup>158</sup> The decision is without prejudice to the June 2002 extension of transition period for certain obligations with respect to pharmaceutical products until January 2016 and is subject to renewal.<sup>159</sup>

However, some of the Decision’s elements have also given rise to concerns. For example, the extension is granted for 7.5 years (as opposed to 15 years as requested by the LDCs). Second, building on what is specified in article 65.5 of TRIPS, the decision requires LDCs to ensure that any changes in their laws, regulations and practice made during the transition period do not result in a lesser degree of consistency with the provisions of the agreement. It is feared that this condition would reduce flexibility for those LDCs which – at the present time – have TRIPS-compliant laws and regulations in place, but nevertheless might wish to modify and revert back to a less stringent IP regime. It has to be noted that such an obligation had not previously existed for LDCs: article 65.5 had only placed such conditions on developing – not least developed – countries. Despite such features – perceived as problematic by some – the decision to extend the LDC transition period has been hailed as a major pro-development success, in the run-up to WTO’s Hong Kong (China) Ministerial Meeting.

The second main LDC-specific provision relates to the transfer of technology. The above has already described article 66 paragraph 2, which obliges developed countries to provide incentives to enterprises and institutions in their territories for the purpose of

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<sup>157</sup> While Zambia introduced the paper on behalf of the LDC Group (IP/C/W/457), numerous LDCs associated themselves orally with the Zambian statement (e.g. Cambodia, Uganda, Rwanda, the United Republic of Tanzania, Senegal and Lesotho).

<sup>158</sup> Decision of the Council for TRIPS on Extension of the Transition Period under Article 66.1 for Least Developed Country Members, of 29 November 2005, IP/C/40.

<sup>159</sup> Amongst others, the decision recalls (prior) commitments for technical and financial cooperation, which will particularly address specific needs to be identified by the LDCs. In that context, WTO is to enhance cooperation with WIPO and other relevant organization, an issue for UNCTAD to consider.

promoting and encouraging technology transfer to LDCs and to enable LDCs to create a sound and viable technological base. To demonstrate good faith towards the LDCs in the context of TRIPS, developed countries must fully implement and operationalize the provision in paragraph 2 of article 66.

In the Doha Decision on Implementation-related Issues and Concerns (WT/MIN(01)/17), ministers reaffirmed that the provisions of article 66.2 of the TRIPS Agreement are mandatory and agreed that the TRIPS Council shall put in place a mechanism for monitoring the implementation of this provision – an issue followed up through a February 2003 TRIPS Council Decision.

#### **4. Transfer of technology**

Technology has become one of the most important determinants of economic development. However, the technological gap between developed and developing countries is widening. Protecting intellectual property is viewed as one means to promote and encourage technological development and innovation, by inducing ToT. In fact, the benefits of IPRs as regards enhancing ToT (as well as attracting FDI) were put forth by the proponents of international rules on IPRs when developing countries objected to negotiating TRIPS on the grounds that they did not see any benefits from adopting higher standards of IPRs.

There is a lot of academic literature on the subject of IPRs and transfer of technology. However, thus far, it has not been possible to demonstrate a direct link, if any, between adoption of higher standards of IPRs and the transfer of technology. A consensus exists, however, that IPRs are one of the many relevant factors that influence the transfer of technology. This recognition is reflected in the TRIPS Agreement, which contains a series of references to transfer of technology or technological objectives etc.

#### **Box 12. Selected TRIPS references to transfer of technology**

##### **Preamble**

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

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

##### **Article 7 – Objectives**

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

##### **Article 8 – Principles**

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

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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 40** (in section 8 on Control of Anti-Competitive Practices in Contractual Licences)

1. Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology.

**Article 66 – Least Developed Country Members**

2. Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least developed country Members in order to enable them to create a sound and viable technological base.

*Source:* WTO TRIPS Agreement.

In addition to the provisions cited in box 11, two other references may be found: one in the Doha Ministerial Declaration on the TRIPS Agreement and Public Health in paragraph 7, and one in paragraph 7 of the WTO General Council Decision<sup>160</sup> relating to the implementation of paragraph 6 of the Doha Declaration.

What is clear from most, if not all, of the provisions listed above is that, while the TRIPS Agreement should, ideally, promote transfer of technology, in practice the situation is different: TRIPS has been cited as leading to situations where there may well be an adverse impact on transfer of technology. This is, in fact, recognized explicitly in article 8.2 and article 40.1 of the agreement. Importantly, IPRs and the difficulties they can create for access to technology range across a broad area of issues, including, for example, access to environmentally sound technologies.<sup>161</sup> The question now is, what can be done to encourage the transfer of technology, and, in particular, to what extent can the TRIPS Agreement help in that context?

Research is ongoing to investigate the different manners how technology is transferred, and how policies (both at the national and international levels) can assist in that context. There are both market and non-market mechanisms for the transfer of technology.<sup>162</sup> The market mechanisms that may result in transfer of technology for developing countries include FDI, joint ventures, licensing and trade in goods and services. For all of this to happen (and to bring about the expected benefits in terms of ToT), the developing country must have the respective economic preconditions in place as well as possess sufficient negotiating strength to effectively engage with the holders of the technology (e.g. the foreign investors).

It is difficult to see how the TRIPS Agreement can help in promoting such market-based mechanisms, unless it is argued that adoption of TRIPS standards by itself makes the country concerned attractive for investment, joint ventures, etc. Thus, TRIPS may make the

<sup>160</sup> See WTO (2003). Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. *Decision of the General Council*. WT/L/540, 2 September.

<sup>161</sup> In a study done by Jayashree Watal in 1998 of the effect of IPRs on technology transfer in the case of India in the context of the Montreal Protocol, the conclusion is clear: "Efforts at acquiring substitute technology have not been successful, as the technologies are covered by IPRs and are inaccessible either on account of the high price quoted by the technology suppliers and/or due to the conditions laid down by the suppliers".

<sup>162</sup> See Maskus KE (2003). Overview of the issues and evidence concerning IPRs and transfer of technology. PowerPoint presentation at WIPO-WTO Joint Workshop on Intellectual Property Rights and Transfer of Technology, Geneva, 17 November.

climate for transfer of technology attractive in principle, but it does not oblige the producers of technological knowledge to transfer it to users of this technology, and users are too weak, economically, to take advantage of the opportunity. Thus, there is no automatic insurance that technological benefits will materialize from the implementation of strict IP standards. Open research questions remain about the exact linkages between IPR obligations (such as in TRIPS) and pro-development outcomes, as well as specific ways for fostering such linkages.

Secondly, there are non-market mechanisms for ToT. These include imitation (reverse engineering or copying), access to patent information, compulsory licensing, temporary migration of scientific and technical personnel and FDI spillovers. As the term indicates, these are not always determined by market strength and power alone, hence the term “non-market mechanisms”. The TRIPS Agreement may affect some of these marginally or not at all. But the TRIPS Agreement does impede the transfer of technology in some of these areas. Imitation and reverse engineering serve as examples in point.

Imitation, as evidenced by reverse engineering or copying, is one of the easiest ways to acquire technology. However, with the introduction of patents as required by article 27 of the TRIPS Agreement (prescribing that patents shall be available without discrimination as to the field of technology), there are obvious limits to reverse engineering or copying. In light of this, it is important that patents be granted in accordance with the strict criteria of “novelty”, “inventive step” and “industrial application” and the duration of patent protection be kept to no more than absolutely necessary to meet the requirements of the TRIPS Agreement. Obviously, “evergreening” or “rolling-over” of patents must be prevented. Similarly, any acceptance of “TRIPS-plus standards” would negatively impact the transfer of technology on fair and equitable terms.

Full and fair access to information given by the patent applicant can constitute another way of ensuring transfer of technology, and this is, in fact, recognized in the TRIPS Agreement. More specifically, article 29 makes it clear that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. Unfortunately, this provision is sometimes not fully respected by patent applicants and this is tolerated in developed countries, not recognizing the fact that this impedes the achievement of developmental and technological objectives. It is therefore important that when national authorities design IP legislation, they pay the respective attention to article 29 of TRIPS.

Other issues include those relating to article 39. In fact, the provision’s high standard of “undisclosed information” by patent holders may act as an impediment to the transfer of technology. Similarly, issues related to compulsory licensing and the local working of patents are relevant for ensuring the transfer of technology. In fact, a compulsory licence, or the mere threat to use it, is sometimes enough to achieve the ToT objective. In sum, however, concerns about the absence of direct and tangible ToT benefits emanating from TRIPS have prevailed in the debate.

How can this issue be resolved? Solutions proposed have ranged from demands to the exclusion from patentability of inventions that may cause serious prejudice to the environment and the right to confer compulsory licences on grounds determined by national legislation.<sup>163</sup> In that context, the specific manner in which the TRIPS Agreement is interpreted and implemented can have an impact on the transfer of technology, and more broadly, remedy the agreement’s development deficit.

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<sup>163</sup> See Correa C (2000). *Intellectual Property Rights, the WTO and Developing Countries*.



For example, the provision in article 40.1 read together with the provision in Article 8.2 could possibly be construed as imposing an obligation on WTO Members to address certain forms of practices that either restrain trade or competition and in addition have the effect of adversely affecting international transfer of technology.<sup>164</sup> The remaining questions are what measures could be adopted to prevent abuse referred to above; and how could one ensure that those measures are consistent with the provisions of the TRIPS Agreement. Once again, it is largely left to the discretion of individual countries to decide on the nature of measures to be taken.

Another example of a provision that can help remedy the agreement's development deficit is article 66.2. In fact, this provision obliges developed countries to provide incentives to their enterprises and institutions for the purpose of promoting and encouraging transfer of technology to LDCs. However, since the entry into force of the TRIPS Agreement, not much had been done by the developed countries to fulfil their obligation under article 66.2. Consequently, ministers in the Doha Declaration on the TRIPS Agreement and Public Health reiterated the commitment in article 66.2 of developed countries towards the LDCs.

The subsequent February 2003 decision on the "Implementation of Article 66.2 TRIPS Agreement" was aimed at establishing a mechanism for ensuring the monitoring and full implementation of the obligations in article 66.2. Ultimately, however, the decision stops short of this objective and merely asks developed countries to submit annual reports with perhaps more detailed information than in the past as well as an opportunity for members to pose questions with regard to information submitted by the developed countries. It is doubtful if this "trade policy review mechanism-style exercise" is enough to force the developed countries to meet their obligation vis-à-vis the LDCs. LDCs would do well to remember that this is a mandatory provision of the TRIPS Agreement and that it is covered by the rules of the WTO dispute settlement mechanism.

Another interesting development is the establishment of the Working Group on Trade and Transfer of Technology. According to the mandate established in paragraph 37 of the Doha Declaration, the Working Group is to examine the relationship between trade and transfer of technology and any possible recommendations in that context. Several developing countries put forward communications to this effect, with Brazil, Cuba, India, the Philippines and several African countries being amongst the main actors.<sup>165</sup> However, members did not manage to agree on any recommendations for the Hong Kong (China) Ministerial Conference. Besides political will, another element that is required is a better understanding of the factors determining and inducing transfer of technology. UNCTAD is undertaking work in this context, contributing to finding ways of assuring development gains.<sup>166</sup> UNCTAD regularly presents the outcomes of its work to the WTO Working Group.

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<sup>164</sup> There is clear acknowledgement in article 40.1 of the TRIPS Agreement that "some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology". Similarly, article 8.2 of the TRIPS Agreement underlines the need for measures to prevent abuse of intellectual property rights by right holders or resort to practices which adversely affect the international transfer of technology.

<sup>165</sup> *Provisions Relating to Transfer of Technology in WTO Agreements*, Communication from Cuba, Egypt, Honduras, India, Indonesia, Jamaica, Kenya, Mauritius, Pakistan and Zimbabwe, WT/WGTTT/3/Rev.1, 21 October 2002; *The Working Group on Trade and Transfer of Technology*, Communication from Cuba, India, Indonesia, Kenya, Pakistan, the United Republic of Tanzania, and Zimbabwe, WT/WGTTT/W/6, 7 May 2003; *Proposed Recommendations of the Working Group in the Lead-up to the Sixth Ministerial Conference*, Communication from Cuba, 1 July 2005, WT/WGTTT/W/9, 1 July 2005; *Steps that Might be Taken within the Mandate of the WTO to Increase Flows of Technology to Developing Countries*, Submission to the Working Group on Trade and Transfer of Technology by India, Pakistan and the Philippines, WT/WGTTT/W/10, 13 October 2005.

<sup>166</sup> UNCTAD (2005). *Transfer of Technology for Successful Integration into the Global Economy – A Case Study of the Electronics Industry in Thailand*. UNCTAD/ITE/IPC/2005/6, United Nations, New York and Geneva;

Another approach that can help to move the issue forward and to remedy – at least in part – the development deficit of TRIPS is to look at bilateral and regional agreements, to see whether there are some lessons to be learnt. In fact, in the case of the FTAA, some language on transfer of technology was being attempted in the draft text. The important thing is to have binding obligations for producers of the technological knowledge (in this case the IPR rights-holders) to transfer technology, failing which the user of the technological knowledge should be free to suspend its obligations with regard to the IPR right-holder.

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UNCTAD (2002). *Transfer of Technology for Successful Integration into the Global Economy – A Case Study of Embraer in Brazil*. UNCTAD/ITE/IPC/misc. 20, United Nations, New York and Geneva; UNCTAD (2002). *Transfer of Technology for Successful Integration into the Global Economy – A Case Study of the Pharmaceutical Industry in India*. UNCTAD/ITE/IPC/misc. 22, United Nations, New York and Geneva; UNCTAD (2002). *Transfer of Technology for Successful Integration into the Global Economy – A Case Study of the South African Automotive Industry*. UNCTAD/ITE/IPC/misc. 21, United Nations, New York and Geneva.

## VI. Conclusion

The TRIPS Agreement has profound implications for the development options of developing and least developed countries. There are, however, ways in which WTO members could shape the TRIPS Agreement with a view to pursuing legitimate socio-economic and development goals. In the context of reviewing the agreement's specific provisions, this paper provides some ideas on how members, given the political will, could reduce the agreement's development deficit. Amongst others, one could suggest that the Doha Declaration offers a model to follow for other, non-health-related TRIPS issues, as well as for introducing a development dimension into other WTO agreements.

Conceptually, there are three different ways in which this could be done. First, one could properly "operationalize" certain provisions which are already available in the TRIPS Agreement (e.g. articles 7 and 8 dealing with Objectives and Principles). Second, one could ensure that the TRIPS Agreement does not limit policy options aimed at development, in other words that TRIPS flexibility is fully available to all WTO members – and implemented accordingly and, if necessary, that additional flexibility be made available. Finally, members could aim at ensuring that the TRIPS Agreement evolves in a manner which makes sure that issues of interest to developing countries are adequately and successfully taken care of. In the areas of traditional knowledge and genetic resources, for example, additional protection under TRIPS may well serve pro-development objectives.

In order to achieve these objectives, Members could use a number of tools:<sup>167</sup>

**Amendment:** An amendment is defined as a formal revision or addition proposed to an agreement. Article IX of the WTO Agreement addresses decision-making and sets out the rules and procedures for an amendment of different provisions in the various WTO agreements. To give an example, the 6 December 2005 solution on TRIPS and Public Health constitutes an amendment to the TRIPS Agreement. More specifically, it turns the previous waiver (the August 2003 decision) into a permanent solution. The amendment will enter into force once it has been accepted/ratified by two thirds of the WTO members, with the target date being 1 December 2007. This shows that the TRIPS Agreement is neither immutable nor cast in stone. It not only needs to – but also can – evolve, taking into account the aspirations of the large WTO membership.

The possibility for an amendment is even recognized in the TRIPS Agreement itself. In paragraph 1 of article 71 it states: "[t]he Council may also undertake reviews in the light of any relevant new developments which might warrant modification or amendment of this Agreement." Besides originating from a review, an amendment of the TRIPS Agreement may also result from negotiations (if agreed upon). Examples of areas where members have called for negotiations with a view to amending the TRIPS Agreement include the extension of additional protection for GIs to products other than wines and spirits, as well as issues related to biodiversity.

However, suggestions about an amendment of the TRIPS Agreement will have to be placed in the context of WTO's political reality. In fact, the difficulties encountered in the context of TRIPS and the Public Health amendment are not encouraging. Not only was the process burdensome and time-consuming, but the ultimate outcome stops short of meeting fully developing countries' original aspirations and expectations. Moreover, some fear that

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<sup>167</sup> For a thorough review of the different options for introducing changes into WTO agreements, see Gabrielle Marceau. While the suggestions were made in the context of the trade and environment debate, many of them are also applicable to the trade and development interface. cf. Marceau, JWT 2001, 1104.

opening up the TRIPS Agreement in one area would also strengthen calls to open up the agreement in other areas, including those that are not conducive to development.<sup>168</sup>

Interestingly, the last sentence of paragraph 1 of article 71 also introduces the concept of a modification. One could argue that, in accordance with the WTO Appellate Body's theory of "effective interpretation" (i.e. giving meaning to each word, and implying that different words cannot mean the same), a modification is different from an amendment. Indeed, Black's Law Dictionary, while defining an amendment as a formal revision or addition to an agreement, gives the meaning of "modification" as a "qualification or limitation of something". This raises the question whether it is possible to use this definition to change the TRIPS Agreement and what are the advantages thereof.<sup>169</sup>

**Interpretative approaches:** Interpretative approaches can serve as another tool to remedy the TRIPS Agreement's development deficit. These approaches can range from members adopting an interpretative understanding, to an authoritative interpretation and to a simple reference about how panels or the AB should interpret certain provisions.

As an example, the Doha Declaration on the TRIPS Agreement and Public Health clearly states that the TRIPS Agreement can and should be interpreted in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. Similarly, the same declaration also prescribed that, in applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the agreement as expressed, in particular, in its objectives and principles. This, again, is interpretive guidance provided by WTO members to treaty interpreters. The way the TRIPS Agreement is "interpreted" is extremely important for development implications of developing countries in terms of whether or not they have the right options available.

An **interpretative understanding** is an international agreement specifying certain provisions of another agreement.<sup>170</sup> Importantly, a separate understanding would not "reopen" discussions on the language of the TRIPS Agreement itself and could thus make it easier for members to agree on.<sup>171</sup>

Another option is to resort to an **authoritative interpretation**. According to article IX:2 of the WTO Agreement, the Ministerial Conference and the General Council can adopt interpretations of any WTO agreement. The Ministerial Conference and the General Council would have to decide by consensus on such an interpretation if consensus could not be reached by a three-fourths majority. While an authoritative interpretation has not the same legal status as an amendment or an understanding, the Appellate Body would still be bound by it when applying the provision in question. Thus, since an authoritative interpretation would be easier to achieve than an amendment or understanding and still have a similar effect, it could be an interesting option.

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<sup>168</sup> This overall tendency towards enshrining higher levels of protection is also visible in the TRIPS Agreement itself. Paragraph 2 of article 71 state that "amendments merely serving the purpose of adjusting to higher levels of protection of intellectual property right achieved, and in force, in other multilateral agreements and accepted under those agreement by all Members of the WTO may be referred to the Ministerial Conference for action in accordance with paragraph 6 of Article X of the WTO Agreement on the basis of a consensus proposal from the Council for TRIPS". This provision exempts such amendments from the otherwise lengthy acceptance process.

<sup>169</sup> One could argue that advantages would be that there is no need to go through the complicated amendment process set forth in article X of the WTO Agreement.

<sup>170</sup> Examples in the WTO context include the understandings on the interpretations of various provisions of GATT.

<sup>171</sup> For similar argument made in the context of GATS, see Krajewski for CIEL. <http://www.ciel.org/Publications/PublicServicesScope.pdf>.

Yet another variation of “interpretation” is to come up with either a decision or a statement by the TRIPS Council amounting to a **clarification** of some provisions of the TRIPS Agreement. This clarification can serve as a halfway house between an outright amendment of the TRIPS Agreement and retention of the existing language of the Agreement.

Finally, WTO members could resort to a **non-binding statement**. Without being legally binding for WTO panels and the Appellate Body, such a statement could/would constitute subsequent practice of the parties according to article 31:3(b) of the Vienna Convention (in fact, it would establish a common understanding of the parties regarding the interpretation of a certain provision). It is therefore unlikely that WTO jurisprudence would ignore such a statement. Nevertheless, a non-binding statement could not render the same legal certainty as the binding methods suggested above.

**Implementation:** If developing countries want to preserve all their options to pursue legitimate socio-economic and technological objectives, it is critically important that they implement the TRIPS Agreement in a proper manner, availing themselves of all flexibilities and safeguards. Again, the Doha Declaration makes clear that the TRIPS Agreement can and should be implemented in a manner supportive of WTO members’ right to protect public health and, in particular, access to medicines for all.

When putting in place legislation to implement the TRIPS Agreement, developing countries need to be cognizant of their right to grant compulsory licences, their right to have a *sui generis* system of plant variety protection and their right to use the full flexibility to define terms such as micro-organisms, inventive step, exhaustion regime, just to name a few. In the end, it is the developing countries, at the national level, which have to implement the TRIPS Agreement. And as pointed out in article 1 of the agreement: “Members shall be free to determine the appropriate method of implementing the provisions of this agreement within their own legal system and practice”. This freedom, it is worth noting, is unconditional and must be availed of by all developing countries.

To conclude, it is suggested that developing countries pursue an integral negotiating agenda in the WTO TRIPS context, combined with the respective actions at the national level. This paper provides an outline of the central elements of such an agenda, and in the end suggests a series of possible methods – namely, amendment, interpretation and implementation of the TRIPS Agreement – which may be pursued with a view to reducing the agreement’s development deficit and maximizing its development potential. In sum, the TRIPS Agreement and, more broadly, the WTO legal framework, offer certain solutions in themselves, and developing countries may be well advised to consider them in their efforts to design a holistic, pro-development approach to the WTO’s intellectual property right regime.

Along these lines, adequate policy space is a central element on the path towards development. However, policy space alone is not enough. Rather, there is need to have sound and specific knowledge and research on how to best and constructively use this policy space, so as to maximize IPRs’ contributions to development and minimize potentially negative effects. This would also require a careful evaluation and assessment of the pros and cons and the overall implications of various policy options, including the ones set out in this paper. The São Paulo Consensus mandates UNCTAD to help address this challenge by contributing with research on the development dimension and implications of the establishment and the enforcement of IPRs. This paper is one step in this direction.



## Annex

### WTO members' communications under the Triple Agenda Item on Biodiversity (2005 and 2006)

IP/C/W/484: Response to Comments Contained in Document IP/C/W/469 Relating to the Peruvian Communication IP/C/W/458. *Communication from Peru.*

IP/C/W/475: Response to Question Raised on the Draft Amendment to TRIPS Article 29bis. *Communication from Brazil.*

IP/C/W/474: Doha Work Programme – The Outstanding Implementation Issue on the Relationship between the TRIPS Agreement and the Convention on Biological Diversity. *Communication from Brazil, China, Colombia, Cuba, India, Pakistan, Peru, Thailand and the United Republic of Tanzania, also circulated to General Council and the TNC.*

IP/C/W/473: The Relationship between the TRIPS Agreement, the Convention on Biological Diversity and the Protection of Traditional Knowledge – Amending the TRIPS Agreement to Introduce an Obligation to Disclose the Origin of Genetic Resources and Traditional Knowledge in Patent Applications. *Communication from Norway, also circulated to General Council TNC.*

IP/C/W/472: The Patent System and Genetic Resources. *Communication from Japan.*

IP/C/W/470: Submission in Response to the Communication from Switzerland (IP/C/W/446). *Communication from Bolivia, Cuba, Ecuador, India, Sri Lanka and Thailand.*

IP/C/W/469: Article 27.3(b), Relationship between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore. *Communication from the United States.*

IP/C/W/459: The relationship between the TRIPS Agreement and the Convention on Biological Diversity. *Communication from Bolivia, Brazil, Colombia, Cuba, India and Pakistan.*

IP/C/W/458: Analysis of potential cases of biopiracy. *Communication from Peru.*

IP/C/W/449: Article 27.3(b), relationship between the TRIPS Agreement and the CBD, and the protection of traditional knowledge and folklore. *Communication from the United States.*

IP/C/W/447: Article 27.3(b), Relationship between the TRIPS Agreement and the CBD and protection of traditional knowledge and folklore. *Communication from Peru.*

IP/C/W/446: The relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the protection of traditional knowledge and folklore and the review of implementation of the TRIPS Agreement under Article 71.1. *Communication from Switzerland.*

IP/C/W/443: The relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the protection of traditional knowledge. Technical observations on issues raised in a communication by the United States (IP/C/W/434). *Communication from Brazil and India.*

IP/C/W/442: The relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the protection of traditional knowledge-elements of the obligation to disclose evidence of benefit-sharing under the relevant national regime. *Communication from Bolivia, Brazil, Colombia, Cuba, Dominican Republic, Ecuador, India, Peru and Thailand.*

IP/C/W/441/rev.1: Article 27.3(b), relationship between the TRIPS agreement and the CBD and protection of traditional knowledge and folklore. *Communication from Peru.*

IP/C/W/438: The relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the protection of traditional knowledge-elements of the obligation to disclose evidence of prior informed consent under the relevant national regime. *Communication from Bolivia, Brazil, Cuba, Ecuador, India, Pakistan, Peru, Thailand and the Bolivarian Republic of Venezuela.*

IP/C/W/434: Article 27.3(b), relationship between the TRIPS Agreement and the CBD, and the protection of traditional knowledge and folklore. *Communication from the United States.*

IP/C/W/429: Elements of the obligation to disclose the source and country of origin of biological resources and/or traditional knowledge used in an invention. *Communication from Brazil, India, Pakistan, Peru, Thailand and the Bolivarian Republic of Venezuela.*

*Source:* WTO webpage.



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