

# **The Doha Agenda and Intellectual Property Rights**

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## I. INTRODUCTION

Knowledge and its accumulation is the central factor in the process of ongoing economic growth and development. The application of knowledge can clearly lead to higher productivity and output, but the process of acquiring knowledge itself is important in the ability to apply the knowledge produced by others. A key component that helps underpin the incentive to accumulate knowledge is the existence of intellectual property rights (patents, trademarks, copyrights, etc). These rights help solve a central tension in the development of knowledge—the process of developing knowledge is much more costly for the first person than it is for those that subsequently acquire the knowledge. In this sense, intellectual property rights provide an incentive for someone to want to be first. While the potency of this incentive varies widely between industries, the importance of this incentive has grown over time with the emergence of industries such as the information and biotechnology sectors. Coupled with the increasing integration of countries, these forces provided the motivation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) as part of the Uruguay Round of trade negotiations. This agreement is both ambitious and unique, which means that it also has to be flexible enough to accommodate the wide range of needs of the members of the World Trade Organization (WTO). The Ministerial Conference at Doha can be seen as an important illustration in which the flexibility of the TRIPS agreement can be realized.

At the Ministerial Conference in Doha, a number of key declarations were made that will directly impact on the operation of the TRIPS agreement. These declarations perform a multi-dimensional function, clarifying and reiterating existing rights and obligations, highlighting particular implementation issues, as well as setting out a negotiating agenda. By providing clarity on a number of critical issues, the Doha Ministerial Conference was an attempt to clear the way for future work on TRIPS. However, exactly what this future work should be and in what areas a mandate has been established is the subject of ongoing debate.

Overall, the Doha Declarations with respect to TRIPS are seen as a major step for developing (and particularly the least developed) countries towards securing flexibility in the use of intellectual property rights, especially with respect to public health issues. Specifically, the Declaration on the TRIPS Agreement and Public Health (hereafter Declaration) helps to ensure that in situations where action needs to be taken to deal with a national emergency, the set of options is not limited by the architecture of international intellectual property rights. More generally, it reiterates the ability of countries to interpret the TRIPS agreement in a way that is beneficial or reflective of their needs. In doing so, it provides some hope that in situations where the TRIPS agreement is open to interpretation, more than one interpretation

will be feasible. The right to exercise flexibility over intellectual property rights is one that has historically been available to countries during their industrializing phase (Kahn 2002). While the TRIPS agreement does limit the flexibility a country has, much work has attempted to emphasize the scope for discretion a country has in the design of its intellectual property rights system. The results of the Doha Ministerial Conference can be seen as an attempt to further stress the flexibility that exists within the TRIPS agreement.

Public health issues were not the only matters relating to the TRIPS agreement covered by the Doha declarations. Some of these other issues were new, such as how traditional knowledge relates to the TRIPS agreement. Other issues had either been or were the subject of ongoing negotiations as part of the built-in agenda. Regardless of the newness of these other issues, in comparison to public health, the agenda set for negotiations was not as well defined. In light of this, the aim of this paper is to review the current negotiating agenda and recent decisions on TRIPS and try to evaluate the extent to which these provide benefits, and determine the nature of the trade-offs that are likely to be involved.

## **II. DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH**

The importance of the relationship between public health and the TRIPS agreement is underscored by the separate declaration made at the Ministerial Conference in Doha. This declaration represents an attempt to clarify a number of points that had become contentious among members. In particular, the high profile of public health emergencies, such as the AIDS crisis, had dramatically revealed the tension between intellectual property rights and public health. To resolve this tension, the Declaration represents a clear statement of where the priority should lie. An expression of how this tension should be resolved is contained in the preambular language of the first four paragraphs of the declaration, which gives the primacy to public health issues. The main statements setting out rights and responsibilities as well as unresolved issues are covered in paragraphs 5 through 7. In relation to public health issues, this section will focus on the potential economic implications of these paragraphs.<sup>1</sup>

### **A. REITERATING RIGHTS**

The need for a special Declaration was not driven so much by a lack of clarity within the TRIPS agreement, but rather the difficulty that many countries had in exploiting the flexibility contained within it. High profile examples with respect to HIV drugs in both South Africa and Brazil pointed to a future

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<sup>1</sup> For an analysis of the legal issues of the Declaration, see Abbott (2002a, 2002b) and Correa (2002).

where even TRIPS-consistent laws would be challenged. In light of these cases, effort to reiterate the rights contained within the TRIPS agreement, especially in relation to public health, became a necessity.

Paragraph 5 is devoted primarily to this objective and reiterates certain rights that are already contained within the TRIPS agreement. In particular, the Declaration (WTO 2001) indicates that:

- 5(b) Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.
  
- 5(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
  
- 5(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

Paragraph 5(b) reaffirms Article 31 of the TRIPS agreement, making clear that countries do have the right to grant compulsory licenses.<sup>2</sup> Paragraph 5(c) adds further weight by specifying that the decision as to what constitutes a national emergency can be taken autonomously by a country, and that there is no need to seek consultation or approval from other parties prior to this decision. Finally, paragraph 5(d) clarifies the tension between Article 6 of the TRIPS agreement, which does not require a country to adopt a particular exhaustion regime (i.e. international exhaustion is not prohibited) and Article 28 of TRIPS agreement, which gives a patent holder the exclusive right to import the patented good.<sup>3</sup> In resolving this tension, paragraph 5(d) reiterates that international exhaustion is consistent with the TRIPS agreement.

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<sup>2</sup> A compulsory license is a license granted by the government for the working of a patent by an entity other than the patent holder. The circumstances when a government can grant a compulsory license are set out in Article 31 of the TRIPS agreement.

<sup>3</sup> Intellectual property rights are typically exhausted once the goods or service have been sold. This means that the further sale or distribution cannot be controlled by the IPR owner. Since IPR only operates within the country granting them, an exhaustion regime can be distinguished by whether it recognizes exhaustion for the first sale anywhere in the world by the IPR owner (international exhaustion) or first sale within the country granting the right (national exhaustion).

By clarifying these points, the Declaration emphasized the flexibility that is contained within the TRIPS agreement. One effect of this declaration is that it may help countries to exploit this flexibility more readily and in a manner that has not been utilized to date. As shown in a recent study relating to the patent laws of 70 developing countries, the flexibility contained within the TRIPS agreement has not been fully exploited. This point is illustrated in Table 1 with reference to the provision for the granting of compulsory licenses.<sup>4</sup>

**Table 1: Grounds for Granting Compulsory Licenses in Developing and Least Developed Countries**

Grounds for Granting Compulsory Licences	Countries Providing such Grounds
Failure to exploit or exploit on reasonable terms	32
Public interest	13
National emergency or health emergency	13
Remedy to anti-competitive practices, unfair competition	11
Failure to obtain license under reasonable terms	4
Failure to work domestically	2
No apparent provisions	2

Source: Thorpe (2002).

Even though Article 31 of the TRIPS agreement allows grounds for the grant of compulsory licenses, by and large they have not been included in the patent laws of many developing countries. The effective implementation of the Doha Declaration in these countries, therefore, would call for an amendment to national laws to incorporate the exceptions and safeguards necessary to protect public health.

It should also be noted that paragraph 5 is a statement about how to interpret the TRIPS agreement—there is nothing that relates exclusively to public health issues. This topic is specifically covered in paragraphs 6 and 7 which identify areas of uncertainty or deficiency in the TRIPS agreement and therefore mandates that negotiations take place around these issues.

## **B. RESOLVING UNCERTAINTIES**

It is clear from paragraph 5 of the Declaration that if a country has the capacity to produce patented products, they can grant compulsory licenses to deal with national emergencies or other situations of extreme urgency. But if a country does not have adequate domestic production capacity to deal with the emergency, the ability to grant a compulsory license does not provide any effective assistance. This issue is particularly relevant to public health where countries require access to the necessary medicines. This is

<sup>4</sup> The Appendix provides greater detail of the characteristics of patent laws for selected Asian countries.

underscored by Table 2, which illustrates that relatively few countries have a fully developed pharmaceutical industry.

**Table 2: Levels of Development in Pharmaceuticals, By Country**

<b>Sophisticated Pharmaceutical Industry and Research Base</b>	<b>Innovative Capabilities</b>	<b>Reproductive Capabilities— Active Ingredients and Finished Products</b>	<b>Reproductive Capabilities— Finished Products from Imported Ingredients only</b>	<b>No Pharmaceutical Industry</b>
Belgium	Argentina	Bahamas	Afghanistan	Andorra
France	Australia	Bolivia	Albania	Antigua and Barbuda
Germany	Austria	Brazil	Algeria	Aruba
Italy	Canada	Bulgaria	Angola	Bahrain
Japan	China, People's	Cuba	Bangladesh	Bermuda
Netherlands	Rep. of	Czechoslovakia	Barbados	Bhutan
Sweden	Denmark	Egypt	Belize	Botswana
Switzerland	Finland	Indonesia	Benin	British Virgin Islands
United Kingdom	Hungary	Macau, China	Brunei Darussalam	Burkina Faso
United States	India	Norway	Cambodia	Burundi
	Ireland	Poland	Cameroon	Central African Republic
	Israel	Puerto Rico	Cape Verde	Chad
	Korea, Rep. of	Romania	Chile	Comoros
	Mexico	Turkey	Colombia	Congo
	Portugal		Costa Rica	Cook Islands
	Spain		Côte d'Ivoire	Djibouti
	USSR		Cyprus	Dominica
	Yugoslavia		Democratic People's Republic of Korea	Equatorial Guinea
			Dominican Rep.	Faeroe Islands
			Ecuador	French Guyana
			El Salvador	French Polynesia
			Ethiopia	Gabon
			Fiji Islands	Greenland
			Gambia	Grenada
			Ghana	Guadeloupe
			Greece	Guam
			Guatemala	Guinea
			Guyana	Guinea-Bissau
			Haiti	Iceland
			Honduras	Lao People's Dem. Rep.
			Hong Kong, China	Libyan Arab Jamah.
			Iran	Liechtenstein
			Iraq	Luxembourg
			Jamaica	Maldives
			Jordan	Martinique
			Kenya	Mauritania
			Kiribati	Mayotte
			Kuwait	Micronesia
			Lebanon	Nauru
			Lesotho	Netherland Antilles
			Liberia	
			Madagascar	
			Malawi	

Sophisticated Pharmaceutical Industry and Research Base	Innovative Capabilities	Reproductive Capabilities— Active Ingredients and Finished Products	Reproductive Capabilities— Finished Products from Imported Ingredients only	No Pharmaceutical Industry
			Malaysia	New Caledonia
			Mali	Niue
			Malta	Oman
			Mauritius	Qatar
			Mongolia	Reunion
			Morocco	Rwanda
			Mozambique	St. Kitts and Nevis
			Myanmar	St. Lucia
			Namibia	St. Vincent-
			Nepal	Grenadines
			New Zealand	Samoa
			Nicaragua	San Marino
			Niger	Sao Tome and
			Nigeria	Principe
			Pakistan	Senegal
			Panama	Suriname
			Papua New Guinea	Swaziland
			Paraguay	Togo
			Peru	Tuvalu
			Philippines	United States Virgin
			Saudi Arabia	Island
			Seychelles	Vanuatu
			Sierra Leone	Western Samoa
			Singapore	
			Solomon Islands	
			Somalia	
			South Africa	
			Sri Lanka	
			Sudan	
			Syrian Arab Rep.	
			Taipei,China	
			Thailand	
			Tonga	
			Trinidad and	
			Tobago	
			Tunisia	
			Uganda	
			United Arab	
			Emirates	
			United Republic of	
			Tanzania	
			Uruguay	
			Venezuela	
			Viet Nam	
			Yemen	
			Zaire	
			Zambia	
			Zanzibar	
			Zimbabwe	

Source: Ballance et al. (1992).



In particular, only a small number of countries have the capacity to produce the active ingredients required for medicines. This suggests that when confronted with a national health emergency, a large number of countries may not be able to make effective use of the right to grant compulsory licenses, revealing a shortcoming of the TRIPS agreement. This motivates paragraph 6 of the Declaration (WTO 2001):

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

If a country does not have any domestic capacity to produce pharmaceuticals, then clearly access to compulsory licenses does not provide any advantage in dealing with a national health emergency. The difficulty arises because of the territorial nature of patent protection. While a country has jurisdiction over the operation of patents within its borders, and the flexibility of this system has been affirmed by paragraph 5, there is little that a country can do to authorize the production of a good in another when the good is patented in that country.

Furthermore, even if the other country was sympathetic and wanted to help, Article 31(f) of the TRIPS agreement imposes a significant constraint on this type of behavior. Specifically, Article 31(f) of the TRIPS agreement says that production under a compulsory license should be predominantly for use in the domestic market. Clearly, granting a compulsory license with the intention to supply a foreign market is in conflict with Article 31(f). So the problem is essentially one that requires not only the rights of the patent holder to be clarified, so that production in a territory that is not experiencing a health emergency can be authorized without the approval of the right holder, but also the constraint imposed by Article 31(f) needs to be relaxed.

Solving these problems generates a series of subsidiary issues. Two of the most prominent are how to determine whether a country lacks the domestic capacity to produce pharmaceuticals and what constitutes a domestic market from a consumption perspective. Establishing clear criteria to determine the extent of domestic capacity is essential. Without proper guidelines, it may be possible to claim that a country does have domestic capacity if they have any technical ability to produce the required medicine. The fact that the resulting price may be extremely high, would deny many countries access to any solution developed

under paragraph 6. Given the autonomy that a country has with respect to deciding when they face a national emergency (see paragraph 5), it would also seem appropriate that a country should have the autonomy to determine whether or not they have sufficient domestic capacity. However, the autonomy to determine whether the domestic supply is insufficient may not be particularly valuable unless the demand side of the domestic market is sufficiently large. This places the definition of the domestic market at the center of any effective solution.

Paragraph 6 puts the focus on the circumstances where countries lack domestic capacity. One reason for a lack of domestic capacity is a small domestic market. So, even if a foreign producer could be granted a compulsory license, the issue emerges that they will also be constrained by the restriction that they can only produce for the small market. This raises the prospect that many proposed solutions to the problem identified by paragraph 6 may not provide relief to the countries in need. One option would be for several countries to pool demand in order to allow potential suppliers to realize economies of scale. But this depends on how broadly a domestic market is defined. It is important to note that the broader the domestic market is defined for consumption purposes, the less likely countries will be given autonomy over deciding the sufficiency of their domestic pharmaceutical production capacity. This suggests that these issues will be very difficult to resolve, as attempts to alleviate one problem are likely to aggravate the other problem.

Even if a country is able to overcome the issues of domestic capacity and domestic demand, another basic problem will be finding a source of supply, as indicated by Table 2. One way of classifying these sources of supply is by considering the extent to which they rely on a solution to the problem identified in paragraph 6 in order to serve a foreign market.

One potential source of supply that does not at present rely on the solution to paragraph 6 is the production available from developing countries that currently do not offer patent protection. For example, India does not provide patent protection for pharmaceutical products, and produces generic versions at a fraction of the price of the patented product. Therefore, a country facing a health crisis could access the required medicine from these off-patent sources. Access to these generic sources is easiest for countries that themselves do not provide patent protection or where the drug is off-patent. Countries in this category are potentially all the developing and least developed countries. For countries where the drug is covered by patent protection, then a solution under paragraph 6 would need to be implemented. In either case, a more imminent problem is that as countries like India fully comply with the TRIPS Agreement (by 2005 at the latest), they will no longer be able to produce and export cheap

generic versions of patented drugs. Thus, such sources of supply are unlikely to form the basis of a long-term solution.

Moreover, the supply of generic drugs from developed countries may similarly be limited. In these countries, firms that produce generic versions of drugs do so only for off-patent pharmaceuticals. Their main interest lies in the introduction of products after patent expiry. For a generics producer to be a source of supply in the case of a health emergency that required access to patented drugs, they would need to develop and implement a method of production, requiring approval of both the methods and the ultimate quality.<sup>5</sup> Production may feasibly require the approval in both the source and recipient countries. Thus, offering to supply the required drug would typically involve considerable investment and time, a consideration that may severely restrict this potential source of supply.<sup>6</sup>

Other factors also suggest that compulsory licenses may not be as effective as they first appear. After all, no country has had extensive experience using compulsory licenses to deal with national emergencies. Together these factors suggest that the ultimate effect might be that a compulsory license is not issued, but instead the government negotiates directly with the patent holder for a reduced price.<sup>7</sup> Given the issue of timeliness and the quality of the product, the patent holder is likely to be in a good bargaining position, and will certainly end up with a better deal than the royalties that would have been earned after a compulsory license had been granted (how these are to be determined is another issue that is likely to be contentious).

The Brazilian case in relation to antiretrovirals provides a good example of this outcome.<sup>8</sup> The Brazilian government was able to use the threat of compulsory licensing to dramatically reduce the price of antiretroviral drugs. Importantly, the credibility of this threat was supported by access to a domestic

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<sup>5</sup> The feasibility of supply may also depend on the importing country's regime for protection of data submitted for marketing approval. If the local regulation strictly follows Article 39.3 of the TRIPS agreement then the registration of the generic product may be relatively straightforward. However, if a TRIPS-plus approach is followed, such as that which operates in the United States and the European Union, then the entry of the generic product may be delayed or frustrated. Note from the Appendix that these TRIPS-plus standards also exist in developing countries. In such situations, generic companies may not be willing to make the substantial investment needed to duplicate the tests necessary to prove efficacy and safety.

<sup>6</sup> The timing of a request for a compulsory license relative to the expiry of a patent may also have an important impact on the potential of supply. Producers of generics may be more interested in satisfying a compulsory license when the relevant patent is about to expire, and therefore access to the domestic (and other) markets may help to justify the investment.

<sup>7</sup> The Cipro cases in both Canada and the United States demonstrate that access to compulsory licenses does not necessarily mean that they are granted or that things always work smoothly. In fact, if one were to use these examples as a template it would lead exactly to the outcome described here—this may also have been the intention of the United States.

industry which had both the ability to reverse engineer the drugs, and the capacity to produce them on a viable scale. The credibility to negotiate is based on actual capacity, not potential capacity. A legal mechanism that facilitates access to foreign sources for a patented pharmaceutical represents access to a potential not an actual source of supply. This suggests that the size of the benefits Brazil has derived from compulsory licensing (or the threat of) may not necessarily be available to countries hoping to utilize a solution to paragraph 6.

Moreover, the ability of the patent holder to restrict access to their pharmaceutical is also suggested by other factors. Prominent among these is the fact that drugs are normally protected by a number of different types of intellectual property—patent (product and process), trademarks, and copyrights. So, the patent holder may have at their disposal a large number of ways to frustrate the process and increase their bargaining power.

While achieving price reductions from the patent holder is an improvement over the current situation, the implications of this outcome are potentially broader. One point that has been raised by the United States in the related context of supplying a compulsory license for a developing or least developed country from a developed country is that this is not consistent with the goal of technology transfer. Here the argument is that if developed countries are allowed to satisfy the compulsory license then they may be able to out-compete developing and least developed countries, frustrating the possibility of technology transfer. This point also seems relevant for the case where the patent holder avoids a compulsory license by offering a lower price. However, the main issue is that the public health emergency must be dealt with in an effective manner, and that this should take top priority, even over development objectives such as technology transfer.

Nevertheless, it is important to acknowledge the incentive structure implied by paragraph 6. Since any solution will facilitate a relatively inexpensive source of supply, the incentive for a domestic industry to develop is likely to be undermined. Furthermore, a government may actively discourage the development of such an industry, since its presence is likely to limit the set of policy options available in a crisis. It is difficult to imagine how an effective solution to the problem defined by paragraph 6 could guarantee that this outcome would not be an unintended consequence.

The ability of a patent holder to be the preferred supplier in a national health emergency may ultimately depend on the mechanism in place to determine who can be granted a compulsory license. If all sources

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<sup>8</sup> See Commission on Intellectual Property Rights [CIPR] (2002).

are potential candidates, and of these sources, a number can actually compete with the patent holder for the compulsory license, then an allocation mechanism may be necessary. A simple tendering process is probably the most attractive option. But the issues of economies of scale and the ability to overcome nonpatent protections (access to diagnostic kits and technology related to treatment) might be critical in determining the success of this mechanism.

A further complication exists that can potentially frustrate the intent of any proposed solution to the problem defined by paragraph 6. What happens when a country does not provide patent protection to pharmaceuticals? The problem is that since a compulsory license can only be granted when a patent exists, the wording of paragraph 6 seems to restrict attention only to cases where a pharmaceutical patent is in force in the importing country. So for countries that either do not provide patent protection for pharmaceuticals, or for whatever reason the required pharmaceutical is off-patent in that country but on-patent in others, there is no basis for a compulsory license.

Given that many of the least developed countries are not currently required to comply with the TRIPS agreement and that these are also the countries facing the most serious public health issues, this raises the possibility that a solution to paragraph 6 may be found that is not available to the countries most in need. This creates the potential that countries may be faced with the difficult decision of not being able to access the solution developed under paragraph 6 unless they also extend patent protection to pharmaceuticals. But this would involve forgoing the benefits that are available from the extended transition periods. This issue is especially relevant in light of paragraph 7 of the Declaration (WTO 2001).

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

With respect to the extension of transition periods for pharmaceuticals, the TRIPS Council has now formulated this text into a decision. This decision also dealt with a number of other matters that may have complicated or undermined the effectiveness of such an extension. Specifically, the decision did waive Article 70.9 of the TRIPS agreement, despite not being explicitly mentioned in paragraph 7.<sup>9</sup> Consequently, least developed countries do not have to provide for exclusive marketing rights while patent protection of pharmaceuticals is not implemented. This does increase the capacity of least developed countries to gain access to pharmaceuticals not protected by patents in other countries, especially developing countries. However, the obvious downside is that this source of supply will be curtailed in 2005 as developing countries fully implement the TRIPS agreement, so the actual benefit should not be exaggerated.

This still leaves other least developed countries as potential suppliers of pharmaceuticals, and coupled with the language of paragraph 7 with respect to technology transfer, it is tempting to think that this might be an opportunity to achieve some infrastructure gains. However, there is uncertainty in that the waiver only applies to pharmaceutical *products* and not *processes*. If this is the case, an implementation date of 2006 undermines the feasibility of this option.<sup>10</sup>

In addition, note that the language in paragraph 7 does not require that the technology transfer occur in the area of pharmaceuticals, rather it is a general call for an appropriate reporting system to be set up to document/monitor all efforts by the developed countries to transfer technology. The issue of technology transfer is discussed in more detail below.

At first blush, the Declaration appears to be a victory for the concerns of developing and least-developed countries (this may still be the case for developing countries, once they fully comply with the TRIPS agreement). However, closer inspection reveals a number of potential problems. In particular, the cross purposes of the declaration appear to offer the most benefits to countries that already provide patent protection. Extending the transition periods to 2016 does not seem to be associated with large benefits for public health issues in and of itself. Instead, the benefits implied by the Declaration may only be realized after patent protection is provided.

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<sup>9</sup>Article 70.9: Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member (General Agreement on Tariffs and Trade 1994).

<sup>10</sup> However, it does seem to be the intention that the decision should extend to processes as well.

### **III. OTHER ISSUES FROM DOHA**

Aside from the Declaration, the Ministerial Conference outlined a number of other areas in which the TRIPS agreement is in need of review. This list of issues covers topics that have been the subject of negotiations as part of the built-in agenda contained within the TRIPS agreement such as geographical indications, patenting of plant and animal varieties, and nonviolation complaints. A number of new issues have also been identified including traditional knowledge, technology transfer, and the relationship between the TRIPS agreement and the Convention on Biological Diversity (CBD). In general, the direction given for negotiations in these areas is not as specific as it is in relation to public health. As a result, much of the work to date has concerned exploring the extent of the mandate for these topics. However, some of these issues will require more discipline in negotiations as recommendations on specific subjects (geographical indications, nonviolation, and technology transfer) are required either by the end of 2002 or by the Fifth Session of the Ministerial Conference. One of the broadest issues to be identified by the Doha Ministerial Declaration is how traditional knowledge relates to the TRIPS agreement.

#### **A. TRADITIONAL KNOWLEDGE<sup>11</sup>**

Traditional knowledge encompasses very different types of knowledge. There is much debate over exactly how to define traditional knowledge, however it is generally considered to include information on the use of biological and other materials for medical treatment and agriculture, production processes, designs, literature, music, rituals, and other techniques and arts. While the elements of this set are broad and diverse, they do bear a resemblance to established forms of intellectual property. However, the standard forms of intellectual property rights were not devised to protect traditional knowledge, which means that their application is not a straightforward matter.

The central tension in relation to traditional knowledge is that it is knowledge that is collective and well known among one group but not well known more generally. Moreover, the manner in which this knowledge is stored typically makes it inaccessible to those that make determinations about intellectual

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<sup>11</sup> According to the World International Property Organization (WIPO), traditional knowledge is defined as tradition-based literary, artistic, or scientific works; performances, inventions, scientific discoveries, designs, marks, names and symbols, undisclosed information, and all other tradition-based innovations and creations resulting from intellectual activity in the industrial, scientific, literary, or artistic fields (WIPO 2001).

property rights (either because it is part of an oral tradition or written down in a language that is unfamiliar to the intellectual property authorities in other countries).

This problem is multi-dimensional with some aspects of traditional knowledge being more trade-related than others. For example, Western science has become more interested in traditional knowledge with the realization that traditional knowledge can be extremely effective in combination with Western scientific techniques in finding solutions to current problems. However, other forms of traditional knowledge, such as folk music, are not as readily commercialized on a global scale. For these forms of traditional knowledge, the issue is whether the negotiations under the TRIPS agreement can offer improvements that are beneficial at a domestic level, rather than at an international level. If domestic concerns are paramount, this raises the issue of whether the WTO is the appropriate location for an agreement on traditional knowledge. The complexity of the issue of how to accommodate traditional knowledge within the intellectual property rights system has led to less of an effort to find a quick solution; rather energy has been devoted to assessing the size and nature of the problem.

## **1. Patents**

The debate turns on whether any new legal instrument is needed. Indeed, it has been claimed that concerns over traditional knowledge and bio-piracy can be handled within the present patent system. For instance, if a company tries to seek a patent based on traditional knowledge, then it is always possible for the patent to be revoked based on appropriate evidence. The key here is defining what is appropriate evidence. In some countries, particularly the United States, the fact that an invention is widely known in a foreign country is not sufficient to revoke a patent; the knowledge must be written down in the foreign country. The cases of Turmeric in the United States and Neem in the European Union illustrate the main issues. In both these cases, patents were initially granted covering uses which were essentially the same as the traditional uses of these plants in Indian medicine. While both of these patents were subsequently revoked, the initial search of prior art did not reveal the traditional uses of these plants.<sup>12</sup>

In such cases, the issue is whether it is appropriate to claim the use of knowledge that is traditional in one part of the world as novel in another. Clearly, it is not an objective of the patent system to encourage this type of behavior. But there still is some merit to having knowledge diffuse more broadly. This raises the question of whether a legal instrument exists that can do this with respect to traditional, but localized, knowledge.

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<sup>12</sup> See CIPR (2002) for the details of these cases.



Contracts have been suggested as a potential solution to this problem. However, using contracts as a solution to the problem of protecting traditional knowledge is likely to suffer from a number of problems. Most obviously, without a clearly defined right, the owners of traditional knowledge (even if they can be clearly identified) are at a severe disadvantage in most negotiating contexts. To facilitate contracts, it has been proposed that databases (covering traditional knowledge relating to medical treatments and genetic material) be constructed and maintained.

Databases can be quite useful, especially if they are made available to patent examiners, since it might help to avoid needless and expensive patent opposition claims. Their effectiveness can be further enhanced if there is some form of recognition of traditional knowledge as well. In this case, the database can be used to facilitate contracts and turns them from a defensive instrument into a more positive instrument. However, it seems unlikely that they can be a complete solution with the temptation to claim that only material in a database is protected. This creates incentives for companies to focus their bio-prospecting efforts on regions that seem to be under-represented by the database.

An alternative interpretation of the problem is that it may be thought that if foreign firms are using a legal loophole to their advantage, then there must be some potential for the owners of traditional knowledge to do the same. This may further undermine the success of any database system. However, as a practical matter there are many reasons why the owners of traditional knowledge don't take similar advantage of the law. Not the least of which is that ownership is not clearly defined, undermining the incentive to undertake the expense necessary to seek a patent abroad. This expense can be quite formidable. For example, filing fees alone for a typical patent in the United States is around \$4,000, while the defense of a patent can require substantially more.

From a different perspective, there is also a question of how to recognize the role of traditional knowledge when a *new* use for a traditional remedy is found.<sup>13</sup> The standard approach would be cross patenting or some form of licensing arrangement. Once again, the problem is that since the rights in relation to traditional knowledge are not well defined, the bases for a standard contractual solution are less clear.

## **2. Trade Secrets**

Not all traditional knowledge is openly available to all members of even a localized community. Healers and other specialized community members are examples where information is purposefully restricted. This raises the possibility that trade secrets law may be used to protect some forms of traditional knowledge.

While this instrument does have some potential, a number of problems also exist. The most obvious is that protection from unfair competition usually involves some breach of contract (e.g., proprietary knowledge that a former employee uses to help a competitor). In such cases, there is a clear relationship between the parties and the breach is also likely to have occurred within the same industry and/or country. Traditional knowledge lacks these elements so the effectiveness of trade secrets law is likely to be undermined.

Moreover, there is nothing to stop the reverse engineering of a product to discover the trade secret (Watal 2001). If most traditional knowledge takes a relatively unprocessed form, then reverse engineering is likely to be a straightforward process. These considerations reduce the potential benefits of trade secrets law as a mechanism to protect traditional knowledge.

## **B. THE TRIPS AGREEMENT AND THE CONVENTION ON BIOLOGICAL DIVERSITY**

The prominence of traditional knowledge and bio-piracy issues can also be traced to the potential conflicts between the TRIPS agreement and other international agreements, most notably the CBD. A particularly contentious issue is that the CBD affirms that countries have sovereign rights over their genetic resources and that any use of these resources should be based on prior informed consent and be for the mutual benefit of both parties.

While debate has centered on whether patents on genetic material, which are a private right, are consistent with the sovereign rights over genetic resources, the CBD also implies extra requirements on the criteria for granting patents. This arises from the requirement to attain prior informed consent for the use of genetic material. The TRIPS agreement does not expressly require this, and it has been proposed that the TRIPS agreement be amended to incorporate as a condition of patentability the disclosure of the genetic

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<sup>13</sup> A recent example relates to the use of *Phyllanthus amarus*. In India this plant has been used for treating a number of conditions. However, tests revealed that it was also beneficial in the treatment of Hepatitis B and E and was subsequently patented in the United States. See Dutfield (2001).

material. Such disclosure could provide a basis for recognizing traditional knowledge and may then be used as part of a contractual framework to ensure that benefits are shared.<sup>14</sup>

However, there has been a general reluctance to amend the TRIPS agreement in this way, citing the increased costs of patenting along with assertions that it upsets the balance of rights and obligations. Moreover, doubts have been expressed that it is possible to uniquely identify the source of genetic material, further adding to the difficulties in satisfying any source disclosure requirement. Since such objections are not insurmountable, there appears to be some scope for amending the TRIPS agreement to reflect prior informed consent. However, these negotiations are unlikely to involve just an amendment to recognize prior informed consent; some increased obligation will be expected in return. One option might be to link the recognition of prior informed consent and traditional knowledge with an increase in the standards of protection for plant and animal varieties. The potential for such trade-offs are discussed below under the heading of protection of plant and animal varieties.

### **C. FOLKLORE AND COPYRIGHT**

While the above has focused on the possibility of using patents and trade secrets to protect traditional knowledge, copyright is also deemed as having the scope to protect the folklore aspect of traditional knowledge. Overall, folklore has not received as much attention in the WTO as other components of traditional knowledge. Nevertheless, many countries are eager to see the rights in regard to folklore more firmly established as over the years traditional peoples and communities have had many of their cultural expressions appropriated without permission or even passed off as the work of others.

However, the adequacy of copyright's ability to protect folklore has been questioned. Along with other forms of traditional knowledge, no one person is associated with the cultural expression and typically, there is a time limit on the duration of protection. While the first shortcoming is one that can be overcome, the second is more problematic. In particular, creating a perpetual right requires a very clear definition and because of the duration, the extent of protection offered is likely to be relatively weak. While there are clearly concerns over the misuse of folklore, the need typically is to find a definition of rights that allows for the use of folklore by others that provides an opportunity for both parties to benefit. These limitations have seen interest in establishing a new legal instrument to protect folklore, with discussions currently underway in WIPO.

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<sup>14</sup> The Hoodia Cactus case is an example where the CBD's requirement of prior informed consent has enabled the traditional custodians of knowledge to have the prospect of sharing in the benefits of the commercialization of their

## **D. GEOGRAPHICAL INDICATIONS**

Geographical indications are identifications of the country or region where the quality, reputation, or other characteristic of a product is essentially attributable to the geographic region. Negotiations over geographical indications are part of the built-in agenda contained within the TRIPS agreement<sup>15</sup>, with the importance of these negotiations further emphasized as part of the Declaration. However, there is much debate about the scope of these negotiations, with a concern that further strengthening of protection for geographical indications is likely to upset the balance of rights and obligations of the Uruguay Round. In particular, the inclusion of geographical indications into the TRIPS agreement was seen as a concession that primarily benefited the European Union, with the size of this benefit reflected in the differential standards of protection required by the TRIPS agreement.

The system of protection currently required under the TRIPS agreement is two tiered.<sup>16</sup> Each Member must provide a means to guard against misleading or deceptive behavior that suggests a good originates from some place other than its true place of origin. This protection is offered to all goods. However, a higher standard of protection is offered to wines and spirits. For these goods, protection is offered regardless of whether or not there is potential for a consumer to be misled.

The stronger protection of wines and spirits also brings with it the need for additional institutions, the development of which are part of the built-in negotiating agenda. While the negotiating agenda clearly calls for a multilateral mechanism for the notification and registration of wines (which was extended to include spirits at Doha), the European Union has identified the extension of the higher standard of protection to more goods as a key objective. This has led to an old world-new world split over negotiations.

To date, debate has focused on mechanisms and modalities. In particular, there is doubt about whether a negotiating mandate exists to extend the higher level of protection available to wines and spirits to other geographical indications. As for establishing a multilateral system for registration, debate centers on the extent to which countries will be obliged to offer protection to registered geographical indications for wines and spirits. Those seeking lower protection are advocating that the system be used as a database,

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knowledge. See CIPR (2002).

<sup>15</sup> See Article 24 of the TRIPS agreement.

<sup>16</sup> See Articles 22 and 23 of the TRIPS agreement.

with the protection offered in specific instances determined by countries individually. However, those seeking higher protection are effectively calling for a global right once registration has occurred.

While the European Union is pushing for an extension of the protection offered to geographical indications, such an extension may also serve to protect aspects of traditional knowledge. In fact, the design of geographical indications protection overcomes two of the problems faced by traditional knowledge that typically arise in relation to other intellectual property rights. Geographical indications are not owned by a single individual, they can apply to a region or even a country. So collective ownership can be accommodated easily, unlike other forms of intellectual property rights. The duration of geographical indications is also not explicitly defined. Since it typically takes quite a while for a region to develop a distinctive reputation for the style or character of its product, defining a right with an open-ended duration helps to facilitate this process. This evolution of reputation for quality over time and the assignment of intellectual property rights to a pre-existing good, have direct parallels to issues that arise in relation to traditional knowledge. In this sense, geographical indications provide a template for the design of intellectual property that relates more specifically to traditional knowledge.

In this context, it is natural to ask what the value of protecting geographical indications is. To an extent, the protection of geographical indications may provide a basis for firms in a region that is known for the distinctive characteristics of its goods to invest and further improve the quality of their goods. This incentive is likely to be stronger if the higher form of protection is extended to all geographic indications, since the exclusivity of the indicator of origin is reserved solely for goods produced in that region. This helps to overcome the free-riding problem associated with such reputation building efforts. It may also serve as a basis for the development of other intellectual property rights, such as trademarks which provide further incentive to cultivate a distinctive character of a good.

This suggests that there is potential for developing countries to benefit from the extension of the higher standard of protection for geographical indications to a broader range of goods. However, the extension of such rights just provides the potential, it does not automatically produce the benefits. These benefits will be the outcome of a process of commercialization based on a reputation that may be under appreciated. Developing such niche markets typically involves large expenditures on advertising and marketing, and is naturally associated with a high degree of risk. Without access to the resources necessary to promote the distinctive nature of the output of a region, the benefits conferred by the protection of geographical indications will not be realized.

A further point to note is that it is not always optimal to limit the exposure that your product gets, even if this exposure is generated by a good that is not authentic. The complexity of information formation and transmission processes can lead to outcomes where a certain amount of free riding is optimal (Takeyama 1994). The higher standard of protection offered to geographical indications may retard the process of information transmission by restricting the use of a particular identifier. Such restriction may seriously diminish product recognition, reducing the value of the geographical indication. This raises the perverse possibility that the extension of a higher standard of protection of geographical indications may actually be detrimental in some situations. In particular, for countries or regions where the ability to invest in advertising or marketing is limited, the benefits of stronger protection for geographical indications may not be realized, and in fact may hamper the exposure of these goods in key markets. Thus, while the extension of a higher standard of protection of geographical indications to a broad range of goods is associated with potential benefits, the risks should also be acknowledged.

#### **E. TECHNOLOGY TRANSFER**

Like a number of other international agreements, the TRIPS agreement includes a requirement to enhance technology transfer to least developed countries. Specifically, Article 66.2 of the TRIPS agreement requires that developed countries provide incentives to their enterprises and institutions to promote technology transfer to least developed countries. By and large, these requirements have not translated into a clear course of action. Partially because the objective of facilitating technology transfer is very broad, but also because there are no specific obligations set down in terms of either reporting or the consequences of not adhering to this requirement.

In an effort to ensure that the obligations of developed country Members under Article 66.2 has some impact, the Declaration mandated the TRIPS Council to develop a mechanism for ensuring the monitoring and full implementation of Article 66.2 (see paragraph 7 of the Declaration above). The process of establishing a mechanism to ensure the monitoring and full implementation was already started by the Ministerial Conference in Doha itself. The basic parameters of the mechanism include a requirement that developed countries submit detailed reports to the TRIPS Council by the end of 2002, specifying the incentives provided for the transfer of technology. In addition, the information provided in these reports is to be updated annually.

While negotiations continue around the appropriate nature of the reporting architecture, it is worth considering what outcomes might be anticipated. From one perspective, it might be argued that

improving intellectual property rights by themselves contributes to increased technology transfer. On this point, a number of studies have attempted to assess the importance of intellectual property rights for the technology transfer decision by looking at the impact of intellectual property rights on the channels that facilitate this transfer.

Chief among these channels is foreign direct investment. There are many determinants of foreign direct investment and a definitive isolation of the independent role of these determinants is very difficult to achieve. Nevertheless, empirical evidence indicates that the level of intellectual property rights protection in a country affects both the willingness to undertake foreign direct investment and the composition of this investment. Significantly, it has been found that for industries in which intellectual property rights are crucial (pharmaceuticals for example), firms may refrain from investing in countries with a weak regime of intellectual property rights protection (Lee and Mansfield 1996). The point to emphasize is that this negative relationship is found for industries that are dependent on intellectual property rights, rather than all forms of foreign direct investment. This point is underscored by research on the impact on intellectual property rights on the composition of foreign investment. In relation to the composition of investment, regardless of the industry in question, multinationals are less likely to set up manufacturing and research and development facilities in countries with weak intellectual property rights regimes and more likely to set up sales and marketing ventures in these markets, since the latter run no risk of technology leakage (Smarzynska 1994).

While these studies suggest that compliance with the TRIPS agreement may well facilitate increases in foreign direct investment (other things being equal), with more of this investment concentrated in technology-related facilities, whether or not this leads to widespread access to technology has been part of an evolving debate. The initial attempts to isolate spillover benefits found no significant spillovers, suggesting that most of the benefit is internalized by the technology owner (Djankov and Hoekman 1999; Aitken and Harrison 1999; Aitken, et al. 1996). However, a more recent strand of the literature has found evidence that the size of the spillover benefits depend critically on whether the host country imposes performance requirements, with performance requirements being negatively correlated with technology transfer.<sup>17</sup> The relationship between sectors that have performance requirements imposed and the dependence on intellectual property rights has not been explored in the literature.

Changes in intellectual property rights may also affect the bargaining position of contracting parties and can make access to technology more difficult in a number of ways. Stronger intellectual property rights

may raise the price of access to technology, directly leading to reduced technology access. Even if the technology is transferred at the higher cost, these increased payments may in turn reduce the resources available for local research and development.

All of these factors suggest that the relationship between technology transfer and intellectual property rights is likely to be very complicated. However, of the evidence reviewed above concerning technology transfer, the key point seems to be the reluctance of firms to undertake foreign direct investment in markets where intellectual property rights are weak or insecure. This highlights a fundamental tension between the desire to increase technology transfer and a desire to allow countries time to transition to a higher standard of intellectual property rights protection. This tension is particularly pronounced in relation to paragraph 7 of the Declaration where both goals are stated. The conflict between these objectives may ultimately lead to a situation where it is possible to argue that incentives to increase the transfer of technology will only be effective in circumstances where a country has a sufficiently high standard of intellectual property rights protection.

This type of conditionality may be unavoidable, since any incentive offered for the transfer of technology is likely to be ineffective if the firms that control the technology feel that the technology is being given away. This puts least developed countries in the position of having to choose between taking the benefits from extended transition periods, or raising standards of intellectual property rights in the hope that they, and the associated incentives offered by developed countries, provide a significant increase in technology transfer.

## **F. NONVIOLATION COMPLAINTS<sup>18</sup>**

Under the General Agreement on Tariffs and Trade, the concept of nonviolation is meant to protect the reasonable expectation of the parties on the benefits derived from concessions made in the area of trade in goods. Even within the context of trade there is considerable uncertainty about its application. Consequently nonviolation typically has been narrowly interpreted. This has led to a situation where there have been very few successful nonviolation complaints.

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<sup>17</sup> See Moran (2002) for a comprehensive review of the role of foreign direct investment in the development process.

<sup>18</sup> “Under Article XXIII:1(b) of the GATT 1994, a Member can bring a “nonviolation” complaint when the negotiated balance of concessions between Members is upset by the application of a measure, whether or not this measure is inconsistent with the provisions of the covered agreement. The ultimate goal is not the withdrawal of the measure concerned, but rather achieving a mutually satisfactory adjustment, usually by means of compensation.” From the Appellate Body in its report on *India – Patents*.



Article 64.3 of the TRIPS agreement requires the TRIPS Council to examine the scope and modalities for nonviolation and situation complaints, and make recommendations to the General Council by the end of 1999. However, the TRIPS Council has not been in a position to carry out this task and has not fulfilled its mandate. The importance of this implementation issue was further emphasized in the Doha Decision on Implementation-Related Issues and Concerns, with the imperative that a recommendation over nonviolation complaints in relation to TRIPS be presented to the Fifth Ministerial conference. Until this issue is resolved, members have agreed not to initiate nonviolation complaints under the TRIPS agreement.

Scope for a nonviolation complaint can potentially arise in a number of ways in relation to the TRIPS agreement. In particular, it has been argued that the *benefit* conferred under the TRIPS agreement is the ability to *acquire, maintain and enforce* intellectual property rights. This is a relatively broad right and the impact of nonviolation complaints will depend on how this measure is interpreted.

The concern has been expressed that uncertainty regarding the interpretation of nonviolation complaints may unduly constrain governments in the development of policy. It has been noted that measures and policies enacted in pursuit of legitimate public policy objectives, such as social, economic development, health, environmental, and cultural objectives, may have an impact on the operation of intellectual property rights, even if fully consistent with the obligations of the TRIPS agreement.<sup>19</sup> It has been argued that, through the process of binding dispute settlement, Members could discover that the vague concept of nonviolation applied to TRIPS obligations may take on a much wider scope than was ever intended. Given this prospect, the concern is that without a clear understanding about the nature of nonviolation complaints, countries may feel unduly constrained in pursuing many public policy goals.

## **G. PROTECTION OF PLANT AND ANIMAL VARIETIES**

During the Uruguay Round, the issue of patenting plant and animal varieties was particularly controversial. This controversy was fueled by the combination of the emergence of the biotechnology industry and the associated ethical issues of patenting life forms. These issues generated considerable uncertainty over what was the appropriate form of protection. Consequently, the discipline required in

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<sup>19</sup> Examples that have been cited as having the potential to generate a nonviolation complaint are: bans on the publication of a book on the grounds of national security; laws on libel, pornography, and hate literature as applied to copyright works; a registration scheme for hand guns that leads to a reduction in exports of patented hand guns; import controls on patented products such as pharmaceuticals, electronic goods, and machine parts; and prohibitions by school authorities on collectible trading cards that lead to reduced sales of trademarked collectible trading cards from another member

this area by the TRIPS agreement only imposes minimal conditions on member countries. Specifically, issues relating to the patenting of plant and animal varieties are covered by Article 27.3(b) of the TRIPS agreement. However, it was also agreed that this Article would be reviewed, and hence the patenting of plant and animal varieties had been a subject of negotiations at the time of the Ministerial meetings in Doha.

While Article 27 of the TRIPS agreement requires that patents be made available in all fields of technology, Article 27.3(b) allows plants and animals, and essentially biological processes for their production to be excluded from patentability.<sup>20</sup> A certain amount of arbitrariness exists in defining what can be excluded, since microorganisms cannot be excluded nor can microbiological or nonbiological processes.

If a country does not protect plants by patents, it must offer at least an effective *sui generis* system of protection. Essentially, plant breeders' rights must be protected by some special kind of right. Plant breeders' rights differ from patents in that they allow a number of other rights to potentially coexist such as farmers' privilege (to save seeds for replanting or for exchange with other farmers) and breeders' exemption (breeders are free to use the protected variety to develop a new one).

A key issue with respect to a *sui generis* system for the protection of plants is determining what an effective system constitutes. Part of this uncertainty surrounds the relationship between the TRIPS agreement and International Union for the Protection of New Varieties of Plants (UPOV). UPOV was initially adopted in 1961 and has been revised in 1978 and again in 1991. While the TRIPS agreement could have referenced the UPOV, and made its adoption a requirement, this was not done. At the time, there were good reasons for not referencing UPOV; specifically the 1991 version had not been widely adopted. However, pressure is now mounting to use it as a model for defining an effective system of *sui generis* protection.

One difficulty in using UPOV as a model for a *sui generis* system is that its 1991 version embodies significantly higher standards than the 1978 version, with the 1978 version closer to the standards that developing countries would find acceptable. While countries can now only join UPOV 1991, it is

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<sup>20</sup> Article 27.3(b): Members may also exclude from patentability plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement (GATT 1994).

possible that they could still use UPOV 1978 as a model for their domestic legislation if they remain outside of UPOV. So modifying the TRIPS agreement to incorporate UPOV 1991 is unlikely to be a straightforward matter.

Another area of debate is that some countries, particularly developing countries, want a *sui generis* system to be consistent with the CBD, which among other things would require prior informed consent for the use of genetic material and the recognition of traditional knowledge.

This last point suggests that there is potential for trade-offs to be made, with a stronger *sui generis* system of protection of plant varieties (say UPOV 1991) offered in exchange for the an extension of the TRIPS agreement to include prior informed consent as a pre-condition of patentability and of an agreement covering traditional knowledge.

Pursuing such linked negotiations are likely to be complicated by a number of factors. During the Uruguay Round, TRIPS negotiations primarily followed the interests of the United States, European Union, and Japan. These countries were able to employ an extremely effective negotiating strategy to set the agenda and achieve their desired outcome (Drahos 2002). Therefore, these countries must have an interest in trading off these issues for negotiations to move forward with any hope of success.

However, the TRIPS-plus results gained from unilateral pressure suggests that the United States and European Union do not necessarily need to make such trade-offs in order to achieve a desired outcome. The ability to pursue TRIPS-plus agreements comes from the discretion that the United States in particular exercises over its trade policy in relation to developing and least developed countries. The threat to withdraw trade preferences ensures a strong bargaining position in negotiations with most developing countries. Table 3 gives an indication of the extent of the bilateral pressure as well as the success that the TRIPS-plus approach has had. Moreover, a number of these TRIPS-plus measures have required the partner country to join UPOV 1991. This suggests that the key developed countries will not necessarily be interested in making trade-offs with developing countries.

**Table 3: United States Bilateralism on Intellectual Property**

	<b>Bilateral Intellectual Property Agreement (BIP)<sup>a</sup></b>	<b>Bilateral Investment Treaty</b>	<b>301<sup>b</sup></b>	<b>WTO Status<sup>c</sup></b>
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	<b>Bilateral Intellectual Property Agreement (BIP)<sup>a</sup></b>	<b>Bilateral Investment Treaty</b>	<b>301<sup>b</sup></b>	<b>WTO Status<sup>c</sup></b>
Albania	1992	1998		M
Argentina		1994	Y	M
Armenia	1992	1996	Y	O
Azerbaijan	1995	1997 <sup>d</sup>	Y	O
Bahrain		1999 <sup>d</sup>	Y	M
Bangladesh		1989	Y	M (LDC)
Belarus	1993	1994 <sup>d</sup>	Y	O
Bolivia		1998 <sup>d</sup>	Y	M
Bulgaria	1991,1994	1994	Y	M
Cambodia	1996			A
Cameroon		1989		M
China, People's Rep. of	1992, 1995, 1996		Y	M
Croatia	1998	1996 <sup>d</sup>		M
Czech Republic	1990	1992	Y	M
Ecuador	1993	1997	Y	M
Egypt		1992	Y	M
El Salvador		1999 <sup>d</sup>	Y	M
Estonia	1994 <sup>d</sup>	1997	Y	M
Georgia	1993	1997		M
Grenada		1989		M
Honduras		1995 <sup>d</sup>	Y	M
Hungary	1993		Y	M
India	1993		Y	M
Jamaica	1994	1997	Y	M
Jordan	2000 <sup>d</sup>	1997 <sup>d</sup>	Y	M
Kazakhstan	1992	1994	Y	O
Korea, Rep. of	1986, 1990	1989	Y	M
Kyrgyz Rep.	1992	1994		M
Lao People's Dem. Rep.	1997 <sup>d</sup>			A
Latvia	1995	1996	Y	M
Lithuania	1994 <sup>d</sup>	1998 <sup>d</sup>	Y	M
Moldova	1992	1994	Y	M
Mongolia	1991	1997		M
Morocco		1991		M
Nicaragua	1997	1995 <sup>d</sup>	Y	M
Panama	1994	1991	Y	M
Paraguay	1998		Y	M
Peru	1997		Y	M
Philippines	1993		Y	M
Poland		1994	Y	M
Romania	1992	1994	Y	M
Russia	1992	1992 <sup>d</sup>	Y	O
Senegal		1990		M
Singapore	1987		Y	M
Slovakia		1992		M
Sri Lanka	1993	1991		M
Surinam	1993			M
Taipei,China	1992, 1993		Y	
Tajikstan	1993		Y	

	<b>Bilateral Intellectual Property Agreement (BIP)<sup>a</sup></b>	<b>Bilateral Investment Treaty</b>	<b>301<sup>b</sup></b>	<b>WTO Status<sup>c</sup></b>
Thailand	1991		Y	M
Trinidad and Tobago	1994	1996		M
Tunisia		1993	Y	M
Turkey		1990	Y	M
Turkmenistan	1993		Y	
Ukraine	1992	1996	Y	O
Uzbekistan	1994	1994 <sup>d</sup>	Y	O
Viet Nam	1997		Y	O

**Notes:**

This Table was compiled from information available on the websites of the Office of the US Trade Representative and WTO which were last visited on 29 August 2001.

<sup>a</sup> BIP includes both agreements specifically on intellectual property rights and trade agreements containing provisions on intellectual property rights. The information here may be incomplete.

<sup>b</sup> A country with a Y in this column has had a 301 action brought against it or been listed, reviewed, or observed under the 301 process. The information here may be incomplete.

<sup>c</sup> The countries listed in this column are developing country Members of the WTO, WTO Members undergoing a transformation from centrally planned economies to free-enterprise economies, or least developed country Members and therefore entitled to the benefits of the transitional provisions in Articles 65 and 66 of the TRIPS agreement.

<sup>d</sup> Signed in this year but had not yet entered into force as at the beginning of 2000.

M = Member

M (LDC) = Least-Developed Country Member

A = LDC in the process of accession to the WTO

O = Observer government which must start accession negotiations within 5 years of becoming an observer.

Source: Drahos (2002).

A further difficulty with trying to trade-off gains in one area of intellectual property rights reform against losses in another is underscored by Table 1. The flexibility, and therefore the source of much of the benefits in the TRIPS agreement, has not been exploited to date by developing and least developed countries. Embarking on further negotiations runs the risk of compounding implementation problems and directing resources away from higher priority areas. This suggests that a strategy of limiting any further increases in the standards of intellectual property rights would be optimal from the perspective of developing and least developed countries.

However, with the prospect of bilateral pressure always in the background, this strategy may not be available, leaving the lesser of the two evils to be multilateral negotiations. Under this option, there is at least the prospect that issues like prior informed consent and traditional knowledge may be represented in some way within the TRIPS agreement. The success of these efforts may depend critically on the coalition building skills of developing and least developed countries. For example, the ability of developing countries to tie their interests with the desire of the European Union to raise standards of protection for geographical indications may prove to be the deciding factor in whether developing countries are able to realize significant benefits from the current TRIPS negotiating agenda.

#### **IV. CONCLUSION**

Given the ambitious nature of the TRIPS agreement it is not surprising that much of the current and future work around this agreement will involve issues of implementation. Also given the large differences in the benefits derived by WTO members from complying with the TRIPS agreement, a rigid insistence on its application is not feasible. Instead, countries must be allowed to interpret the agreement in a way that is most suitable to their needs. Of course, there must be limits to this interpretation, and the results from Doha—especially in relation to public health—demonstrate that when conflict does arise between national interest and intellectual property rights, compromise is possible. Nevertheless, it should be recognized that while the TRIPS agreement can be modified to ensure that intellectual property rights are not an obstacle to dealing with public health emergencies, this action is not sufficient to ensure that the appropriate medicines will be available. An effective approach to public health crises, such as the AIDS epidemic, will require other resources, especially in the least developed countries, where there is no current obligation to abide by the TRIPS agreement.

Aside from public health issues, the prospects for future changes to the TRIPS agreement appear to be relatively limited. In areas where the developing and least developed countries could potentially benefit the most (the recognition of traditional knowledge and the extension of the protection of geographical indications), the approach has been one of exploring the issues rather than the examination of explicit proposals. Further complicating these issues has been uncertainty surrounding the appropriate forum for negotiations. On the other side, issues that developed countries would like to see addressed (such as protection for digital products placed on the internet) are unlikely to be received favorably. While it may be possible to link these issues and contain any trade-offs within the domain of the TRIPS agreement, developing countries are more likely to achieve a higher net benefit from any concession over intellectual property rights when it is matched by greater market access for their goods. The implication of this calculus is that the most trade-related aspect of negotiations over intellectual property rights will be the

extent of improvements in market access offered by developed countries in return for the implementation of the current standards in TRIPS by developing and least developed countries.

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### Appendix: Overview of Patent Laws in Selected Asian Countries

	India	Pakistan	Sri Lanka	Philippines	Malaysia	Viet Nam	People's Rep. of China
<b>PATENTS</b>							
Search & Examination	Yes	No clear substantive examination. Opposition period is however provided.	Grant published	Substantive examination after grant.	Grant published. Applicant may request modified sub exam when he has a granted patent for the same invention elsewhere (<70% of normal cost.		Substantive examination after publication
Novelty	Absolute (for inventive step use only in India is considered)	Absolute	Relative – oral and use only in Sri Lanka.	Absolute	Absolute – including oral & use disclosure worldwide	Absolute	Relative. Local public use only taken into account.
Exhaustion regime	International	Unclear. Law refers to products put on the market.	International	National	International		Appears international
Early working (Bolar)	Yes – within 3 years of end of patent life	Not explicitly allowed	Not specifically allowed	Not specifically allowed	Yes		Not specifically provided
Compulsory licensing	Failure to work in India. Public requirement not met or not met on reasonable terms	For reasons of public interest including health. To remedy anti-competitive practice	No provision	For reasons of public interest and to remedy anti-competitive practices. Nonworking.	Demand not being met or being met on unreasonable terms.		Failure to obtain reasonable license. Public interest, national emergency or extraordinary situation.
2 <sup>nd</sup> Medical use	Specifically excluded		Not specifically excluded	Not specifically excluded	Yes SS14(4)	Yes	Allowed

	<b>India</b>	<b>Pakistan</b>	<b>Sri Lanka</b>	<b>Philippines</b>	<b>Malaysia</b>	<b>Viet Nam</b>	<b>People's Rep. of China</b>
Disclosure requirements (origin of material)	Yes. Section 25-ground for opposition		No		Apparently not		
Patents on plants and animals	No	No	Specifically excluded	Plant varieties and animal breeds excluded	Plant and animal varieties excluded	Plant and animal varieties excluded (United States Agreement requires inventions covering more than one variety to be patentable).	Plant and animal varieties excluded
Pharmaceutical products	No. Mailbox provisions apply.	Not until 2005. Mailbox provisions apply.	Yes		Yes	Yes	Yes
Protection of undisclosed information			Article 39(3) wording in proposed legislation.	Data apparently protected against use by second applicant.	By common law. Would apparently prevent second applicant using previously submitted test data.	Protected. (United States Agreement prevents second applicant from relying on previously submitted data.)	

	India	Pakistan	Sri Lanka	Philippines	Malaysia	Viet Nam	People's Rep. of China
Protection of community intellectual property Rights				Specific legislation provided protection in perpetuity for community-based innovations. Commercial users of the innovation must pay at least 50% of net sales to the Community.			

**PLANTS AND PLANT GENETIC RESOURCES**

Access legislation for genetic resources	Draft legislation requires patent applicant to seek consent of National Biodiversity Authority before patent based on GM obtained from India.			Yes. Act does not however appear to impose any requirements on patent applicants or authorities. Act does require PIC and benefit sharing.			
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	<b>India</b>	<b>Pakistan</b>	<b>Sri Lanka</b>	<b>Philippines</b>	<b>Malaysia</b>	<b>Viet Nam</b>	<b>People's Rep. of China</b>
Plant Variety Legislation	Provides for benefit sharing claims by communities and NGOs. Applicant must disclose details of community-based genetic material used to develop the protected variety.	Provides protection for EDV.	<i>Sui generis</i> system being prepared. Will protect EDV. Exceptions cover private and research. Farmers' exception may be provided for certain varieties to enable limited use of farm saved seed. National Exhaustion regime.	<i>Sui generis</i> system providing protection for EDV. Plant Variety Act 2000	Being drafted	UPOV consistent legislation issued in 2001. (United States Agreement calls for either UPOV 78 or 91 standard).	Yes
Plant variety right exceptions	Broad research exemption. Broad farmers' rights. Payment from central gene fund available to local conserves of biological resources.	Broad farmers' rights to cover traditional saving, exchanging, and selling. Broad research exception. National Exhaustion.		Small farmers can save and exchange seeds. Broad research exemption but not covering EDV.			Rights extend only to production or selling for commercial purposes.

Source: Thorpe (2002).