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Compulsory Licensing for Public Health Needs:

The TRIPS Agenda at the WTO after the Doha Declaration on Public Health

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Frederick M. Abbott

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Executive Summary

1. Ministers to the WTO directed the TRIPS Council to find ways to facilitate effective use of compulsory licensing to address public health needs. This paper analyses relevant legal issues from the perspective of developing Members and makes recommendations for action.

2. Developing Members sought to address the obstacles created by Article 31(f) at Doha and presented concrete proposals. These involved interpreting Article 31 to allow Members to recognize and give effect to compulsory licenses granted by other Members, and interpreting Article 30 to allow for export to meet public health needs. These proposals met resistance from some developed Members.

3. The Doha Declaration provided for extension of transition periods for LDCs to implement and enforce pharmaceutical product patent protection. The extension provides some flexibility for continuing importation of low-priced drugs, and may facilitate the creation of local manufacturing capacity. However, there is considerable uncertainty regarding the applicability of mailbox and exclusive marketing rights requirements that should be addressed by the TRIPS Council. LDCs may want to pursue a broadening of the subject matter scope of the extension.

4. Compulsory licensing is an important public policy tool for all WTO Members. Developing Members in particular have a compelling need to use compulsory licensing to improve access to medicines, vaccines and other public health related inventions. There are preconditions to the effective use of compulsory licensing that are difficult for many developing countries to meet. This leads to problems in producing needed products and in establishing a network of low price suppliers.

5. The TRIPS Council may recommend amendment, waiver or interpretation of TRIPS Agreement provisions. The amendment and waiver mechanisms are not constrained by existing text, and provide the maximum flexibility. Amendment may be politically more difficult and time-consuming. Waiver presents political and timing advantages.

The Ministerial Conference and General Council may formally interpret the TRIPS Agreement, and in so doing are bound to respect the terms, context, and object and purpose of the agreement. They are not, however, bound by previous interpretations by panels and the Appellate Body.

The TRIPS Agreement authorizes the TRIPS Council to review and propose amendments and modifications. The TRIPS Council is not limited by the express terms of the Doha Declaration regarding the subject matter of its work program.

6. The relatively modest use of compulsory licensing by developing Members to date is explained by a variety of factors. Recognizing the multidimensional nature of the problem, the restriction imposed by Article 31(f) that the licensee must "predominantly" supply the local market operates as a significant restriction on the capacity of developing Members to make and acquire medicines and other public health related products. Prospective importing Members are limited as to the sources of products, and prospective exporting Members are limited in their capacity to establish economies of scale.

7. The problems created by Article 31(f) may be ameliorated somewhat by creating streamlined parallel compulsory licensing arrangements and regional patent arrangements. Creative legal structures such as pharmaceutical production export zones (PPEZs) might be contemplated. When compulsory licenses are granted to remedy anticompetitive practices, the limitation imposed by Article 31(f) does not apply. Each of these solutions is problematic for operational or interpretative reasons. As a practical matter, it is difficult to interpret Article 31(f) in a manner that addresses the concerns of developing Members.

8. The express text and context of Article 30, particularly in light of paragraph 4 of the Doha Declaration, allows Members to authorize the making and export of patented public health related products to address unmet health needs in countries without the financial resources to provide access to medicines for all.

Article 30 authorizes "limited exceptions", meaning deviations from general rules within established boundaries. These exceptions should not "unreasonably conflict" with the "normal exploitation" of patents. Exports of public health related products to markets requiring low price access do not so conflict. Exceptions should not "unreasonably prejudice" the "legitimate interests" of patent holders, taking into account the legitimate interests of third parties. The interests of patent holders are protected if exports are not authorized for developed Member markets, and if there is not systematic diversion to those markets. Individuals in developing Members with need for access have legitimate interests to be taken into account.

Discretion whether to authorize an exception under Article 30 is in the hands of the Member that would grant the authorization.

9. Patent holders are entitled to adequate remuneration in the circumstances of the case when subject to compulsory license. When compulsory licenses are issued both in the country of export and import, the patent holder will ordinarily be compensated within the importing Member. When no license is required for importation, the patent holder will be compensated in the exporting Member. There is no basis for suggesting that patent holders are entitled to double-compensation when products are exported and imported under compulsory license.

10. Some have argued that Article 31 of the TRIPS Agreement is subject to the Article 27:1 rule against discrimination as to field of technology. There is good reason to conclude that Article 30 is not so subject. Article 27:1 does not in any case prevent Members for bona fide reasons from adopting rules that differentiate among patents in diverse fields of technology. Ministers in fact differentiated among fields of technology in the Doha Declaration.

11. As a first best solution, Developing Members should propose amending the TRIPS Agreement to delete Article 31(f). This would permit compulsory licensing predominantly for export, thereby eliminating the most serious impediment to manufacture and trade in public health related products, including medicines and vaccines. If Article 31(f) is deleted, an amendment to Article 30 may be useful, though not essential. A waiver of Article 31(f) might be adopted pending conclusion of amendment of the TRIPS Agreement.

Article 27:3(a) of the TRIPS Agreement might be amended to permit Members to exempt public health related inventions from patenting, recalling that this position was advocated by a number of developing Members during the Uruguay Round negotiations. Article 8:1 should be amended so that the safeguard provision relating to intellectual property is consistent with the safeguard provisions relating to goods and services.

12. As an alternative to amendment of the TRIPS Agreement, the Ministerial Conference and General Council may adopt an interpretation of Article 30 making clear that Members may authorize the making, sale and export of public health related products without the consent of patent holders. Such an interpretation might indicate:

1. Authorization to make, sell and export patented public health related products is a limited exception to the rights of patent holders;

2. Such authorization does not conflict with the normal exploitation of the patent when:

   a. Undertaken to address unmet public health needs in countries of import, and;
   b. Financial constraints in countries of import restrict attention to the public health requirements of all individuals**.**

3. Such authorization does not prejudice the legitimate interests of patent holders, taking into account the legitimate interests of third parties when:

   a. The authorization is not directed to supplying a developed importing Member;
   b. Without prejudgment as to the form such mechanism may take, the country of import accepts to provide the patent holder in the country of export with a reasonable opportunity to prevent the systematic diversion to developed Members of products supplied under exception.

4. Nothing in the foregoing precludes Members from authorizing exceptions regarding developed Members as circumstances justify.

   Whether there is manufacturing capacity in a prospective importing Member is a factor that may be taken into account when determining whether that Member has unmet public health needs.

Compulsory Licensing for Public Health Needs:
The TRIPS Agenda at the WTO after The Doha Declaration on Public Health

Frederick M. Abbott*
February 2002

I. Background

Ministers to the WTO directed the TRIPS Council to find ways to facilitate effective use of compulsory licensing to address public health needs. This paper analyses relevant legal issues from the perspective of developing Members and makes recommendations for action.

Prior to the WTO Doha Ministerial Conference in November 2001, developing (including least developed) Members of the WTO had identified an important set of limitations imposed by the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement") that would adversely affect their access to medicines. These Members sought to incorporate in the Ministerial Declaration to be adopted in Doha an acknowledgement of their right to take steps to avoid these adverse effects.

In certain respects, the Doha Declaration on the TRIPS Agreement and Public Health ("Doha Declaration") effectively addressed concerns of developing Members, in particular by including a decision in favor of implementation of the TRIPS Agreement in a manner supportive of public health and access to medicines for all. This decision should favorably influence future interpretations and negotiations within the TRIPS Agreement framework from the standpoint of developing Members.

Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health provides:

> "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." [1]

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[1] Ministerial Conference, Fourth Session, Doha, 9 - 14 Nov. 2001, WT/MIN(01)/DEC/2, 20 Nov. 2001.

Paragraph 6 of the Doha Declaration directs the WTO Council for TRIPS ("TRIPS Council") to address the problems that Members with insufficient or no manufacturing capacity may have in making effective use of compulsory licensing, and to report to the General Council by the end of 2002. Paragraph 6 frames in a rather limited way a set of concerns raised by developing Members. This set of concerns relates to the foreseeable reduction of off-patent medicines that will be available for export and import as TRIPS Agreement transition periods applicable to developing and least developed countries expire. It concerns the ability of Members to grant compulsory licenses that predominantly supply import markets of other Members, and the right of Members to make use of the Article 30 TRIPS Agreement exception to authorize the making and export of pharmaceutical products. Ultimately, it implicates deeper concerns regarding restrictions the TRIPS Agreement imposes on Members in the adoption of exceptions to patenting and on safeguard measures taken to address public health needs.

II. Lead-Up to the Doha Ministerial Conference

Developing Members sought to address the obstacles created by Article 31(f) at Doha and presented concrete proposals. These involved interpreting Article 31 to allow Members to recognize and give effect to compulsory licenses granted by other Members, and interpreting Article 30 to allow for export to meet public health needs. These proposals met resistance from some developed Members.

Paragraph 6 of the Doha Declaration reflects the failure to reach agreement on measures that developing and least developed Members proposed to deal with the issue of compulsory licenses issued predominantly to satisfy import requirements of Members. The measures proposed by developing Members[2] stated:

> "5. A compulsory license issued by a Member may be given effect by another Member. Such other Member may authorize a supplier within its territory to make and export the product covered by the license predominantly for the supply of the domestic market of the Member granting the license. Production and export under these conditions do not infringe the rights of the patent holder.
>
> …
>
> 7. Under Article 30 of the TRIPS Agreement, Members may, among others, authorize the production and export of medicines by persons other than holders of patents on those medicines to address public health needs in importing Members."[3]

[2] In this paper, the term "developing" country or Member will be used to refer to both developing and least developed WTO Members, except as the context indicates otherwise.

[3] The developing country group non-paper draft declaration submitted to the TRIPS Council on September 18, 2001 included the following additional provisions relevant to the subject matter of paragraph 6:

> " 3. Each Member has the right to allow other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, and to determine the grounds upon which such use is allowed.
>
> …
>
> 4. In the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use, Members may grant compulsory licenses without prior efforts on the part of the user to obtain authorization from the right holder.
>
> …

The practical and legal background of this issue was addressed by this writer in a paper prepared and distributed in advance of the Doha Ministerial.[4] To briefly summarize key points:

1. Granting patent protection on pharmaceutical products tends to result in increased prices for those products. Developing countries require a continuing supply of generic (off-patent) medicines within their financial means to address disease threats and disease burdens.

2. The world supply of generic drugs is decreasing as a result of implementation of the TRIPS Agreement. The decrease will accelerate when on January 1, 2005, developing countries are required to implement pharmaceutical product patent protection, and grant patents as appropriate to pharmaceuticals in the mailbox pipeline.

3. Compulsory licenses are an important tool by which developing countries may authorize continuing production or importation of generic medicines.

4. It is generally accepted that under the terms of the TRIPS Agreement a developing country may issue a compulsory license in respect to a locally-patented drug, and that license may be satisfied by importation of the drug, provided there is a source country where the rights of a patent holder would not be infringed by the making and export of the drug.

5. It is important to identify the legal mechanisms by which countries that grant compulsory licenses (and countries where no patent protection is in force) may import generic drugs from countries where patent protection exists. Such opportunities may be restricted by the existing terms of the TRIPS Agreement, including Article 31(f).

6. The potential legal solutions discussed in the September 2001 paper included:

a. Recognition by an exporting country of a compulsory license granted in an importing country, giving effect to the license as an exception to the rights of the exporting country patent holder;

b. Agreement that Article 30 (Exceptions to Rights Conferred) of the TRIPS Agreement permits authorizing the making and export of patented drugs under certain circumstances;

c. Using the doctrine of frustration to authorize export of a predominant part of production notwithstanding Article 31(f) of the TRIPS Agreement.

> 6. Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) of Article 31 of the TRIPS Agreement where use of the subject matter of a patent is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive."

Non-Paper on Ministerial Declaration on the Trips Agreement And Public Health, Submission by the African Group, Bangladesh, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Haiti, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand, and Venezuela.

[4] Frederick M. Abbott, *The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference*, Quaker United Nations Office – Geneva, Occasional Paper 7, September 8, 2001, published in 5 J. WORLD INTELLECTUAL PROP. 15 (2002), available as Occasional Paper at http://www.quno.org..

The potential legal solutions set out in subsections 6(a) and (b) above are consistent with paragraphs 5 and 7 of the developing country group proposal for a Ministerial Declaration on the TRIPS Agreement and Public Health, quoted above.[5] The potential solution set out in subsection 6(c) above is consistent with the adoption of a waiver of Article 31(f).

The European Commission presented an analysis of legal issues regarding compulsory licensing substantially prior to the Doha Ministerial.[6] The EU summarized this analysis in its submission to the TRIPS Council on access to medicines,[7] stating:

> "13. Article 31 has been further criticised for requiring that goods manufactured under a compulsory licence be 'predominantly for the supply of the domestic market of the Member authorising such use.' This provision is sometimes said to prevent a small country that has no production facilities of its own from obtaining cheap medicines from abroad under a compulsory licence. This is an important argument, as the Agreement does not appear to offer any legal certainty on the issue. What can be said is that a WTO Member is free to grant a compulsory licence for the importation of goods which are under patent in its own territory, as long as the imported goods have been produced in a country where they are not patented, or where the term of protection has expired. However, the EC and their member States also point to another possible interpretation of the Agreement (see DG Trade website http://www.cc.cec:8082/comm/trade/pdf/med_lic.pdf) that would allow a Member to issue a compulsory licence to a manufacturer in another country, provided the government of that other country recognised the licence (which it would not be obliged to do under the Agreement), and provided that all the goods manufactured under the licence were exported to the country granting the licence. It should be noted, however, that it is far from certain whether such a 'permissive' reading of the Agreement would stand scrutiny by a panel or the Appellate Body.
>
> The EC and their member States are ready to discuss this matter in order to reach consensus on this issue among all WTO Members."

In its paper presented in the lead-up to Doha, the United States stated on this issue:

> "Paragraph (f) is also very important for our discussion today, because questions have been raised about whether a compulsory licence can be granted under a patent to a supplier from another country. Paragraph (f) states that compulsory licences should be authorized predominantly for supply of the domestic market of the Member authorizing the use.
>
> In our view, the nationality of the recipient of a compulsory licence is not relevant for purposes of Article 31. What is relevant, in such a case, would be whether the licence results in infringement of a patent for the same product in the licensee's country.
>
> Obviously, if no patent for the drug has been granted in the licensee's country, no infringement would occur. If such protection does exist, however, and the

[5] *See* note text at note 3, *supra.*

[6] European Commission, Compulsory Licensing and Data Protection, *Legal Issues Related to Compulsory Licensing Under the TRIPS Agreement, An EU Contribution*, made available at <http://europa.eu.int/comm/trade/pdf/med_lic.pdf> (undated document with file creation date Feb. 13, 2001).

[7] Communication from the European Communities and Their Member States, *The relationship between the provisions of the TRIPs agreement and access to medicines,* IP/C/W/280, 12 June 2001.

> compulsory licensee chooses to manufacture the drug in its country for export to the country that granted the compulsory licence, a problem is created. If the patentee successfully sued the producer in the other country, the compulsory licence originally granted would be ineffective in supplying of the needed pharmaceutical.
>
> For this reason, one must consider whether it would be appropriate to limit eligibility for compulsory licences to those parties that can assure the government granting the licence that they will be able to supply the market without interruption that might result from infringement of a patent in their own country.
>
> The non-national could make such assurances either because no patent existed in its home country, because it had obtained a voluntary licence from the patentee in its home country that allowed it to produce the patented pharmaceutical for the supply of the other market, or because it planned to produce the patented pharmaceutical in the territory of the country granting the compulsory licence.
>
> The EC has identified a possible interpretation of the Agreement with respect to whether a compulsory licence can be granted under a patent to a supplier from another country even where patent infringement might otherwise be considered to have occurred. This proposal raises questions that should be addressed if there is further discussion of this concept."[8]

III. Changes Brought About in Doha

The Doha Declaration provided for extension of transition periods for LDCs to implement and enforce pharmaceutical product patent protection. The extension provides some flexibility for continuing importation of low-priced drugs, and may facilitate the creation of local manufacturing capacity. However, there is considerable uncertainty regarding the applicability of mailbox and exclusive marketing rights requirements that should be addressed by the TRIPS Council. LDCs may want to pursue a broadening of the subject matter scope of the extension.

a. Extension of LDC transition time period

In addition to providing for further negotiations regarding compulsory licensing in paragraph 6, the Doha Declaration at paragraph 7 directed the TRIPS Council to authorize the extension until January 1, 2016 of the transition period for least developed Members (hereinafter "LDCs") to implement or enforce pharmaceutical patent protection. The terms of this extension are somewhat ambiguous in that it is not clear from the express text whether LDCs are required to implement mailbox and exclusive marketing rights provisions prior to the end of the transition deadline.[9] There is some indication that

[8] Intervention of the delegation of the United States under item N (Intellectual Property and Access to Medicines) of the agenda of the Council for TRIPS meeting of 18-22 June 2001, JOB(01)/97/Add.5, Council for TRIPS, 28 June 2001.

[9] The express text of paragraph 7, second sentence, exempts LDCs from the obligation to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement, and the obligation to enforce rights provided for under those sections. By its express terms, paragraph 7, second sentence, does not address obligations under Article 70:8 and 70:9 of Part VII of the Agreement. In the absence of some contrary understanding reached at Doha, Article 70:8 would appear to continue to apply, and require least developed Members to maintain "mailbox" application mechanisms that allow for the receipt and retention of pharmaceutical patent applications until coverage is provided under local law. Pharmaceutical patent applications received before

paragraph 7 was understood by negotiators in Doha not to require that mailbox and exclusive marketing rights requirements be implemented or enforced.

If an LDC is required to implement mailbox protection, it must establish a procedure under which it will accept for filing pharmaceutical product patent applications filed abroad. Until the LDC establishes patent protection, the patent application remains dormant. However, during the period of dormancy, the LDC is required to grant exclusive marketing rights to the patent holder for a maximum period of five years following marketing approval of its drug.[10] For almost all intents and purposes, the grant of exclusive marketing rights will be as effective as granting a patent in preventing generic drugs from entering the LDC market. Beyond that, however, when the dormancy period of the mailbox application ends, the drug covered by the application will be patented (assuming it meets relevant criteria). An entire "pool" of drugs that may be generic in an LDC during the mailbox transition period will come under patent at the end of the period. If, however, there is no mailbox system in place, holders of patents outside the LDC will not be able to obtain patents after the transition period has ended because the inventions covered by the patents will no longer be novel in the patenting sense. Thus, if there is no mailbox system in place, drugs that are generic (off-patent) during the transition period will remain generic after the transition period ends.

The issue whether mailbox and exclusive marketing rights requirements are applicable to LDCs during the extended transition period is of considerable importance and should be addressed by the TRIPS Council in connection with operationalizing the extension envisaged by paragraph 7.

In a limited set of circumstances, the transition period extension in favor of LDCs will allow them additional access to generic medicines. This is when a medicine is off patent in a developing Member such as India (and may be exported), but prior to the extension would be on patent in the LDC. The transition period extension relieves the LDC from the obligation to enforce local patents, so the LDC will be able to import the drug for so long

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January 1, 2016 would have priority dates preserved and be reviewed under patentability criteria as of the priority dates. Patent protection would be available for the remainder of the patent term counted from the priority date.

Absent a contrary understanding reached at Doha, Article 70:9 also appears to apply. If so, exclusive marketing rights should be granted to the patent applicant for a maximum period of five years following marketing approval of the pharmaceutical product in the least developed country, provided that a pharmaceutical patent has been granted and marketing approval has been obtained by the patent applicant in another Member. A pharmaceutical patent applicant with exclusive marketing rights in a least developed Member has the effective equivalent of patent rights because, while it may not have exclusive rights to make or import the covered drugs, it presumptively will be able to prevent the marketing of generic equivalents, and it may thereby control the local market.[9] Exclusive marketing rights may be even more burdensome to LDCs than patents if they are understood not to be subject to the same exceptions (*e.g.*, Article 30, TRIPS Agreement) to which patents are subject, or to compulsory licensing (Article 31, TRIPS Agreement).

Reports from some negotiators at Doha indicate an understanding that paragraph 7, second sentence, was intended to exempt LDCs from mailbox and exclusive marketing rights requirements otherwise established by Articles 70:8 and 70:9 of the TRIPS Agreement. Since paragraph 7, third sentence, instructs the TRIPS Council to give effect to the mandate of paragraph 7, it is important that the Council clarify the meaning of the Declaration when it takes this action. If the Council fails to implement paragraph 7, second sentence, based on a common understanding that least developed Members are exempt from mailbox and exclusive marketing rights requirements, the legal situation regarding these requirements will be uncertain.

[10] Provided also that a patent has been granted and marketing approval obtained in another WTO Member.

as it remains off-patent in India.[11] For drugs that go on-patent in India (and other developing Members) after January 1, 2005, either because applications filed during mailbox period are converted to patents, or because of newly-filed applications, no relief will be provided for LDCs that otherwise wish to import drugs. Those drugs will be on-patent in the country of export and more expensive.

LDCs that are not required to implement or enforce pharmaceutical patent protection until 2016 will have a certain added measure of flexibility even as to drugs that are covered by patent in non-LDC Members. LDCs will be free to increase their own capacity to manufacture generic drugs, and export and import those drugs among themselves, without contravening the TRIPS Agreement. Since there are fourteen (14) years until patent protection will be mandated, there is a reasonable amount of time if plans are initiated soon to bring manufacturing facilities within LDCs on-line and recover investment capital prior to the end of the transition period. If the LDCs are not required to implement mailbox protection, drugs for which production is commenced during the transition period will be available indefinitely as generics. If mailbox protection is required, the end of the transition period will also mark the end of access to low priced drugs made available as a consequence of the extension, until such time as patents issued on the basis of mailbox applications expire.

The value of this added flexibility is highly dependent on the capacity of the LDCs to increase manufacturing capacity, and this will depend on factors such as the availability of World Bank grants or loans to provide working capital, and the availability of technical assistance.

Also, paragraph 7 of the Doha Declaration is somewhat ambiguous regarding whether LDCs are relieved from implementing and enforcing pharmaceutical process patent protection during the extended transition period.[12] If LDCs are not so relieved, then under TRIPS Agreement Article 66:1, pharmaceutical process patent coverage must be implemented by January 1, 2006. This may limit the capacity of LDCs to initiate production. In giving effect to paragraph 7, the TRIPS Council should clarify that it extends to pharmaceutical process patents.

Moreover, it is important to observe that the transition period extension provided in paragraph 7 only affects WTO TRIPS obligations. LDCs with patent laws that provide

[11] There is an additional complication in that the drug in India may be subject to exclusive marketing rights, and it is not clear whether such rights would entitle the mailbox application holder to block exportation as well as local supply.

[12] The relevant part of paragraph 7 reads:

> "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…"

This language might be construed to cover pharmaceutical process patents if those patents are considered issued with respect to pharmaceutical products, such that the exemption from implementing or enforcing patent protection with respect to pharmaceutical products is considered to encompass processes involved in their making. The patent "rights provided for" in Article 28:1(b) of Section 5, Part II of the TRIPS Agreement are rights in respect to process patents, and those may be construed to be related to the subject matter of "pharmaceutical products".

pharmaceutical product protection are in the same internal legal situation as they were prior to the Declaration. If a government or a third party seeks to make, use, sell or import a patented drug without the consent of the local patent holder there is still the prospect of legal claim by the patent holder for infringement. In order to avoid the situation in which local enforcement of pharmaceutical patent rights can proceed, governments of LDCs with pharmaceutical patent coverage will have to take domestic legislative or executive action, as may be permitted by the national constitution, to amend or suspend operation of relevant provisions of the patent law.[13]

Under the terms of Article 66:1 of the TRIPS Agreement, "[t]he Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of [the transition] period." If the TRIPS Council does not accept and clarify that paragraph 7 extends to pharmaceutical process patents, it may be useful at this stage for LDCs to seek an extension of the transition period to cover such patents for the same period as pharmaceutical product patents. More generally, LDCs may wish to consider an extension of the transition period applicable to all intellectual property rights covered by the TRIPS Agreement until at least 2016. This would at least simplify changes to national legislation that may be required to implement the extension introduced by paragraph 7 of the Doha Declaration. It would also provide access to a wider scope of patented technologies consistent with the needs of LDCs for low cost technology transfer.

In sum, paragraph 7 provides additional flexibility for importation by LDCs, and in the intra-LDC context for the manufacture and sale of generic medicines that are on-patent elsewhere. However, there are a number of obstacles to overcome in making use of this flexibility, including setting up the proper internal legal regimes and obtaining the financial (and technical) resources to establish manufacturing and distribution facilities. Furthermore, it is imperative to resolve the issue whether mailbox and exclusive marketing requirements are also subject to exception pursuant to paragraph 7. If mailbox and exclusive marketing rights requirements must be implemented, this will materially reduce the time during which generic products may be available.

b. Other Doha developments

The Doha Declaration expressly recognizes that Article 31 of the TRIPS Agreement does not limit the grounds upon which compulsory licenses may be issued (para. 5(b)), and that each Member has the right to determine the circumstances constituting national emergency or other circumstances of extreme urgency. Although it is helpful that clarity has been added to these elements of the compulsory licensing regime under the TRIPS Agreement, these provisions of the Doha Declaration merely confirm previously unambiguous text.

Paragraph 5(d) unequivocally confirms the right of Members to determine without challenge their own policies and rules regarding exhaustion of rights and parallel trade. Certain implications of this decision are discussed later in this report.

[13] Section 7 of Part II of the TRIPS Agreement establishes obligations in Article 39 regarding data protection that are also exempted from implementation or enforcement pursuant to paragraph 7. Without considering the controversial scope of Article 39:3 obligations, it is noted that LDCs may also need to take internal measures to disapply rules they may have adopted regarding this subject matter.

Paragraph 4 of the Doha Declaration includes a decision supporting the rights of WTO Members to take steps to protect public health, and promoting access to medicines for all. The legal implications of paragraph 4 also will be evaluated later in this report.

IV. The Objectives of the Discussion

> *Compulsory licensing is an important public policy tool for all WTO Members. Developing Members in particular have a compelling need to use compulsory licensing to improve access to medicines, vaccines and other public health related inventions. There are preconditions to the effective use of compulsory licensing that are difficult for many developing countries to meet. This leads to problems in producing needed products and in establishing a network of low price suppliers.*

Compulsory licensing has long been recognized as the most important tool for addressing the adverse effects of the patent grant on public welfare.[14] Exploiting compulsory licensing may involve the actual grant and implementation of a license. It may also involve the threat of a license that results in a patent holder revising its own pricing or supply strategy.

a. Capacity to exploit

The effective use of compulsory licensing as a tool of public policy presupposes that certain conditions are met:

1. There must be a party within the country granting the license that is able to exploit it, either by manufacturing the subject invention or importing it. This requires, *inter alia*, technical expertise and financial capital;

2. If local manufacturing is to be undertaken, there must be sufficient purchasing power among the population to justify investments undertaken by the party exploiting the license (or export opportunities must be available). If the local population is small and/or poor, there may not be a consumer base adequate to provide an adequate return on investment;

3. The government may act as the party exploiting the compulsory license (e.g., for government use), and/or it may act as purchasing agent on behalf of the population acquiring the exploited invention. In either case, the government will require technical expertise and financial resources.

4. Legal and political infrastructure must be in place to permit the granting and supervision of the license.

As a general proposition, developed country Members of the WTO are able to satisfy the foregoing conditions, and are therefore able to effectively exploit compulsory licensing. Developing countries and LDCs are situated along a spectrum of capacity to exploit compulsory licensing.

[14] *See* EDITH TILTON PENROSE, THE ECONOMICS OF THE INTERNATIONAL PATENT SYSTEM, Ch. XI (1951: Johns Hopkins Press)

b. Need to exploit

Countries are in substantially different circumstances regarding the extent to which they may need to use compulsory licensing as a policy instrument. Countries in the OECD with high levels of purchasing power maintain strong production bases that are distributed among member countries, and rely on production from developing countries. Countries with high levels of purchasing power and strong industrial bases are unlikely to require the use of compulsory licensing except in exceptional circumstances, such as for remedial purposes when producers are found to be engaged in anticompetitive behaviors, or to address supply emergencies. The recent Anthrax episode in the United States illustrates that developed countries may confront supply emergencies that require the threat and/or grant of compulsory licenses.

Countries with lower levels of purchasing power and weaker industrial bases are more likely to require the use of compulsory licensing as a tool to address public policy objectives.

1. The price of goods is a more significant determinant of market demand in low-income countries because consumers have fewer resources to allocate among goods. Compulsory licensing is an instrument for obtaining lower prices on goods protected by patent.

2. Although countries are at substantially different stages of technology capacity development, in general there is a wide disparity between the research and development capacities of developing and developed countries. The vast preponderance of patented technology is owned and controlled by enterprises based in developed countries. Developing countries on the whole are in a position of reliance on technological development in the developed countries, and are in the position of systemic net payers for technology. For a variety of reasons, the technology needs of developing countries often may not be met by acquisition of technology licenses on voluntary terms. Compulsory licensing provides a means for developing countries to obtain technology necessary for development and social welfare.

3. A weak industrial base implies dependence on imports for goods. Suppliers based outside the territory of a country are less sensitive than local suppliers to internal economic and political pressures to provide goods at prices affordable within the country.

c. The pharmaceutical sector

There is substantial evidence that the availability of generic (off-patent) drugs, especially from multiple sources, substantially reduces prices. A report from the WHO indicates:

> "Very different degrees of competition characterise different sub-components of the pharmaceuticals market. Some drugs which are available over the counter, such as cough syrup, and many generics (such as aspirin) are produced in conditions which resemble those of a perfectly competitive market - multiple producers and purchasers, minimally differentiated products, information asymmetries unimportant, low barriers to entry. Each firm in such a market tends to be a price taker, and price will be close to marginal cost.

> "At the other end of the pharmaceuticals market, a relatively small number of firms have limited monopolies (limited in time and subject to therapeutic competition) for complex drugs (such as anti-retrovirals), available only on prescription. This sub-market is characterised by information problems, and legal barriers to entry posed by patent protection. Here price is commonly several times the marginal cost of production, particularly in the early years of patent life. Profits generated under patent protection are a reward for risk-taking and innovation - in the form of research and development expenditures - by the patent-holding company.
>
> "Competition is perhaps the most powerful policy instrument to bring down drug prices for off-patent drugs. In the United States, when a patent expires the average wholesale price falls to 60% of the branded drug's price when there is just one generic competitor, and to 29% with 10 competitors. The concept of marginal cost is important because it reveals the value of resources used in making a product. In a competitive environment, marginal cost is close to the market price of the product. However, determining marginal cost is difficult. So other approaches to determining a price for a particular drug, including using the price of unpatented therapeutic equivalent drugs, and pharmacoeconomic analysis, have been proposed. With price at, or close to marginal costs, some essential drugs may still remain unaffordable to poor people. In these instances additional international financing should be considered." [footnotes omitted][15]

Compulsory licensing is a means for reducing the adverse effects of patents on price and availability. It is essential to many developing countries that sources of generic or low-cost drugs be made available. However, it is difficult for many of these countries to manufacture drugs, and it is particularly difficult for them to manufacture a variety of drugs such as may reasonably be necessary to meet the demands of the local market. As such, the problem is two-fold: (1) establishing manufacturing capacity and (2) establishing a network of low-cost suppliers.

V. WTO Constitutive Principles

The TRIPS Council may recommend amendment, waiver or interpretation of TRIPS Agreement provisions. The amendment and waiver mechanisms are not constrained by existing text, and provide the maximum flexibility. Amendment may be politically more difficult and time-consuming. Waiver presents political and timing advantages.

The Ministerial Conference and General Council may formally interpret the TRIPS Agreement, and in so doing are bound to respect the terms, context, and object and purpose of the agreement. They are not, however, bound by previous interpretations by panels and the Appellate Body.

The TRIPS Agreement authorizes the TRIPS Council to review and propose amendments and modifications. The TRIPS Council is not limited by the express terms of the Doha Declaration regarding the subject matter of its work program.

[15] Working paper by Andrew Creese and Jonathan Quick, *Differential Pricing Arrangements and Feasibility: Context Setting Paper*, World Health Organization, 21 Jan. 2001.

a. Action by decision-making bodies

Paragraph 6 of the Doha Declaration does not prejudge the form of recommendation that the TRIPS Council will provide to the General Council.[16] The Ministerial directive to the TRIPS Council allows the recommendation of an amendment, waiver and/or interpretation of the TRIPS Agreement. Theses options are not mutually exclusive (though, of course, an amendment creating new text may render interpretation of old text superfluous). An interpretation or waiver might be adopted pending conclusion of an amendment to the agreement.

b. Amending the TRIPS Agreement

The WTO Agreement and TRIPS Agreement provide several alternatives for amending the TRIPS Agreement.[17] Any Member or the TRIPS Council may submit a proposal for amendment to the WTO Ministerial Conference,[18] following which the proposal will be subject to the ordinary amendment procedures of the WTO.[19] The Ministerial Conference may approve by consensus submitting the amendment to Members.[20] If there is no consensus, approval by a two-thirds majority of the Ministerial Conference is typically required.[21] An amendment becomes effective for Members that have accepted it following their two-thirds acceptance.[22] Under an alternative procedure, Members may by three-fourths majority adopt an amendment that is binding on all Members, including those that do not accept it, leaving non-accepting Members with the option of withdrawing from the WTO (or obtaining a waiver from the Ministerial Conference).[23]

An amendment is a change to the terms of a treaty, and as such is generally not limited by its existing terms.[24] In proposing an amendment to the TRIPS Agreement, the TRIPS Council would not be constrained by the existing terms of the text. (Nonetheless, the TRIPS Agreement is integrated with the WTO Agreement, and amendments to the TRIPS Agreement must be compatible with other aspects of the WTO regulatory framework, which itself is subject to amendment.)

[16] Options for interpreting or amending the TRIPS Agreement were analyzed in Abbott, QUNO Occasional Paper 7, *supra* note 4.

[17] In addition to the procedures discussed in the text, the WTO and TRIPS Agreements also establish an expedited amendment procedure for cases in which the purpose of the amendment is to "adjust . . . 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." TRIPS Agreement, art. 71:2. This procedure is not relevant to the subject matter of this paper.

[18] The TRIPS Council establishes its own rules of procedure, subject to approval by the WTO General Council. WTO Agreement art. IV:5.

[19] *Id.,* art. X:3-4.

[20] *Id*., art. IX:1.

[21] *Id*. art. X:1. Each WTO Member has a vote in the Ministerial Conference. Id. art. IV:1.

[22] *Id*. art. X:3.

[23] *Id.*

[24] The WTO Agreement imposes different requirements for amending different elements of the agreement, for example, a strict consensus approval requirement with respect to amending Article I of GATT 1994. WTO Agreement, art. X:2.

Members may require the approval of their national parliaments prior to accepting an amendment to the TRIPS Agreement.[25] One of the reasons the GATT 1947 was traditionally amended following the process of a "round" was that the requirement of parliamentary approval is potentially subject to political controversy and delay within Members (formerly "Contracting Parties").[26] The most expedient means of developing GATT law was to incorporate a package of developments in a single amending instrument that could be presented to parliaments, rather than attempting to obtain modifications on a case-by-case basis. The package optimally would be designed to include a balance of elements favourable to constituencies in different countries so as to provide each parliament with an incentive for approval, even if some elements of the package were perceived as unfavourable.

There is nothing in the WTO Agreement that would prevent Members from adopting and referring to Members for approval a single modification to the TRIPS Agreement. In adopting such a modification, Members would need to consider the political viability of obtaining its approval within the constitutional systems of Members.

In this regard, it is useful to note that the mandate of the Doha Ministerial included a number of subject matter areas outside paragraph 6 of the Declaration on the TRIPS Agreement and Public Health. The Ministerial Declaration provided for additional negotiations on the subject of geographical indications of origin.[27] It also instructed the TRIPS Council to examine the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD), the protection of traditional knowledge and folklore, and other new developments.[28] The Decision on Implementation Issues includes direction to the TRIPS Council to continue examination of issues regarding non-violation nullification or impairment causes of action in TRIPS dispute settlement and to make recommendations to the Fifth Ministerial Conference.[29] It also includes a "standstill agreement" that non-violation complaints will not be initiated prior to that conference.

Because a package of amendments to the TRIPS Agreement might not be agreed upon for some years, one might look at the mechanisms of waiver or interpretation as stepping stones on the way to a formal amendment of the agreement.

c. Waiver

Article IX:3-4 of the WTO Agreement establishes the decision-making mechanism of "waiver" regarding the Multilateral Trade Agreements ("MTAs"), including the TRIPS Agreement.[30] In Doha, the Ministerial Conference approved two waivers, one at the request

[25] While most states require the approval of parliament for the ratification of treaties, rules vary with respect to parliamentary approval of amendments. Whether an amendment requires parliamentary approval may depend upon its perceived significance or materiality. *See generally* PARLIAMENTARY PARTICIPATION IN THE MAKING AND OPERATION OF TREATIES: A COMPARATIVE STUDY (Stefan A. Riesenfeld & Frederick M. Abbott eds., 1994)(Martinus Nijhoff).

[26] *See* OLIVIER LONG, LAW AND ITS LIMITATIONS IN THE GATT MULTILATERAL TRADING SYSTEM (1985).

[27] Ministerial Declaration, adopted 14 Nov. 2001, WTO Doc. WT/MIN(01)/DEC/1, para. 18.

[28] *Id*., para. 19.

[29] Decision on Implementation Issues, adopted 14 Nov. 2001, WT/MIN(01)/17, para. 11.1.

[30] Article IX provides:

> "3. In exceptional circumstances, the Ministerial Conference may decide to waive an obligation imposed on a Member by this Agreement or any of the Multilateral Trade

of the EU and ACP state Members of the WTO (waiving MFN obligations regarding a preferential trading arrangement),[31] and one at the request of the EU (waiving certain geographic allocation obligations regarding tariff rate quotas).[32]

The request for a waiver originates with a Member(s) and, in relation to an MTA, is initially submitted to the relevant Council. Following receipt of the report of the Council, the Ministerial Conference may approve the waiver by consensus (or three quarters vote).

A rather important advantage of the waiver is that, unlike amendment, the approval of a waiver by the Ministerial Conference is not also subject to approval by parliamentary bodies within Members. It may be distinctly easier from a political standpoint to achieve a result by waiver as compared to amendment.[33]

The waiver has an advantage over interpretation in that discretion of the Ministerial Conference in granting a waiver is not bounded by the express text of the TRIPS Agreement. A waiver may be tailored to meet specific objectives, inter *alia*, by establishing defined conditions of application.

One drawback of the waiver mechanism is that it is temporary, although there is no definitive outer limit to duration established by the WTO Agreement. As illustration, the waiver granted in respect to the EU-ACP preferential arrangement states a duration of seven (7) years (until Dec. 31, 2007).

The consequence of potential limitation of the duration of a waiver is that WTO Members (and enterprises within them) may have difficulty engaging in long term planning regarding

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> Agreements, provided that any such decision shall be taken by three fourths of the Members unless otherwise provided for in this paragraph.
>
> (a) A request for a waiver concerning this Agreement shall be submitted to the Ministerial Conference for consideration pursuant to the practice of decision-making by consensus. The Ministerial Conference shall establish a time-period, which shall not exceed 90 days, to consider the request. If consensus is not reached during the time-period, any decision to grant a waiver shall be taken by three fourths of the Members.
>
> (b) A request for a waiver concerning the Multilateral Trade Agreements in Annexes 1A or 1B or 1C and their annexes shall be submitted initially to the Council for Trade in Goods, the Council for Trade in Services or the Council for TRIPS, respectively, for consideration during a time-period which shall not exceed 90 days. At the end of the time-period, the relevant Council shall submit a report to the Ministerial Conference.
>
> 4. A decision by the Ministerial Conference granting a waiver shall state the exceptional circumstances justifying the decision, the terms and conditions governing the application of the waiver, and the date on which the waiver shall terminate. Any waiver granted for a period of more than one year shall be reviewed by the Ministerial Conference not later than one year after it is granted, and thereafter annually until the waiver terminates. In each review, the Ministerial Conference shall examine whether the exceptional circumstances justifying the waiver still exist and whether the terms and conditions attached to the waiver have been met. The Ministerial Conference, on the basis of the annual review, may extend, modify or terminate the waiver." [footnote omitted]

[31] European Communities – The ACP-EC Partnership Agreement, Decision of 14 Nov. 2001, WT/MIN(01)/15, 14 Nov. 2001.

[32] European Communities – Transitional Regime for The EC Autonomous Tariff Rate Quotas On Imports Of Bananas, Decision of 14 Nov. 2001, WT/MIN(01)/16, 14 Nov. 2001.

[33] A person or group within a Member might challenge its government's consent to a waiver on the theory that it constituted a *de facto* amendment of the treaty. While this might have a legal effect within the domestic law of the Member being so challenged, this would not affect the waiver at the WTO level.

the supply of medicines. Reliance on the waiver puts off decisions regarding the TRIPS Agreement that may be of vital importance to developing country interests.

Bearing in mind the inherent limitations of the waiver as a legal mechanism, it is nonetheless important to consider that objectives of developing Members not otherwise achievable within the present text of the TRIPS Agreement may be accomplished via waiver.

d. Interpretation under Article IX:2

Article IX:2 of the WTO Agreement provides:

> "The Ministerial Conference and the General Council shall have the exclusive authority to adopt interpretations of this Agreement and of the Multilateral Trade Agreements. In the case of an interpretation of a Multilateral Trade Agreement in Annex 1 [that includes the TRIPS Agreement], they shall exercise their authority on the basis of a recommendation by the Council overseeing the functioning of that Agreement. The decision to adopt an interpretation shall be taken by a three-fourths majority of the Members. This paragraph shall not be used in a manner that would undermine the amendment provisions in Article X."

A precondition of the adoption of an interpretation of the TRIPS Agreement is a recommendation by the TRIPS Council.[34] This precondition is effectively built into paragraph 6 of the Doha Declaration.

Article 31 of the Vienna Convention on the Law of Treaties ("VCLT") states:

> "1. A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.
>
> 3. There shall be taken into account, together with the context:
>
> (a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions;
>
> (b) any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation;"

Article IX:2 of the WTO Agreement and Article 31 of the VCLT, taken together, suggest that a formal interpretation adopted by the Ministerial Conference or General Council would definitively interpret the TRIPS Agreement, bounded by the limitation that the interpretation should not constitute an amendment.

An interpretation can resolve textual ambiguity, adding clarity to words capable of conveying different meanings. If the language of the TRIPS Agreement leaves room for interpretations, the Ministerial Conference or General Council can establish definitive binding interpretations. Interpretations may not do violence to the text of the Agreement.

[34] Article IX:2 refers to action on the "basis" of a recommendation by the relevant Council. This appears to leave room for the Ministerial Conference to adopt a recommendation that differs from the recommendation by the Council, since a requirement to approve a specifically recommended text could have been stated.

Ministers acting in Doha adopted a "declaration". As discussed further in Section VIII, infra, the declaration is best characterized as a decision of the Members, giving it a legal effect very similar to that of an interpretation. As a variation on an interpretation, Members might adopt a declaration to supplement the one adopted in Doha. This would establish a certain consistency in constitutive process, though there is little apparent reason to prefer this option to a formal interpretation.

e. The role of Appellate Body and panel reports in the interpretative process

TRIPS Agreement Article 31 concerning compulsory licensing has not yet been the subject of a WTO dispute settlement report, and there is limited jurisprudence on its potential interpretation based on DSU proceedings.[35] Article 30 has been subject to detailed interpretation by a panel in the Canada – Generic Pharmaceuticals case. [36]

In deciding on an interpretation of the TRIPS Agreement, the TRIPS Council and General Council (and the Ministerial Conference) are not bound by interpretations of the TRIPS Agreement that a panel or the Appellate Body may have developed in the context of a case previously decided between Members. There are several provisions of the WTO Agreements that inform this conclusion.

First, as noted above, Article IX:2 of the WTO Agreement grants to the Ministerial Conference and General Council "the exclusive authority to adopt interpretations of this Agreement and of the Multilateral Trade Agreements".

Second, Article 3:2 of the Dispute Settlement Understanding (DSU) provides that: "Recommendations and rulings of the DSB cannot add to or diminish the rights and obligations provided in the covered agreements."

Third, pursuant to Article 3:2 of the DSU, the role of the Dispute Settlement Body (DSB) is: "to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law." As a matter of customary international law, a decision of a judicial tribunal involving state parties does not bind states not party to the dispute.[37]

Fourth, Article 3:9 of the DSU provides:

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[35] There is reference to Article 31 in the panel report in Canada-Generics regarding an understanding that Article 31 is subject to Article 27. In the Canada-Generics decision, in the context of interpreting Article 30, the panel indicated that Article 31 is subject to the rule of non-discriminatory treatment of patents with respect to place of invention, field of technology and whether products are imported or locally produced. The proposition that Article 31 is subject to Article 27:1 was accepted by the parties in the Canada-Generics case, and the panel confirmed the parties' understanding. Canada-Generics, at paras. 7.90-7.91.

[36] Canada – Patent Protection of Pharmaceutical Products, Report of the Panel*,* WT/DS114/R, March 17, 2000 (hereinafter 'Canada-Generics"). The jurisprudence of the panel in that case will be discussed later in this report.

[37] A recent WTO panel report (*India – Measures Affecting the Automotive Sector*, WT/DS146/R, 21 Dec. 2001) discusses, *inter alia*, the relevance of the public international law principle *res judicata* in the WTO legal order. The panel noted constraints in applying determinations made in a case involving two Members to another case involving related subject matter but different parties.

International judicial tribunals, including the WTO Appellate Body, can and often do refer to prior judicial determinations for guidance in subsequent cases, and in order to promote consistent application of rules.

> "9. The provisions of this Understanding are without prejudice to the rights of Members to seek authoritative interpretation of provisions of a covered agreement through decision-making under the WTO Agreement or a covered agreement which is a Plurilateral Trade Agreement."

In a DSU proceeding, a WTO Member might be able to challenge another Member on grounds that an "interpretation" decided by the Ministerial Conference or General Council is WTO inconsistent. The Appellate Body might rule that the interpretation exceeded the bounds of the interpretative power under Article IX:2 of the WTO Agreement and customary international law. Whether the Appellate Body might in such circumstances "overrule" an interpretative decision of the Ministerial Conference or General Council is a WTO constitutive question that might well be controversial.[38] There is, however, no reason at this juncture to attempt to resolve this issue. For present purposes, the Ministerial Conference and General Council have the power to render formal interpretations of the WTO Agreements (including the TRIPS Agreement) without being bound by prior decisions of panels or the Appellate Body. The TRIPS Council, General Council and Ministerial Conference are constrained in the interpretation of the TRIPS Agreement by its text, context, object and purpose.

Article 31(3)(b) of the VCLT also indicates that there should be taken into account "any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation." This may be relevant to decisions of the DSB.

The adoption of DSB reports is a means of transforming the decision of arbitrators (i.e., panellists) and a quasi-judicial body (i.e., the Appellate Body), into a political decision of WTO Members. In undertaking that transformation of decision-making, the Dispute Settlement Body is not adopting an interpretation of the WTO Agreements in the sense of Article IX:2 of the WTO Agreement since that power is exclusively reserved to the Ministerial Conference and General Council. It may be argued that the specific language of Article IX:2 restricting the power to interpret is intended to signal that DSB-adopted Appellate Body and panel reports should not be considered interpretative agreements in the sense of Article 31(3)(b) of the VCLT. Even if adopted panel and Appellate Body reports are considered state practice that evidences interpretation, this would not limit the Ministerial Conference and General Council from adopting a formal interpretation differing from that state practice since they are accorded the specific authority to do so under Article IX:2 of the WTO Agreement.[39]

The express text of the WTO Agreement makes clear that the Ministerial Conference and General Council have the power to interpret the TRIPS Agreement provided that the interpretation is not inconsistent with the text and context of the agreement in light of its

[38]The question whether the International Court of Justice has the power to rule on the consistency of a UN Security Council decision with the UN Charter and international law is indeed controversial. *See*, *e.g.,* Libyan Arab Jamahiriya v. United States (Provisional Measures), International Court of Justice, order of April 14, 1992, and including separate opinions of Judges expressing views on juridical relationship between Security Council and Court of Justice (http:// www.icj-cij.org/).

[39] The DSU states in several places that actions of the DSB may not add to or diminish the rights of Members under the WTO Agreements. This seems to suggest that the actions of the DSB cannot interpret the agreements so as to limit the flexibility of Members to otherwise interpret them. If under general principles of customary international law, the decision of a judicial body in a case between state parties does not bind states not party to the agreement, it would seem anomalous if the act of the DSB had a more significant legal effect.

object and purpose. The Ministerial Conference and General Council may look to prior DSB reports for guidance, but are not bound to them as precedent from which no deviation is permitted.

f. The text of paragraph 6 of the Declaration

At Doha, the Ministerial Conference directed the TRIPS Council to address the problem of "Members with insufficient or no manufacturing capacities in the pharmaceutical sector" making effective use of compulsory licensing, and to report to the General Council regarding a solution.

In considering this directive, it should be recognized that the TRIPS Council is not constrained in proposing amendments, waivers or interpretations by the terms used in paragraph 6. Article 71:1 of the TRIPS Agreement provides for periodic review of the agreement by the TRIPS Council with a view toward possible amendment, and also provides:

> "The Council may also undertake reviews in the light of any relevant new developments which might warrant modification or amendment of this Agreement."

Individual Members may propose amendments or waivers to the Ministerial Conference without the consent of the TRIPS Council.[40] An interpretation should be undertaken "on the basis of a recommendation by" the TRIPS Council.[41]

In sum, while the Ministerial Conference has instructed the TRIPS Council to expeditiously solve a particular problem, this does not preclude the TRIPS Council from addressing other problems, or prevent a Member or group of Members from proposing an amendment, waiver or interpretation to the TRIPS Council and/or the Ministerial Conference.

VI. The TRIPS Agreement

> *The relatively modest use of compulsory licensing by developing Members to date is explained by a variety of factors. Recognizing the multidimensional nature of the problem, the restriction imposed by Article 31(f) that the licensee must "predominantly" supply the local market operates as a significant restriction on the capacity of developing Members to make and acquire medicines and other public health related products. Prospective importing Members are limited as to the sources of products, and prospective exporting Members are limited in their capacity to establish economies of scale.*

a. A multi-dimensional problem set

Article 31 of the TRIPS Agreement permits all WTO Members to grant compulsory licenses regarding, inter *alia*, pharmaceutical products and processes. The terms of Article

[40] Waiver request must be submitted to the relevant Council, but only for a "report". WTO Agreement, art. IX:3(b).

[41] *Id*., art. IX:2. The text of the WTO Agreement is not clear on this point, but it would seem reasonable to conclude that the Ministerial Conference in using a recommendation as the "basis" for its action could choose to modify it.

31 are in general permissive and flexible. As confirmed by paragraphs 5(b) and (c) of the Doha Declaration, Article 31 does not limit the grounds upon which licenses may be granted, and it permits each Member to determine in its own discretion what constitutes a national emergency or circumstances of extreme urgency (thereby establishing an exception from pre-grant negotiation). There is substantial flexibility in terms of the administrative processes that may be adopted to implement a compulsory licensing regime.

To date, developing countries have made limited use of compulsory licensing as a tool to address public health issues.[42] This stems from a number of causes: (1) the TRIPS Agreement has only recently begun to increase the incidence of patent protection: (2) use has been opposed by developed country WTO Members and interested industry groups within them, and a strong political commitment to act in the face of this opposition is required; (3) some developing countries have expressed concern regarding a potential backlash from foreign direct investors (4) developing country enterprises may find it easier to reach accommodation with foreign patent holders than to challenge them through the compulsory licensing process for various economic and administrative reasons and, as noted earlier; (5) effectively implementing compulsory licensing requires that certain preconditions relating to administrative, financial and technical capacity be met, and these conditions are often not met in developing countries.

Addressing the limited use by developing countries of the compulsory licensing tool will require that substantial attention be paid to putting into place appropriate legal infrastructure. In this regard, developing countries will need to seek advice and assistance from sources such as UNCTAD, WHO and non-governmental organizations (NGOs) attentive to their interests.

Addressing the problem of limited use will also require access to and coordination of financial and technical resources.

The solution to the limited use of compulsory licensing by developing countries requires addressing a number of important elements.

b. Article 31(f)

Recognizing the multi-dimensional nature of the problem, the TRIPS Agreement nevertheless establishes certain obstacles to effectively addressing access to medicines through compulsory licensing. The most widely noted of these potential obstacles is Article 31(f), which provides:

> "(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;"

Article 31(f) establishes a limitation: the terms of the compulsory license should include the condition that the licensee uses the patented invention predominantly to supply the domestic market of the Member granting the license.

[42] *See* Abbott, QUNO Occasional Paper 7, *supra note 4*.

The word "predominantly" would generally appear to refer to the major part or majority,[43] and would generally suggest that more than fifty percent of the production by a compulsory licensee should be intended for supply of the domestic market of the Member granting the license.

It might be suggested that "predominantly" also refers to a situation in which the domestic market of the Member granting the compulsory license takes the greatest share of supply as among those Members receiving supplies. To illustrate: the granting Member may receive forty percent (40%) of the supply, while three other Members each individually receive twenty percent (20%). In that context, supply of the domestic market of the granting Member would predominate over the supply of any other individual WTO Member. The difficulty with this interpretation is that it potentially reduces the term "predominantly" to a nullity, for example, if there were 80 Members receiving supplies under compulsory license, perhaps only two percent (2%) might need to be supplied to the market of the Member granting the license to maintain its predominance.

The limitation imposed by Article 31(f) creates two inter-linked problems:

1. By restricting the availability of export drugs made under compulsory license, it limits countries that are not in a position to support manufacturing under compulsory license (or where patent protection is not in force) in the availability of supply of generic import drugs, and;

2. By requiring compulsory licensees to supply a predominant part of their production to the domestic market, it limits the flexibility of countries to authorize the export of compulsory-licensed drugs and thereby to exploit economies of scale.

Article 31(f) creates difficulties on the demand and supply side of the generic drug pipeline.

The demand side problem is self-evident. If a developing Member lacks manufacturing capacity for a particular drug, and there are no Members that are able to supply it by export under compulsory license (or exception), there may be no affordable supply of the drug.

The supply side problem is identified because there are WTO Members, including developing Members, with the capacity to address the drug import needs of a wide range of developing Members under compulsory license, but that may be inhibited from undertaking this role because of the Article 31(f) limitation.

1. Implementation by importation

Neither Article 31 in general, nor Article 31(f) in particular, state or imply that a compulsory licensee must produce the invention within the territory of the Member granting the license.

[43] "Predominant" is defined as an adjective as: "(1) Having supremacy or ascendancy over others; predominating. (2) Constituting the main or strongest element; prevailing. (3) Rising high over." NEW SHORTER OXFORD DICTIONARY, at 2329.

Under Article 31, a compulsory licensee may import products in the implementation of its license.[44]

The ability of a compulsory licensee to satisfy a domestic market by importation depends upon the availability of off-patent products in exporting countries, or upon some legal mechanism under which the potential rights of patent holders in exporting countries will not be infringed.

When pharmaceutical patent protection is not implemented or enforced in a WTO Member (such as an LDC subject to an extended transition period), that Member will not be required to issue a compulsory license to satisfy its import requirements in a TRIPS-consistent manner.

2. Legal mechanisms for non-infringement in the country of export

If no patent has been granted in the country of export, or if a patent in that country has expired, there will be no infringement by a party exporting in fulfilment of the compulsory license in the country of import.

The patent holder in the country of export may consent to the exportation, perhaps because that patent holder is different than the patent holder in the country of import.[45] There would be no infringement in either country if the importer also acted under compulsory license.

The producer in the country of export may itself be implementing a compulsory license, and would be entitled to export a non-predominant part of its production. In this case, there would be no infringement in either country. Both the exporter and importer would act under compulsory license (or, there would be no patent protection in the importing country).

If the producer in the country of export is implementing a compulsory license issued as a remedy for anticompetitive conduct, the restriction regarding predominant part established by Article 31(f) does not apply, pursuant to Article 31(k).

3. Potential infringement in the country of export

If (a) the drug is under patent in the country of export (b) the patent holder does not consent to the export (c) no compulsory license has been issued, or has been issued but cannot be used for export because of a "predominant part" problem, then the importing country that has issued the compulsory license may not be able to satisfy its requirements without a potential infringement of patent holder's rights in the country of export.

From the standpoint of TRIPS Agreement obligation, the issuance of a compulsory license in the country of import does not constitute non-compliance with TRIPS obligations, even if

[44] Imports into country A might be exported to country B. A compulsory licensee that imported to implement the license, but exported a predominant part of the imports, would be acting inconsistently with Article 31(f).

[45] The patent holder may be the same in both Members, and in theory it might consent to export to the Member that has issued the compulsory license regarding its own patent. It is difficult to foresee the circumstances in which this might occur.

prospective imported products are under patent in a country of export.[46] If exports originate in another Member in a manner inconsistent with the exporting country's obligations under Article 28 of the TRIPS Agreement, it is the obligation of the exporting country to take steps in regard to its obligations.

VII. Article 31-Based Solutions

> *The problems created by Article 31(f) may be ameliorated somewhat by creating streamlined parallel compulsory licensing arrangements and regional patent arrangements. Creative legal structures such as pharmaceutical production export zones (PPEZs) might be contemplated. When compulsory licenses are granted to remedy anticompetitive practices, the limitation imposed by Article 31(f) does not apply. Each of these solutions is problematic for operational or interpretative reasons. As a practical matter, it is difficult to interpret Article 31(f) in a manner that addresses the concerns of developing Members.*

As noted above, Article 31(f) limits the grant of compulsory licenses for export to cases in which export supply does not represent the predominant part of the licensed activity. In this section, several possible means for addressing supply requirements of importing countries within the express text of article 31(f) are examined. There are a number of "creative" alternatives, though each presents difficulties either in the sense of (a) operational challenges, or (b) pressing the boundaries of interpretation. The overall conclusion is that the text of Article 31(f) presents serious obstacles to compulsory licensing to satisfy the requirements of export markets.

a. Parallel compulsory licensing

A country of export might choose to recognize the grant of a compulsory license issued by an importing country. In principle, this could be accomplished through the parallel grant of a compulsory license in the country of export. This procedure has three potential drawbacks. First, the granting mechanisms foreseen by Article 31 are procedurally cumbersome, although the use of national emergency/extreme urgency determinations to avoid pre-grant negotiations with the patent holder might accelerate the process. Second, the exporting country faces the limitation imposed by Article 31(f) regarding predominance of the domestic market. Third, establishing this type of arrangement presupposes implementing legislation in the country of export to adapt its compulsory licensing rules.

Administrative burdens of parallel compulsory licensing might be mitigated in countries of export by the establishment of streamlined procedures. For example:

1. A request for issuance of a parallel compulsory license might be triggered by a request from a country that had previously issued a compulsory license.

2. If the license request is based on a national emergency in the importing country, that might result in the prompt issuance of the parallel license to fulfil import requirements

[46] In the U.S. paper, *supra* note 8, there is some suggestion of liability on the part of the importing Member, though the reasons for this are not clear.

without negotiations with the patent holder, with compensation in the exporting country presumptively based on established guidelines.

(a) Article 31(b) of the TRIPS Agreement provides that a Member may grant a compulsory license absent prior negotiation with patent holders "in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use". There is nothing in the express text that limits an emergency to the territory of the Member that is issuing the compulsory license.

3. If the license request is not based on a national emergency in the importing country, the request might initiate a time period during which negotiations on a commercial license would be undertaken with the local patent holder. If such negotiations are unsuccessful within a set period, a license might issue based on the grounds for grant in the requesting country.

(a) As noted in a prior report, the concept of "comity" provides a basis for one WTO Member to recognize the grounds of grant of a compulsory license in another Member as the basis for its own grant of a parallel license.[47] The determination of the first Member would not be "binding" on the second Member, but would rather provide the basis for voluntary recognition.

(b) As an alternative to comity, a WTO Member requested to supply exports might be considered an agent acting on behalf of the requesting (importing) Member. The separate legal identity of the exporting Member might be ignored. The compulsory license issued in the importing Member might be deemed satisfied within its domestic market.

(c) Article1 31(a) of the TRIPS Agreement requires that each authorization be considered on its own merits, but this does not imply that parallel authorizations could not be based on the same set of underlying facts.

4. The patent holder would hold administrative rights under Article 31 in each Member.

There are, in short, legal and administrative mechanisms that might be used to reduce the expense and delays generally associated with compulsory licensing procedures, yet remaining within the interpretative parameters of Article 31. These administrative solutions would not, however, eliminate the problem that a country of export would be required to supply a predominant part of the compulsory license production to its domestic market (unless the agency concept is adopted and the distinct legal identity of the exporting country is ignored).

b. Regional market arrangements

One important potential solution to the Article 31(f) problem is the creation of integrated regional patent regimes that would allow for the grant of regional compulsory licenses. The European Union is a regional organization Member of the WTO and would presumably be entitled to consider its member states to constitute a single domestic market from the standpoint of Article 31(f). Although neither the European Patent Convention (in force, though not a Union legal instrument) nor the Community Patent Convention (not in force),

[47] *See* Abbott, QUNO Occasional Paper 7, *supra* note 4.

provide for the grant of a Union-wide compulsory license, it is difficult to see an objection as a matter of legal principle to such a mechanism.[48]

The WTO legal instruments foresee and allow the formation of customs unions and free trade areas (GATT Article XXIV), and regional services arrangements (GATS Article V). The WTO legal instruments do not generally impose restrictions on the capacity of such arrangements to jointly adopt and implement regional legislation. [49] It would not appear necessary for such an arrangement to be a Member of the WTO (as is the European Union) in order to be considered a single domestic market in the sense of Article 31(f) of the TRIPS Agreement. The EU, it should be recalled, was traditionally considered a Contracting Party to the GATT 1947 even though not formally a party to the agreement.

The TRIPS Agreement might be constructively interpreted to contemplate that a group of countries establishing a common patent regime would be entitled to issue a common compulsory license with effect in all states of the arrangement, with the further understanding that supply of the group market under such arrangement constituted domestic supply within the meaning of TRIPS Article 31(f).

c. The legal fiction of the pharmaceutical production export zone (PPEZ)

A country issuing a compulsory license may request that a country with export capacity recognize and give effect to its license by authorizing the supply from its territory of drugs that will fulfil the terms of the license. The physical location of manufacture may be the exporting country, but there is the possibility of establishing a legal fiction that would avoid legal issues otherwise associated with potential infringement of patent rights in the country of export.

One such legal fiction would be to permit the creation of analogues to "foreign trade zones" within the territory of exporting countries in which acts may be undertaken without implicating the otherwise applicable local rights of patent holders.

Under existing GATT rules, foreign trade zones have been tolerated as areas within the territory of a Member that are considered outside the customs territory of the Member for tariff assessment purposes,[50] with the consequence that goods may be imported into and worked upon in the zone without being subject to the payment of customs duties. In the United States, for example, the foreign trade zone (FTZ) concept is used quite extensively.[51] Imported goods may be brought into an FTZ, worked into a product in a

[48] The individual EU member states may be resistant to recognizing a right of one member state to grant a license that is effective for all EU markets. That is, however, a political issue.

[49] Article 4(d) of the TRIPS Agreement requires that intellectual property rights related privileges be granted on a most favored nation (MFN) basis. The creation of a regional patent arrangement should generally comply with MFN requirements; that is, be non-discriminatory. Allowing for the grant of region-wide compulsory licenses would not appear to be discriminatory *vis-à-vis* Members not party to the arrangement, but the MFN requirement is noted here for the sake of completeness.

[50] From a GATT 1994 standpoint, the legal fiction of the FTZ is presumably justified on the basis that goods in the FTZ are part of "traffic in transit" within the meaning of GATT Article V:1. However, to the extent that goods are worked within the FTZ, this pushes the limits of the "in transit" concept. FTZs may also in some cases provide exemption from certain tax obligations, but that aspect is not considered here. *See* note 53 *infra* as to subsidy aspects.

[51] *See* 19 USC § 81a, et seq. , and US International Trade Administration, Foreign Trade Zones (June 2000), http://ia.ita.doc.gov/ftzpage/tic.html, visited January 9, 2002.

different tariff classification, and exported with no tariff consequences, or imported into the U.S. at the lowest applicable tariff rate. The FTZ is within the physical geographic boundaries of the United States. From the standpoint of non-application of tariffs, the FTZ is a legal fiction.[52]

A potential country of export that wished to recognize and give effect to a compulsory license granted by another Member could designate a particular manufacturing site a "pharmaceutical production export zone" (PPEZ) and authorize a manufacturer to produce there without incurring domestic legal consequences from the patent holder. The designated manufacturer could be prohibited from importing the products into the country where production is undertaken, or to other countries that had not issued corresponding compulsory licenses.

The acceptance of a legal fiction such as the PPEZ would provide a relatively uncomplicated solution to the obstacle potentially raised by Article 31(f) of the TRIPS Agreement. Since the PPEZ plant would not legally be within the country of export, no local compulsory license would be needed to authorize production. The supply would be for the domestic market of the Member granting the compulsory license. Moreover, no reliance on Article 30 would be required in the country of export since there would be no exception to the rights of the patent holder that are not recognized in the PPEZ.

The rights of the patent holder to remuneration and administrative protections would remain in the country that had granted the compulsory license.

To make this system genuinely effective, it might be necessary to allow production facilities in countries of export to serve dual purposes; that is, to produce at some times for general purposes, and some times for PPEZ purposes. If it is necessary to construct special facilities solely to serve as PPEZ facilities, the expense might be an obstacle to use of the legal fiction.

In addition, the legal fiction would depend on a determination that PPEZ exports are not considered subsidized by virtue of non-recognition of patent holder rights within the zone. Although a claim of subsidization would not arise from an importing Member that authorized the compulsory license, such a claim might arise from a third Member that objected to potential interference with its export trade.

A key issue regarding the concept of the PPEZ is whether the legal fiction may be established without reliance on Article 30 (discussed in the Section VIII), or the adoption of a waiver. The principal grounds for suggesting that neither an Article 30 exception nor a waiver may be required is that FTZs are in use by WTO Members to authorize importing, working and exporting goods without payment of tariffs, and this common practice is accepted among Members. By operating FTZs, WTO Members provide preferential tariff treatment to certain manufactured goods, namely those destined for export markets. This acts as a subsidy of exports (reducing the cost of exports by the extent of the waived customs duties). It may also result in differential treatment of imports and exports of like products, and constitute derogation from MFN tariff obligations. WTO Members may at least implicitly have removed certain duty drawback or remission schemes (including those

[52] Although at early stages a U.S. manufacturer needed to be located within a particular geographic area in order to qualify for FTZ treatment, in later stages the law provides for subzones that may be established for individual company manufacturing sites where specifically approved.

manifested in FTZs) from challenge as export subsidies by reference in Annexes to the Subsidies Agreement. [53] If this is so, it may be more the result of recognition of the need to tolerate a widely used practice than a neutral policy determination that such schemes do not constitute export subsidies. Members might, by the same token, decide that PPEZs should be tolerated even if to do so requires the acceptance of a legal fiction.

d. Anticompetitive practices remediation

Article 31(k) of the TRIPS Agreement[54] exempts compulsory licenses issued to remedy anticompetitive practices from the Article 31(f) requirement. A WTO Member that determined the existence of anticompetitive conduct on the part of a patent-holding pharmaceutical company might well grant one or more licenses regarding that company's patents that could be used to supply the markets of any number of developing Members. Whether the grant of a parallel compulsory license would be required in importing Members would depend on the presence or absence of local patent protection, and the rule of international exhaustion followed in the importing Member. The latter issue is discussed in Section XII of this paper.

Since major research-based pharmaceutical companies have recently been found by OECD country authorities to have engaged in systematic anticompetitive conduct,[55] there is reason for developing countries to explore joint investigation into the business practices of these companies.

e. Article 31(f) conclusion

There are approaches to interpretation of Article 31(f) that may provide flexibility in the authorization of compulsory licensing for export. These include establishing expedited mechanisms for the parallel grant of compulsory licenses, creating regional patent systems allowing for joint compulsory licensing, the creation of pharmaceutical production export zones (PPEZs), and using compulsory licenses to remedy anticompetitive conduct.

The use of compulsory licensing in the export context as a remedy for anticompetitive conduct requires no interpretative clarification. However, a threshold finding of anticompetitive conduct is required under Article 31(k). It might be difficult to establish such conduct in all cases in which compulsory licensing for export would be sought. Moreover, it seems doubtful that as a policy matter developed Members of the WTO would

[53] The Agreement on Subsidies and Countervailing Measures appears to assume that a duty drawback or remission scheme that does not provide for remissions or drawbacks of charges in excess of those paid on inputs consumed (including incorporated) in the exported product will not be considered to have benefited from a subsidy. *See* Subsidies Agreement, Annex 1(i) and Annex II. For a recent analysis of export subsidization in the tax treatment context, *see* United States – Tax Treatment For "Foreign Sales Corporations", AB-1999-9, WT/DS108/AB/R, 24 Feb. 2000, and; United States Tax Legislation (DISC), Report of the Panel presented to the Council of Representatives on 12 November 1976, (L/4422 - 23S/98).

[54] Article 31(k) reads in part: "Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive."

[55] *See, e.g.,* remedial measures regarding the vitamin price-fixing conspiracy, referenced in Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements, Prepared Testimony of James M. Griffin Deputy Assistant Attorney General Antitrust Division, Before the Senate Judiciary Committee, FED. NEWS SERV., May 24, 2001.

wish to point to competition law proceedings as the only viable option for granting necessary licenses.

Some other potential approaches raise serious operational issues (e.g., parallel and regional licensing), suggesting that they may not become meaningful alternatives for some time. Other potential approaches (e.g., PPEZs) involve strained interpretations of the WTO agreements that, even though perhaps customarily accepted in other contexts, may nevertheless be subject to successful challenge in dispute settlement unless formally approved by interpretation, waiver or amendment.

The restrictions imposed by Article 31(f) will limit the available supply of generic drugs for developing countries, a condition that will be increasingly problematic, as developing countries are required to implement pharmaceutical patent protection in 2005. Interpreting the express text of Article 31(f) in a way that relaxes its restrictions presents serious difficulties. Alternative approaches should be considered.

VIII. Article 30-Based Solutions

The express text and context of Article 30, particularly in light of paragraph 4 of the Doha Declaration, allows Members to authorize the making and export of patented public health related products to address unmet health needs in countries without the financial resources to provide access to medicines for all.

Article 30 authorizes "limited exceptions", meaning deviations from general rules within established boundaries. These exceptions should not "unreasonably conflict" with the "normal exploitation" of patents. Exports of public health related products to markets requiring low price access does not so conflict. Exceptions should not "unreasonably prejudice" the "legitimate interests" of patent holders, taking into account the legitimate interests of third parties. The interests of patent holders are protected if exports are not authorized for developed Member markets, and if there is not systematic diversion to those markets. Individuals in developing Members with need for access have legitimate interests to be taken into account.

Criteria for authorizing exceptions under Article 30 may include:

1. Whether the importing country is confronting an unaddressed health need;

2. Whether the importing country has the financial resources to pay for on-patent drugs or other public health related inventions, whether locally produced or imported, to supply the needs of "all" those in need of treatment;

3. Whether the exporting country has the capacity to supply low-price pharmaceuticals or other public health related inventions.

Discretion whether to authorize an exception under Article 30 is in the hands of the Member that would grant the authorization.

Authorization of the export of public health related inventions without the consent of the patent holder is not dependent on Article 31(f). Article 30 of the TRIPS Agreement expressly authorizes Members to provide limited exceptions to patent rights under certain conditions. Members should be able to authorize exports of products under patent in their

territories as an exception to the rights of patent holders when local producers are able to provide low price products, and when such products are needed by importing Members. Use of the Article 30 exception for exports would be most consistent with implementing the TRIPS Agreement in a manner supporting public health and promoting access to medicines for all as decided by Ministers in paragraph 4 of the Doha Declaration.

Use of the Article 30 exception may or may not be dependent in the country of import on the issuance of a compulsory license that overcomes potential objection to importation from a local patent holder. This will depend on whether there is patent protection provided in the country of import (which might, for example, be an LDC that is not enforcing such protection), and on whether the patent holder in the country of import is considered to have a right to consent to importation. It is generally accepted that a compulsory license may be satisfied by importation if products are lawfully available from countries of export. No formal interpretation of Article 31 would be needed to allow compulsory licenses for import to be used in connection with exports undertaken under Article 30.

It is important to note that the decision whether to authorize an Article 30 exception resides in the country from which exports are undertaken. A WTO Member authorizing an Article 30 exception makes the determination whether a potential conflict with rights of the patent holder will be unreasonable. If a Member considers that to authorize an exception would undermine its interests in attracting research and development investment, or foreign direct investment, it might refuse to authorize an exception. Members may choose to balance the interests of patent holders and social welfare interests in access to medicines by using the flexibility in Article 30 to establish exceptions. The application of the balancing will be within the good faith discretion of the Member making the determination.

a. Interpretation of express text

Article 30 of the TRIPS Agreement provides:

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

The express text of Article 30 establishes three basic criteria for establishing exceptions to the Article 28 enumerated rights of patent holders.[56]

1. "Limited exceptions"

Article 30 of the TRIPS Agreement states that Members may provide "limited exceptions to the exclusive rights conferred by a patent". The common meaning of "limited" is that the

[56] In this subsection, I have deliberately avoided reference to decisions by WTO panels for reasons enumerated in Section V, *supra*. However, the Canada-Generics panel report is discussed in Section VIII.c.4 , *infra*.

subject matter is bounded by constraints.[57] Standing alone, the term "limited" does not indicate that the established boundaries should be narrow. Subject matter that is "limited" is differentiated from subject matter that is "unlimited", or not subject to boundaries.

An "exception" is a deviation or derogation from a rule or principle.[58] As with the term "limited", the term "exception" standing alone does not connote a particular degree. Exceptions to rules may be infrequent and minor, or they may be frequent and substantial.

"Limited exceptions" to rights are deviations from rules that are constrained within boundaries.

Based on this element of the express text of Article 30, the General Council of the WTO may render an interpretation of Article 30 that establishes deviations from the rights of patent holders set out in Article 28 that are constrained by boundaries.

2. "provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent"

The term "unreasonably" is flexible.[59] The term combines the root "reasonable", with the prefix "un". Something that is "reasonable" appeals to logic or is equitable. Something that is "un-reasonable" does not appeal to logic, or is inequitable. A party or subject matter acts "unreasonably" if it acts in a way that does not appeal to logic, or inequitably.

"Conflict" means to stand in opposition.[60]

"Normal" means to be within the generally accepted parameters of conduct.[61]

"Exploitation" means use.[62]

The plain meaning of the phrase "provided that such exceptions do not unreasonably conflict with the normal exploitation of the patent" is that deviations from the enumerated rights of patent holders should not operate inequitably in the context that patents are ordinarily used.

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[57] "Limited" as an adjective is defined as "(1) Appointed, fixed. (2) Confined within definite limits; restricted in scope, extent, amount, etc.; (of an amount or number) small; (of an income) low; (of monarchy, government, etc.) exercised under limitations of power prescribed by a constitution." NEW SHORTER OXFORD DICTIONARY, at 1592.

[58] "Exception" is defined as a noun as "(1) The action of excepting someone or something from a group, the scope of a proposition, etc.; the state or fact of being so excepted." "Except" is defined as a verb as "(1) Specify as not included in a category or group; exclude (from)." *Id.*, at 872.

[59] "Unreasonable" is defined as an adjective as "(1) Not endowed with reason; irrational. (2) Not based on or acting in accordance with reason or good sense. (3) Going beyond what is reasonable or equitable; excessive." *Id*, at 3503. "Reason" as a noun is defined as "(1) The mental faculty (usually regarding as characteristic of humankind, but sometimes also attributed in a certain degree to animals) which is used in adapting thought or action to some end; the guiding principle of the human mind in the process of thinking." *Id*., at 2495.

[60] "Conflict" as a verb is defined as "(1) Fight, struggle (with). (2) Engage in battle, assault. (3) Of principles, interests, etc.: clash, be incompatible." *Id.,* at 476.

[61] "Normal" is defined as an adjective as "(3) Constituting or conforming to a type or standard; regular, usual, typical; ordinary, conventional. Also, physically or mentally sound, healthy." *Id*. , at 1940.

[62] "Exploitation" is defined as a noun as "The action or practice of exploiting something or someone." *Id*. , at 889. "Exploit" is defined as a verb as "(1) Accomplish, achieve, perform" and "(4) … utilize for one's own ends, take advantage of, (a person, esp. an employee, etc.)". *Id.* , at 888.

3. "and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties"

"Unreasonably" is defined above.

"Prejudice" means to act adversely in relation to the subject matter.[63]

"Legitimate" means within the expectations of law or social custom.[64]

"Interests" refer to that which a party considers themselves affected by, or in some circumstances to that which a person is entitled.[65]

"Taking account of" means considering within the framework of analysis or concern.

"Third parties" are those persons or enterprises that are not directly part of the referenced relation.[66]

As a matter of ordinary meaning, exceptions that "do not unreasonably prejudice the legitimate interest of the patent owner, taking account of the legitimate interests of third parties" means that subject deviations should not inequitably affect expected entitlements of the patent holder, considering the effect on persons that are not directly within the government-patent holder relation.

4. The significance of footnote 7

Footnote 7 to Article 31 of the TRIPS Agreement states that "'Other use' refers to use other than that allowed under Article 30."

Article 31 establishes rules and procedures regarding the grant of compulsory licenses. The plain meaning of footnote 7 is that an exception under Article 30 and a compulsory license under Article 31 are different legal mechanisms to which different rules and procedures apply.

Article 31 sets forth relatively detailed steps regarding the granting and administration of compulsory licenses, including a requirement that adequate remuneration in the circumstances of the case is paid, and that a predominant part of licensed products be for the supply of the local market. Article 30, by way of contrast, does not specify procedures for the authorizing of exceptions, does not address the issue of remuneration, and does not include geographic limitations.

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[63] "Prejudice" is defined as a verb as "(1) Affect adversely or unfavourably; injure or impair the validity of (a right, claim, etc. b. injure materially; damage." *Id.*, at 2333.

[64] "Legitimate" is defined as adjective as "(2a) Conformable to, sanctioned or authorized by, law or principle; lawful, justifiable, proper. b. Normal, regular; conformable to a recognized standard type; … d. Sanctioned by the laws of reasoning; logically admissible or inferable." *Id.*, at 1563.

[65] "Interest" is defined as a noun as "(1) The fact or relation of having a share or concern in, or a right to, something, esp. by law; a right or title, esp. to (a share in property or a use or benefit relating to property … (2) A thing which is to the advantage of someone; a benefit, (an) advantage (3) The relation of being involved or concerned as regards potential detriment or (esp.) advantage." *Id*., at 1393.

[66] "Third party" is defined as "(a) a party or person besides the two primarily concerned; (b) a bystander" *Id.*, at 3283.

The text of Article 31(f) indicates that compulsory licensing is not intended for use predominantly for supply of export markets. It cannot be said that an interpretation of Article 30 that authorizes the supply of export markets under specified conditions is a compulsory license within the meaning of Article 31. It is a legal mechanism not contemplated by Article 31. It is a use allowed under Article 30, and not under Article 31.

Footnote 7 does not say that if a compulsory license may not be issued within Article 31 rules and procedures, there can be no exception under Article 30. Article 30 provides for "exceptions" to patent holder rights, including rights under Article 31. Article 30 is not by its terms limited regarding the potential subject matter of exceptions.

b. Application of interpretation based on express text

Based on the express text of Article 30, the concept of "limited exception" does not significantly constrain the possible interpretations that may be decided upon by the General Council. The exceptions must include defined boundary(ies).

The main issue is what is the "normal exploitation" of the patent, and what type of deviation from that normal exploitation would be "unreasonable" as a matter of treaty interpretation.

1. Normal exploitation of the patent right

(a) Right to export

It must first be observed that a right to consent to "export" is not an enumerated right of patent holders under Article 28 of the TRIPS Agreement. There is an enumerated right of "import", making evident that TRIPS negotiators considered the movement of patented articles in international trade. This author is not aware of national or regional patent laws that specifically enumerate a right of "export" (although the U.S. Patent Act addresses this subject indirectly).[67]

Patent holders within a country may ordinarily be in a position to claim infringement based on exports because exporters have "made" or "sold" the subject invention within the territory of the exporting country. This will not always be the case. A product covered by patent made abroad, and merely transiting territory, would not be covered by an enumerated patent right.

Because Article 28 does not enumerate a right of export, there is no "normal" right under the TRIPS Agreement to export a patented drug. There is, however, a normal right to "make" and "sell" a patented drug.

(b) Higher income market conditions

A patent grant confers rights within the territory of the country granting the patent. The patent serves several purposes from the standpoint of the patent holder. It precludes potential competitors from selling an infringing product on the market covered by the

[67] *See* 19 USC §271(f), as discussed in Abbott, QUNO Occasional Paper 7, *supra* note 4.

patent. It also precludes potential competitors from manufacturing infringing products within the market covered by the patent.

In light of the integration of world markets, a significant portion of products manufactured within a country may be exported. The right to prevent potential competitors from establishing competing manufacturing facilities within a particular country that engage in exportation may confer an advantage on the patent holder in the sense that potential competitors are forced to locate their facilities where there is no patent protection and, if a patent is in force worldwide, not to manufacture for export at all.

The right to prevent others from manufacturing for export may be a valuable commercial right in some contexts.

(c) Lower income market conditions

In other contexts, the right to manufacture for export may have very limited commercial value. One such context is export to countries with low income and limited effective demand for the potentially exported products. If there is no effective market for the products of a patent holder, the right to export to a market, or to prevent others from manufacturing and exporting to that market, will have a minimal value.

Although patent holders may regard unexploited patents as having a certain value in their capacity to block commercial activities of others, unexploited blocking patents do not serve a socially useful purpose.

Patents are granted to encourage inventors and investors to undertake socially useful activities. When patents are not exploited, the bargain between society and the inventor/investor is broken. There is no justification for allowing an inventor/investor to block manufacture and export to markets where patented products are required and where there is minimal interference with the commercial value of the patent to the inventor/investor.

An interpretation of Article 30 that would authorize the making and export of patented pharmaceutical products to low income markets would not interfere with "normal" exploitation, and would not in any event constitute an "unreasonable" conflict with such exploitation.

(d) Developing country requirements as criteria

Recall that paragraph 4 of the Doha Declaration states:

> "Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."

Article 30 should be interpreted in a manner that promotes access to medicines for all.

The appropriate base criterion for an Article 30 exception is whether it would address a legitimate need in the importing country, not whether there is manufacturing capacity in

that country, or whether it would desirable to create manufacturing capacity in that country.

This suggests criteria such as:

1. Whether the importing country is confronting an unaddressed health need;

2. Whether the importing country has the financial resources to pay for on-patent drugs or other public health related inventions, whether locally produced or imported, to supply the needs of "all" those in need of treatment;

3. Whether the exporting country has the capacity to supply low-price pharmaceuticals or other public health related inventions.

When addressing public health and pharmaceuticals, the issue for developing countries is: what solution will bring disease-fighting remedies to the market in the shortest time at the lowest cost? If a drug can be manufactured at a low-cost facility in any WTO Member, and it would be feasible for a plant to supply a low-income country, it would be economically inefficient to require a prospective importing Member to gear up its own manufacturing facility for the same drug.

2. Unreasonable prejudice to the interests of the patent holder, taking into account third party interests

An authorization to make and export under certain conditions might unreasonably prejudice the interests of the patent holder.

An authorization to supply a high-income market might under some circumstances unreasonably conflict with the normal exploitation of the patent, and unreasonably prejudice the interests of the patent holder.

An authorization regarding a low-income market might unreasonably prejudice the interests of the patent holder if the exports were systematically diverted to high-income markets, thereby undermining the commercial return on the patent.

The interests of the public in obtaining affordable access to medicines and other public health related inventions must always be taken into account in evaluating the effect on patent holders.

c. Additional interpretative factors

1. The Vienna Convention on the Law of Treaties

As discussed above, the VCLT provides that treaties are to be interpreted "in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose" (Article 31(1)). The context includes the text, preambles and annexes (Article 31(2)). Further,

> "3. There shall be taken into account, together with the context:

> (a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions;
>
> (b) any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation;" (Article 31).

Article 32 of VCLT provides, in relevant part:

> "Supplementary means of interpretation
>
> Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of article 31, or to determine the meaning when the interpretation according to article 31:
>
> (a) leaves the meaning ambiguous or obscure; or
> (b) leads to a result which is manifestly absurd or unreasonable."

The two previous subsections of this report considered the ordinary meaning of the express text of Article 30 and its implementation in respect to authorization of making and export of pharmaceuticals under patent. It is important also to consider whether there is additional "context and in light of the object and purpose" in relation to Article 30 of the TRIPS Agreement acting as a material constraint on interpretation.

As an initial matter, it should be noted that the preparatory work or negotiating history of a treaty or international agreement is optionally examined under Article 32, VCLT, only as a secondary source to confirm an interpretation or resolve an ambiguity.

2. The Doha Declaration

The Doha Declaration on the TRIPS Agreement and Public Health states:

> "4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.
>
> In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."

Paragraph 4 is stated in terms of an agreement among WTO Ministers acting on behalf of Members. This agreement is most reasonably considered a "decision" of WTO Members under Article IX:1 of the WTO Agreement.[68] This decision of WTO Members would appear to constitute an agreement on the method of application of the agreement within

[68] Article IX:1 of the WTO Agreement provides in relevant part.

> "1. The WTO shall continue the practice of decision-making by consensus followed under GATT 1947. Except as otherwise provided, where a decision cannot be arrived at by consensus, the matter at issue shall be decided by voting. At meetings of the Ministerial Conference and the General Council, each Member of the WTO shall have one vote…. Decisions of the Ministerial Conference and the General Council shall be taken by a majority of the votes cast, unless otherwise provided in this Agreement or in the relevant Multilateral Trade Agreement."

the meaning of Article 31(3)(a) of the VCLT, and to be the substantive equivalent of an interpretation of the TRIPS Agreement.

Ministers in Doha should be assumed to have acted with a purpose. The only apparent purpose for agreeing on a method of application of the TRIPS Agreement is to have an effect on the way in which the agreement is implemented by WTO Members.

Article 30 of the TRIPS Agreement "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all." Interpreting Article 30 to allow for exceptions to make and export pharmaceutical and other public health related products when needed by developing countries would be most consistent with the decision of WTO Ministers.

3. Negotiating history

Under Article 32 of the VCLT, the use of supplementary sources of interpretation such as preparatory work is discretionary. The treaty interpreter "may" refer to supplemental sources. Recourse may confirm an interpretation arrived at consistently with Article 31, VCLT. A Member in the implementation of the TRIPS Agreement, or the Ministerial Conference or General Council deciding on an interpretation under Article IX:2 of the WTO Agreement, may refer to supplemental sources to confirm the interpretation, or may not. There is nothing in VCLT rules suggesting that the negotiating history of an agreement would limit an interpretation within the express text, context, and object and purpose of the agreement.

Article 30 of the TRIPS Agreement was adopted as a compromise solution following the inability of negotiators during the Uruguay Round to agree on a list of exceptions to patent holder rights that might be recognized by Members.[69] Negotiations concerning such a list

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[69] In his July 23, 1990, report on the status of work in the TRIPS Negotiating Group, the Chairman (Lars E. R. Anell) presented a draft composite text on the analogue to Article 30 that was completely reworked by the time the Dunkel Draft text was distributed in late 1991. The July 1990 draft included alternative "A" (developed country supported) and "B" (developing country supported) proposals. It provided:

"2.2 Exceptions to Rights Conferred

2.2 [Provided that legitimate interests of the proprietor of the patent and of third parties are taken into account,] limited exceptions to the exclusive rights conferred by a patent may be made for certain acts, such as:

2.2.1 Rights based on prior use.

2.2.2 Acts done privately and for non-commercial purposes.

2.2.3 Acts done for experimental purposes.

2.2.4 Preparation in a pharmacy in individual cases of a medicine in accordance with a prescription, or acts carried out with a medicine so prepared.

2.2.5A Acts done in reliance upon them not being prohibited by a valid claim present in a patent as initially granted, but subsequently becoming prohibited by a valid claim of that patent changed in accordance with procedures for effecting changes to patents after grant.

2.2.6B Acts done by government for purposes merely of its own use."

Chairman's Report to the GNG, Status of Work in the Negotiating Group, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, MTN.GNG/NG11/W/76, 23 July 1990.

proceeded contemporaneously at WIPO, and no agreement was reached in that forum.[70]

The most that may be said about the negotiating history of Article 30 is that it does not resolve uncertainty regarding the meaning of the express text. The draft on exceptions in the 1990 Anell text is wholly different than the final text that emerged as Article 30 in the Dunkel Draft text in late 1991.[71] There was no agreement on the Anell text.

The list of exceptions set out in the Anell text included several that would have significant economic consequences, including a right in favor of prior users and a right of experimental use.[72] The extent of an exception and the conflict with normal exploitation of the patent is a matter of degree.

4. The Canada-Generics panel report

To date, there has been one DSU panel report regarding interpretation of Article 30, the decision in Canada-Generic Pharmaceuticals. [73] As discussed in Section V, the General Council and Ministerial Conference are not bound to follow the jurisprudence of a panel report in the adoption of an interpretation of the TRIPS Agreement. While Members that are parties to a specific dispute are obligated to comply with a decision of the DSB, that decision

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[70] The corresponding provision under negotiation at WIPO provided:

> "Article 19(3)(a). Notwithstanding paragraphs (1) and (2), any Contracting Party shall be free to provide that the owner of a patent has no right to prevent third parties from performing, without his authorization, the acts referred to in paragraphs (1) and (2) in the following circumstances:
>
> (i) where the act concerns a product which has been put on the market by the owner of the patent, or with his express consent, insofar as such an act is performed after that product has been so put on the market in the territory of that Contracting Party, or, in the case of a group of States constituting a regional market, in the territory of one of the member States of such group;
>
> (ii) where the act is done privately and on a non-commercial scale, provided that it does not significantly prejudice the economic interests of the owner of the patent;
>
> (iii) where the act consists of making or using for exclusively experimental purposes, provided that it does not significantly prejudice the economic interests of the owner of the patent;
>
> (iv) where the act consists of the preparation for individual cases, in a pharmacy or by a medical doctor, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared.
>
> Article 19(3)(b). The provisions of paragraphs (1) and (2) shall not be interpreted as affecting the freedom that Contracting Parties have under the Paris Convention for the Protection of Industrial Property to allow, under certain circumstances, the performance of acts without the authorization of the owner of the patent."

WIPO, Committee of Experts on the Harmonization of Certain Provisions in Laws for the Protection of Inventions, Eighth Session, Geneva, June 11 to 22, 1990, Draft Treaty on the Harmonization of Patent Laws; Draft Regulations Under the Draft Treaty (Articles 9 to 24; Rule 7), Document prepared by the International Bureau of WIPO, HL/CE/VIII/3, February 15, 1990.

[71] The "Dunkel Draft" refers to a draft text prepared by the WTO Secretariat under the direction of then-GATT Director General, Arthur Dunkel Trade Negotiations Committee, Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, MTN.TNG/W/FA, 20 Dec. 1991.

[72] Quotation and citation in note 69*, supra*. The "Anell" text refers to the draft composite text prepared by the Chairman of the TRIPS Negotiating Group.

[73] The panel in *U.S.-Copyright Act* also considered interpretation of Article 9(2) of the Berne Convention from which the text of Article 30 is partly derived. United States – Section 110(5) of the Us Copyright Act, Report of the Panel, WT/DS160/R, 15 June 2000.

does not bind other Members in their development of TRIPS-compatible interpretations. Moreover, the Appellate Body (AB) has yet to address interpretation of Article 30. The history of WTO DSU proceedings so far is that the AB often disagrees with legal analysis by panels, and it cannot be assumed that the analysis in Canada-Generics would be sustained at the AB level.[74]

The panel in Canada-Generics interpreted the phrase "limited exception":

> "7.30 The Panel agreed with the EC that, as used in this context, the word 'limited' has a narrower connotation than the rather broad definitions cited by Canada. Although the word itself can have both broad and narrow definitions, the narrower being indicated by examples such as 'a mail train taking only a limited number of passengers', the narrower definition is the more appropriate when the word 'limited' is used as part of the phrase 'limited exception'. The word 'exception' by itself connotes a limited derogation, one that does not undercut the body of rules from which it is made. When a treaty uses the term 'limited exception', the word 'limited' must be given a meaning separate from the limitation implicit in the word 'exception' itself. The term 'limited exception' must therefore be read to connote a narrow exception - one which makes only a small diminution of the rights in question.
>
> 7.31 The Panel agreed with the EC interpretation that 'limited' is to be measured by the extent to which the exclusive rights of the patent owner have been curtailed. The full text of Article 30 refers to 'limited exceptions to the exclusive rights conferred by a patent'. In the absence of other indications, the Panel concluded that it would be justified in reading the text literally, focusing on the extent to which legal rights have been curtailed, rather than the size or extent of the economic impact. In support of this conclusion, the Panel noted that the following two conditions of Article 30 ask more particularly about the economic impact of the exception, and provide two sets of standards by which such impact may be judged. The term 'limited exceptions' is the only one of the three conditions in Article 30 under which the extent of the curtailment of rights as such is dealt with."

The panel interpreted "normal exploitation" of the patent right:

> "7.54 The Panel considered that 'exploitation' refers to the commercial activity by which patent owners employ their exclusive patent rights to extract economic value from their patent. The term 'normal' defines the kind of commercial activity Article 30 seeks to protect. The ordinary meaning of the word 'normal' is found in the dictionary definition: 'regular, usual, typical, ordinary, conventional'. As so defined, the term can be understood to refer either to an empirical conclusion about what is common within a relevant community, or to a normative standard of entitlement. The Panel concluded that the word 'normal' was being used in Article 30 in a sense that combined the two meanings.
>
> 7.55 The normal practice of exploitation by patent owners, as with owners of any other intellectual property right, is to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity. The specific forms of patent exploitation are not static, of course, for to be effective exploitation must adapt to changing forms of competition due to technological development and the evolution of marketing practices.

[74] The Chair of the *Canada-Generics* panel was Prof. Robert Hudec, a leading authority on international trade law.

> Protection of all normal exploitation practices is a key element of the policy reflected in all patent laws. Patent laws establish a carefully defined period of market exclusivity as an inducement to innovation, and the policy of those laws cannot be achieved unless patent owners are permitted to take effective advantage of that inducement once it has been defined."

The panel interpreted "legitimate interests" in relation to the patent holder and to third parties:

> "7.68 … Although the European Communities' definition equating 'legitimate interests' with a full respect of legal interests pursuant to Article 28.1 is within at least some of these definitions, the EC definition makes it difficult to make sense of the rest of the third condition of Article 30, in at least three respects. First, since by that definition every exception under Article 30 will be causing 'prejudice' to some legal rights provided by Article 28 of the Agreement, that definition would reduce the first part of the third condition to a simple requirement that the proposed exception must not be 'unreasonable'. Such a requirement could certainly have been expressed more directly if that was what was meant. Second, a definition equating 'legitimate interests' with legal interests makes no sense at all when applied to the final phrase of Article 30 referring to the 'legitimate interests' of third parties. Third parties are by definition parties who have no legal right at all in being able to perform the tasks excluded by Article 28 patent rights. An exceptions clause permitting governments to take account of such third party legal interests would be permitting them to take account of nothing. And third, reading the third condition as a further protection of legal rights would render it essentially redundant in light of the very similar protection of legal rights in the first condition of Article 30 ('limited exception').
>
> 7.69 To make sense of the term 'legitimate interests' in this context, that term must be defined in the way that it is often used in legal discourse - as a normative claim calling for protection of interests that are 'justifiable' in the sense that they are supported by relevant public policies or other social norms. This is the sense of the word that often appears in statements such as 'X has no legitimate interest in being able to do Y'. …"

The panel's interpretation of "limited exception" is somewhat more restrictive than that suggested by this author on the basis of the express text. In the panel's view, a limited exception should be narrow and result in a small diminution of the rights in question. The panel rejected Canada's stockpiling exception as not sufficiently limited because it imposed no restraint on the quantity of drugs that could be produced before expiration of the patent term. The panel allowed Canada's regulatory review exception. The panel stressed in each case that the "limited exception" test did not address economic impact, but rather the apparent extent of the exception in legal terms. The panel indicated that economic impact would be evaluated in the context of "normal exploitation".

There is room for an Article 30 "limited exception" for making and export to developing countries even within the parameters of the panel's interpretation of those terms. "Export" is not an enumerated right of patent holders, and there is no express conflict with patent holder rights if others are permitted to export. "Making for export to developing countries needing low-cost pharmaceuticals and other public health related products" is limited within specified boundaries, and involves only a small part of the patent holder's rights.

The panel indicated that "normal exploitation" of patent rights meant that the capacity to earn ordinary commercial returns should not suffer significant detraction. Limitation of the right to consent to export to low-income developing countries should not significantly detract from the returns ordinarily earned by pharmaceutical industry patent holders, for example. Of some interest in the Canada-Generics case is that the regulatory approval exception approved by the panel is far more economically significant to the pharmaceutical sector than the stockpiling exception disapproved by the panel.

The panel indicated that "legitimate interests" should be understood in a social welfare sense, and that the interests of patent holders in earning commercial returns are subject to balancing with other interests, including social welfare interests of third parties. In that sense, an Article 30 exception for making and export to developing countries would not unreasonably prejudice the legitimate interests of patent holders.

d. Compulsory license in importing countries

The use by one WTO Member of an Article 30 exception for making and export is not dependent on the issuance of a compulsory license authorizing importation in another WTO Member. If a product is under patent in the country of import, the patent holder in that country would ordinarily be able to assert an infringement claim regarding prospective imports.[75] This situation will not pertain in certain important circumstances.

LDCs that are not required to implement or enforce patent protection until 2016 will not be required to issue compulsory licenses for imports of drugs produced under export exception in developed and developing countries, provided that the LDCs are not required to provide exclusive marketing rights. If such rights are provided, then the issuance of compulsory licenses directed at exclusive marketing rights may be required.

Pharmaceutical inventors may or may not widely patent their inventions, and there may be importing countries where patent protection, even if potentially available, has not been secured. There may be cases in which a patent has been ruled invalid in a potential importing country, and yet remain valid and enforceable in a potential exporting country.

The use of an Article 30 exception for making and export to developing countries may be undertaken in a variety of circumstances, a number of which will not involve the grant of a compulsory license in the importing country.

[75] Under a broad definition of exhaustion of rights doctrine, the party (not the patent holder) placing the drug on the market might be construed to exhaust the right of the holder to further interfere with the marketing and sale of the drug in the country of importation. This would assume that placing a patented good on the market under the terms of an exception would exhaust the patent holder's rights. Such an interpretation of exhaustion doctrine might be based on an idea that the exception by definition operated to exhaust any rights of the patent holder in the invention, and there is no "consent" of the patent holder required for the exhaustion doctrine to operate. However, if an exception to the patent holder's right means that the patent holder has no right *ab initio*, perhaps no right could be exhausted in relation to the importing country.

IX. The Issue of Remuneration

Patent holders are entitled to adequate remuneration in the circumstances of the case when subject to compulsory license. When compulsory licenses are issued both in the country of export and import, the patent holder will ordinarily be compensated within the importing Member. When no license is required for importation, the patent holder will be compensated in the exporting Member. There is no basis for suggesting that patent holders are entitled to double-compensation when products are exported and imported under compulsory license.

Article 30 does not address remuneration. In circumstances in which exceptions are authorized to export to developing Members, it is unlikely that any remunerative adjustments in favor of patent holders would be made.

a. Compulsory licensing

Article 31(h) of the TRIPS Agreement provides:

> "the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;"

Attached as Annex 1 to this report is a general analysis of the remuneration requirement of Article 31(h) authored by the writer of this report. Some of the key points made in regard to the remuneration requirement are:

1. The level of remuneration depends on the particular circumstances of the case and may take into account various factors, including (but not limited to) the economic value of the authorization;

2. "Adequate" refers to a sufficient amount meeting minimum standards;

3. Commercial market royalty rates are one possible benchmark for remuneration, but may be difficult to ascertain or be unreflective of the value of the license for a variety of reasons. Detailed analysis of underlying costs is an alternative, as are government-established guidelines. Factors such as government subsidization of research and development (R & D) and tax treatment are relevant. Royalties may be based on wholesale selling prices, net of tax liabilities.

4. Public welfare interests may be taken into account in establishing remuneration. For example, distinction might be drawn between licenses issued to further industrial policy objectives and licenses issued to supply needed medicines;

5. Article 31(k) expressly recognizes that "The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases." If a compulsory license is issued to remedy a situation in which the patent holder has unfairly benefited, the remuneration may be correspondingly diminished.

If a developing WTO Member issues a compulsory license that is satisfied by importation of products not protected by patent in the export market, the level of royalty will be entirely dependent on the importing country's remuneration determination.

If a developing Member issues a compulsory license that is satisfied by the issuance of a parallel compulsory license in an exporting Member, there will be remuneration obligations arising in both the exporting and importing Members. In such circumstances, compensation in the importing Member should generally be adequate to satisfy the interests of the patent holder since the importing Member is the primary locus of exploitation of the patent. In any case, cooperation in determining the level of remuneration between authorities in the importing and exporting Members would be foreseen. The patent holder is not entitled to a double-benefit because there are licenses granted in the importing and exporting markets. Rather, a single adequate return based on the production and sale of the subject pharmaceutical would be foreseen.

In circumstances such as the grant of a regional compulsory license, it may be reasonable to determine the level of remuneration based on the regional market.

If a pharmaceutical production export zone (PPEZ) is established in the exporting country, there should be no remuneration obligation arising in the territory of export since that territory will not form part of the area in which the patent holder exercises rights. Remuneration would be calculated based on factors in the country of import that grants the compulsory license.

As noted above, a compulsory license granted in a country of export to remedy anticompetitive practices may be adjusted to take into account the remedial nature of the license.

b. Exceptions

Article 30 is silent on the issue of compensation or remuneration. It provides that Members may provide "limited exceptions" to patent holder rights that do not unreasonably conflict with normal exploitation or unreasonably prejudice the patent holder, taking into account third party interests.

WTO Members have taken into account economic effects on patent holders in the establishment of some exceptions. For example, a number of governments that have established regulatory review exceptions have also adopted patent term extensions.[76] In the Canada-Generics proceeding, a number of these Members argued that patent holders would be treated unfairly if subject to effective shortening of the patent term based on their own regulatory review obligations, if second comers to the regulatory review process would be able to enter the market immediately upon expiration of the patent term. Extending the patent term based on the patent holder's regulatory review was said to redress the economic effects of the exception.

The panel in the Canada-Generics case rejected the argument that a regulatory review exception would fail to meet the requirements of not conflicting with normal exploitation of the patent (or prejudicing legitimate interests) if it did not include a compensatory patent term extension. The panel found that the patent holder did not have a normal expectation of

[76] This economic issue was argued *in extenso* in the *Canada-Generics* case, and references to relevant national legislation are included in the panel report.

relief from the effects of regulatory review. A regulatory review exception could be granted under Article 30 without a compensatory patent term extension adjustment.

Article 30 neither compels nor prohibits WTO Members from establishing some form of compensatory adjustment in the establishment of exceptions. An exception without any compensatory adjustment will reflect a governmental determination that the patent holder is not inhibited in the normal exploitation of the patent or unfairly prejudiced. Whether an adjustment is incorporated with an exception might influence a DSU panel in rendering a determination whether the rights of the patent holder are unreasonably prejudiced.

Unlike the compulsory license in which remuneration ordinarily flows from the licensee to the patent holder, a compensatory adjustment in the Article 30 exception context might ordinarily be in the form of government policies in countries of export that benefit pharmaceutical patent holders without direct involvement by enterprises exploiting the exception. For example, a WTO Member that provides R & D tax incentives to pharmaceutical enterprises may well consider that it is adequately compensating those enterprises for use that might be made of patents by other enterprises in the context of supplying developing countries. Similarly, a WTO Member that permits private enterprises to make use of publicly funded R & D without compensation might well consider that exceptions to patent rights based on the authorization of exports would offset any economic diminution resulting from exploitation of the exception.

There is nothing in the text of Article 30 that would preclude the General Council or Ministerial Conference from rendering an interpretation regarding the balancing of economic interests in the authorization of compulsory licensing for making and export of pharmaceuticals. For example, a formal interpretation may be adopted to provide that WTO Members authorizing production and export within certain parameters would be deemed to be within the scope of a permissible Article 30 exception without compensatory adjustment in respect to patent holders. This would in effect establish a "safe harbor" for Members choosing to establish an exception.

Entitlement to the safe harbor might be based on an evaluation of the factors justifying the grant of the exception as enumerated above. As a general rule, exceptions granted to satisfy the import requirements of low-income countries with unmet health needs would not be expected to require compensatory adjustments in countries of export.

In some circumstances in which an Article 30 exception is used, a compulsory license will be issued in the country of import. This will provide remuneration to the patent holder based on exploitation of the invention in the relevant consumer market. Under such circumstances, there would be no apparent basis for contemplating a compensatory adjustment in the country of export.

X. Application of Article 27:1 of the TRIPS Agreement

Some have argued that Article 31 of the TRIPS Agreement is subject to the Article 27:1 rule against discrimination as to field of technology. There is good reason to conclude that Article 30 is not so subject. Article 27:1 does not in any case prevent Members for bona fide reasons from adopting rules that differentiate among patents in diverse fields of technology. Ministers in fact differentiated among fields of technology in the Doha Declaration.

Article 27:1 of the TRIPS Agreement provides in relevant part:

> "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."

The issue may arise in TRIPS Council discussion whether rules regarding compulsory license for export or Article 30 exceptions may be addressed to pharmaceutical product and process patents, or to public health related patents, and not other patents.

Based on the express text of the TRIPS Agreement, some have argued that Article 31 (addressing compulsory licensing) is subject to Article 27:1 prohibiting discrimination as to field of technology.[77] Article 70:6 stipulates the date prior to which Article 27:1 is not applicable to compulsory licensing, and the suggestion is that by implication Article 31 is subject to Article 27:1 after that date.

Notwithstanding the decision of the panel in the Canada-Generics case, there are inadequate grounds to conclude that Article 30 (addressing exceptions) is subject to Article 27:1 on the basis of the express text. The panel determined that Article 30 is subject to Article 27:1 on grounds that there was no reason to distinguish the situation of Article 31. In this respect, the panel substantially downplayed the plain language of Article 30 that is to authorize "exceptions" from the rights otherwise afforded to patent holders. An exception that otherwise meets the criteria of Article 30 should not be subject to a particular patent holder right enumerated in Article 27:1 any more that it should by definition remain subject to other patent holder rights. Article 31, by way of contrast to Article 30, is not framed in terms of "exception" to patent holder rights.

Even if Articles 30 and 31 are subject to Article 27:1, the express text of Article 27:1 nonetheless permits an interpretation of Articles 30 and 31 that is directed only to the field of pharmaceutical or public health related technology. Article 27:1 provides that patent rights shall be enjoyable "without discrimination". Discrimination refers to unfair or unjustifiably adverse treatment. It is a pejorative term.

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[77] Article 70:6 (Protection of Existing Subject Matter) states:

> "Members shall not be required to apply Article 31, or the requirement in paragraph 1 of Article 27 that patent rights shall be enjoyable without discrimination as to the field of technology, to use without the authorization of the right holder where authorization for such use was granted by the government before the date this Agreement became known."

If Article 27:1 is expressly stated not to apply to "use without authorization of the right holder" prior to the date the TRIPS Agreement became known, by logical implication it is to be applied after the date the TRIPS Agreement became known. Some developing Members do not accept this interpretation.

If specific rules applicable to pharmaceutical or public health patents are necessary to address important public interests, this does not constitute "discrimination" against the field of pharmaceutical technology. It constitutes recognition of legitimate public interests in differential treatment. Such determinations would be fully consistent with paragraph 4 of the Doha Declaration that expressly acknowledges the need to support access to medicines "for all".

In adopting paragraphs 6 and 7 of the Doha Declaration, Ministers have clearly acknowledged that the pharmaceutical sector may be treated differently than other sectors regarding the enjoyment of patent protection. Paragraph 6 specifically addresses insufficient manufacturing capacity in the pharmaceutical sector, and finding a solution to this particular problem regarding compulsory licensing. Paragraph 7 provides for the grant of an extension of the general LDC transition time period solely in respect to pharmaceutical products. The practice of WTO Members is to permit legitimate distinctions among fields of technology.

XI. Amendment and Waiver

> *By amending the TRIPS Agreement to delete Article 31(f), Members would permit compulsory licensing predominantly for export, thereby eliminating the most serious impediment to manufacture and trade in public health related products, including medicines and vaccines. If Article 31(f) is deleted, an amendment to Article 30 may be useful, though not essential. A waiver of Article 31(f) might be adopted pending conclusion of amendment of the TRIPS Agreement.*
>
> *The TRIPS Agreement might be amended to permit Members to exempt public health related inventions from patenting, recalling that this position was advocated by a number of developing Members during the Uruguay Round negotiations. Article 8:1 should be amended so that the safeguard provision relating to intellectual property is consistent with the safeguard provisions relating to goods and services.*

A detailed analysis of the options open to developing countries under Articles 30 and 31 of the TRIPS Agreement reveals that interpreting the existing text in a manner favorable to addressing public health concerns is problematic. In respect to Article 31(f), the operational and legal difficulties are such that, absent reliance on an Article 30 exception, the legal risks in working with the present text are great. Particularly in light of Paragraph 4 of the Doha Declaration, Article 30 may provide a reasonable degree of flexibility, but the ambiguities inherent in the three-factor test (analysed earlier in this paper) also create a situation of uncertainty that developing countries in particular may find inhibiting. In the final analysis, the interests of developing countries may be best addressed by amending the TRIPS Agreement. As a temporary measure pending formal amendment, a waiver might be adopted to implement the options that may be used in amendment.

a. Amendment and waiver alternatives

There are several provisions of the TRIPS Agreement that might be amended to better accommodate the interests of developing countries in obtaining access to medicines and other public health related products.

1. Authorizing Exemption from Subject Matter Scope of Patent Protection:

Throughout much of the TRIPS Agreement negotiations, a number of developing countries supported authorizing exemption from patenting of inventions relating to health and nutrition. Recognizing the difficulties that implementation of patent protection for public health related inventions has created, Members now might decide to authorize exempting such inventions from the subject matter scope of patent protection. This could be done by amending Article 27:3(a) to state that therapeutic treatment of humans includes pharmaceutical products and processes, and other inventions related to the prevention, diagnosis or treatment of disease.

2. Consistency of Safeguard Clauses:

Article 8:1 of the TRIPS Agreement acknowledges that Members may adopt measures necessary to protect public health, provided that such measures are otherwise "consistent" with the agreement. GATT 1994 (Article XX(b)) and GATS (Article XIV(b)) permit Members to adopt measures "necessary to protect human, animal or plant life or health" that are otherwise inconsistent with those agreements. It is exceedingly difficult to explain why the WTO agreement most likely to impact on public health also most stringently restricts protecting public health. This could be remedied by deleting the phrase "provided that such measures are consistent with the provisions of this Agreement", and otherwise conforming Article 8:1 with the language of the comparable GATT 1994 and GATS provisions. With these changes, WTO Members might rely on the dispute settlement process and well-developed GATT-WTO jurisprudence to refine the conditions under which amended Article 8:1 is applied in the TRIPS and public health context.

3. Broaden Scope of Exceptions Provision:

Article 30 might be amended to reduce reliance on the ambiguous three-factor test, perhaps by the addition of a new paragraph. This might, for example, state that Members may authorize exceptions to the rights of patent holders "in a manner supportive of the right to protect public health and, in particular, to promote access to medicines for all. To accomplish this objective, Members may authorize exceptions for the making, sale and export of inventions relating to public health as they consider appropriate." This would track paragraph 4 of the Doha Declaration decided by the Ministerial Conference.

4. Remove Restriction on Compulsory Licensing for Export:

Article 31(f) requires that a predominant part of compulsory licensed products be supplied to the market of the Member granting the license. If Article 31(f) is deleted, Members may grant compulsory licenses all or in predominant part for the supply of export markets. This would permit prospective importing Members to request products to which they might not otherwise have access, and enable prospective exporting Members to authorize the making and sale for export of products by parties other than the patent holder. This would enable

prospective exporting Members to grant licenses for making and export on their own initiative, for example in response to global demand for necessary medicines.

Regarding item 4, whether prospective importing Members will be required to issue parallel compulsory licenses will depend on a number of factors: (a) if there is no patent or no enforcement of patents (e.g., by an LDC) in the importing Member, no additional measures would be required in the importing Member; (b) if there is a patent in the importing Member, the patent holder might consent to importation, and no additional measures would be required; (c) if there is a patent in the importing Member, that Member might recognize a doctrine of international exhaustion of patent rights that would rely on the legitimate marketing of the product in the export market to extinguish rights of the patent holder to claim infringement in the importing Member, and (d) if there is a patent in the importing Member, and that Member does not recognize a doctrine of international exhaustion based on the legitimate marketing of the product in the country of export, the country of import may issue a parallel compulsory license authorizing import without the consent of the local patent holder.

A waiver might be contemplated as an interim measure to remove the restriction imposed by Article 31(f) in the same manner that an amendment would eliminate that provision.

b. The exhaustion issue

Paragraph 5(d) of the Doha Declaration provides:

> "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."

The exhaustion of a patent holder's rights to control the sale, use, and importation of products may be based on its consent to the first sale or marketing of the product. It may also be based on a sale or marketing of the product authorized by a government under compulsory licensing or otherwise.

The EU and US each proposed to incorporate in the Declaration on the TRIPS Agreement and Public Health a limit on international exhaustion to marketing with the consent of the patent holder.[78] Such limitation was not included in the Doha Declaration. Instead, paragraph 5(d) leaves each Member "free to establish its own regime for such exhaustion without challenge." This appears to leave each Member with the discretion to determine whether it will recognize compulsory-licensed marketing or sale of a product in a country of export as exhausting the patent holder's rights in the country of import to consent to importation and resale.

Pursuant to Article 31(h) of the TRIPS Agreement, the patent holder in the country of export is entitled to adequate compensation in the circumstances of the case for the compulsory licensing of its product for export. Assuming that a first sale or marketing under compulsory license in the country of export exhausts the patent holder's rights in

[78] *See* EU and U.S. (with like-minded) negotiating texts presented during pre-Doha negotiations.

the country of import, the patent holder will nonetheless be adequately compensated in the country of export.

c. Recommendations regarding amendment

Each Member of the WTO should be able to decide whether it is in its best public policy interests to grant patents on public health related inventions. For this reason, developing countries may want to place on the agenda of the TRIPS Council the general question of public health related patenting.

Developing Members should place the issue of amending Article 8:1 on the agenda of the TRIPS Council. There is no justification for placing public health interests in patents and other forms of intellectual property below such interests in goods and services in the WTO hierarchy of norms.

From the standpoint of the Ministerial mandate in paragraph 6 of the Declaration on the TRIPS Agreement and Public Health, the most direct amendment proposals involve Articles 30 and 31. Amending Article 30 to clearly authorize exceptions for making and export of public health related inventions would effectively address the problem identified by paragraph 6. The advantage of an Article 30 approach is that it minimizes need for the use of compulsory licensing administrative machinery in prospective exporting Members.

Amending Article 31 by deleting subparagraph 31(f) would also resolve the problem identified in paragraph 6 of the Doha Declaration. This approach would effectively establish the administrative machinery for adequate compensation in countries of export, and in such regard might be more acceptable from an OECD industry standpoint. Such an amendment would be neutral as to field of technology, and this may present advantages from the standpoint of some Members.

XII. Interpretation

As an alternative to amendment of the TRIPS Agreement, the Ministerial Conference and General Council may adopt an interpretation of Article 30 making clear that Members may authorize the making, sale and export of public health related products without the consent of patent holders. Such an interpretation might indicate:

1. Authorization to make, sell and export patented public health related products is a limited exception to the rights of patent holders;

2. Such authorization does not conflict with the normal exploitation of the patent when:

a. Undertaken to address unmet public health needs in countries of import, and;

b. Financial constraints in countries of import restrict attention to the public health requirements of all individuals.

3. Such authorization does not prejudice the legitimate interests of patent holders, taking into account the legitimate interests of third parties when:

a. The authorization is not directed to supplying a developed importing Member;

> *b. Without prejudgment as to the form such mechanism may take, the country of import accepts to provide the patent holder in the country of export with a reasonable opportunity to prevent the systematic diversion to developed Members of products supplied under exception.*
>
> *4. Nothing in the foregoing precludes Members from authorizing exceptions regarding developed Members as circumstances justify.*
>
> *Whether there is manufacturing capacity in a prospective importing Member is a factor that may be taken into account when determining whether that Member has unmet public health needs.*

In anticipation of the Doha Ministerial Conference, developing Members prepared a set of specific recommendations intended to address the problems associated with the restriction on compulsory licensing established by Article 31(f) of the TRIPS Agreement. Those recommendations were set out at the beginning of this paper, and are reiterated here:

> "5. A compulsory license issued by a Member may be given effect by another Member. Such other Member may authorize a supplier within its territory to make and export the product covered by the license predominantly for the supply of the domestic market of the Member granting the license. Production and export under these conditions do not infringe the rights of the patent holder.
> …
>
> 7. Under Article 30 of the TRIPS Agreement, Members may, among others, authorize the production and export of medicines by persons other than holders of patents on those medicines to address public health needs in importing Members."[79]

The analysis in this paper supports the foregoing proposals made in advance of the Ministerial.

In effect, Article 30 must be interpreted so as to allow the making, sale and export of patented products to address public health needs in importing countries as a way to operationalize the capacity of Members to produce for export to meet the compulsory licensing requirements of importing Members. If an interpretation authorizing production

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[79] The developing country group non-paper draft declaration submitted to the TRIPS Council on September 18, 2001 included the following additional provisions relevant to the subject matter of paragraph 6:

> " 3. Each Member has the right to allow other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, and to determine the grounds upon which such use is allowed.
> …
> 4. In the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use, Members may grant compulsory licenses without prior efforts on the part of the user to obtain authorization from the right holder.
> …
> 6. Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) of Article 31 of the TRIPS Agreement where use of the subject matter of a patent is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive."

Non-Paper on Ministerial Declaration on the Trips Agreement And Public Health, Submission by the African Group, Bangladesh, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Haiti, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand, and Venezuela.

for export is adopted, there is no need to adopt an additional specific interpretation of Article 31, unless some Member(s) elects to place in doubt whether a compulsory license may ordinarily be fulfilled by importation. If doubt is expressed on this issue, it may also be prudent to adopt an interpretation of Article 31 making clear that Members may fulfil compulsory licenses granted within their territories by importation.

The decision whether to authorize an Article 30 exception should be understood to be in the hands of the Member making that determination. For the purpose of providing guidance to Members and the Dispute Settlement Body, it may be useful to indicate that:

1. Authorization to make, sell and export patented public health related products is a limited exception to the rights of patent holders;

2. Such authorization does not conflict with the normal exploitation of the patent when:

   a. Undertaken to address unmet public health needs in countries of import, and;

   b. Financial constraints in countries of import restrict attention to the public health requirements of all individuals**.**

3. Such authorization does not prejudice the legitimate interests of patent holders, taking into account the legitimate interests of third parties when:

   a. The authorization is not directed to supplying a developed importing Member;

   b. Without prejudgment as to the form such mechanism may take, the country of import accepts to provide the patent holder in the country of export with a reasonable opportunity to prevent the systematic diversion to developed Members of products supplied under exception.

4. Nothing in the foregoing precludes Members from authorizing exceptions regarding developed Members as circumstances justify.

Whether there is manufacturing capacity in a prospective importing Member is a factor that may be taken into account when determining whether that Member has unmet public health needs.

Paragraph 6 of the Doha Declaration refers to addressing the situation of "WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector" that may face difficulties in making effective use of compulsory licensing. By its terms, paragraph 6 implies that if an importing Member has insufficient manufacturing capacity to address its public health requirements by issuing compulsory licenses, an exporting Member would be entitled to rely on that insufficiency as the basis for authorizing a limited export exception to patent holder rights within the meaning of Article 30.

There may be some LDCs with literally no pharmaceutical manufacturing capacities, and in such case that fact without more may appear to justify invocation of an Article 30 exception to supply exports to those countries. Most countries, whether developing or developed, are not in a position to supply all of their needs for patented pharmaceuticals.

All countries rely on imports to satisfy some of their requirements for patented pharmaceuticals.

There may be various obstacles to granting compulsory licenses for supply of the local market that range from lack of adequate manufacturing facilities present within the country, to the absence of potential licensees that are willing and /or capable of manufacturing locally. In some countries capacity to manufacture pharmaceuticals may be owned or controlled by the same companies that hold local patents, and there will be no enterprises willing to take on the role of compulsory license supplier.

This suggests that insufficiency of manufacturing capacity should not be the principal criteria for determining whether a country may obtain imported public health related products. Instead, the state of manufacturing capacity might be one factor relevant to determining whether there are unmet health needs within that country.

The interpretative conditions should not be understood to exclude developed countries from obtaining imports that rely on an Article 30 exception authorization by an exporting Member. There are situations that may arise in which a developed Member urgently requires public health related products within its territory, and may need to rely on exports from persons other than the patent holder to meet its needs.

XIII. Conclusion

> *In order to permit them to address vital public health interests, developing Members of the WTO should propose to amend the TRIPS Agreement to delete Article 31(f). They should also propose to amend Article 8:1 to make it consistent with the safeguard provisions in the GATT 1994 and GATS. Pending conclusion of these amendments, waivers should be pursued.*
>
> *As an alternative, or an interim solution, developing Members should propose a formal interpretation of Article 30 that will acknowledge the right of all Members to authorize exceptions for the making, sale and export of public health related inventions without the consent of patent holders in appropriate circumstances.*

Developing Members of the WTO must be enabled to meet their public health needs by importing pharmaceuticals and other public health related inventions under patent in countries of export. This objective may be best accomplished by amending the TRIPS Agreement to delete Article 31(f) presently requiring that compulsory licenses be issued predominantly for the supply of the local market. Article 30 may also be amended by adding a paragraph indicating that exceptions may be authorized to address public health needs through making, sale and export of public health related products without the consent of the patent holder.

Developing Members should pursue an amendment of Article 8:1 of the TRIPS Agreement to make safeguards applicable to intellectual property rights consistent with safeguards applicable to goods and services. Interim waivers regarding Article 31(f), Article 30 and the last clause of Article 8:1 might precede amendment.

Developing Members may also wish to place on the agenda of the TRIPS Council a proposal to amend Article 27:3(a) of the TRIPS Agreement to allow exceptions from patent subject matter protection regarding public health related inventions.

As a second best alternative to amendment, developing Members may propose a formal interpretation of the TRIPS Agreement. The language of Article 31(f) does not readily lend itself to favourable interpretation. It may be most useful to pursue an interpretation of Article 30 authorizing exceptions to the rights of patent holders consistent with paragraph 4 of the Doha Declaration.