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The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference

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On June 19, 2001, the WTO TRIPS Council held its first meeting on the implications of the TRIPS Agreement for access to medicines and public health. In connection with that meeting, and a follow on meeting of July 25, 2001, WTO Members have made a number of specific observations regarding the terms, structure and spirit of the Agreement.

This report analyzes issues presented by the TRIPS Agreement and its present and prospective impact on access to medicines. A number of these issues have previously been raised and analyzed by this author and other commentators, and the discussions initiated in the TRIPS Council already focus on several of them. Nevertheless, it may be useful to consider in a relatively concise and systematic format the central elements of discussion in connection with the prospective Ministerial Conference in Doha on November 9-13, 2001.

There are two ultimate objectives of this report. The first is to assist Members in formulating recommendations regarding a possible Doha Ministerial Declaration on TRIPS and Public Health, or a near-term formal interpretation of the TRIPS Agreement. The second is to raise issues that might more appropriately be the subject of a longer-term review of the TRIPS Agreement.

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I. Background

The negotiating history of the TRIPS Agreement has been discussed extensively by expert commentators, including active participants in the negotiations, and it is generally accepted that the developing and least developed countries were placed under great political and economic pressure to accept terms that did not adequately take into account their specific interests.[1] It is understood that although the obligations established by the TRIPS Agreement were likely to have a substantial impact on prices of and access to medicines, there was very limited participation by public health experts and officials in the negotiating process, although pharmaceutical industry representatives played a major role in pressing for conclusion of the Agreement. Against this background, it is not surprising that developing (including least developed) Members of the WTO face difficulties in implementing the Agreement.

II. The Present Availability of Off-Patent Medicines and the End of the Transition Periods

In partial recognition of the social and economic adjustments that developing Members would face as they provided patent protection for pharmaceutical products, the TRIPS Agreement allows those Members that did not provide such protection until January 1, 2005 to implement it. Absent extension, least developed Members have until January 1, 2006. In the interim, under the so-called "mailbox" rule, developing countries are required to establish mechanisms for receiving and preserving priority in regard to pharmaceutical patent applications, and to allowing for the grant of exclusive distribution rights when prescribed conditions are satisfied.

At present, producers with the capacity and willingness to supply the world market with low-price medicines under patent in developed countries are principally located in developing countries such as Brazil, China and India. Producers in these countries are able to manufacture under local law in compliance with TRIPS because pharmaceuticals were not patentable until recently (*e.g.*, in the case of Brazil[2]) or are not yet patentable (*e.g.*, in the case of India[3]). Developing and least developed countries that do not provide patent protection for pharmaceutical products are currently permitted under TRIPS to import low-price medicines from Brazil, China and India because there is no TRIPS-mandated export or import restriction.

A. U.S. pressures to encourage accelerated implementation, and U.S. resistance to extensions

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[1] *See* Contributions on TRIPS in THE POLITICAL ECONOMY OF INTERNATIONAL TRADE LAW: ESSAYS IN HONOR OF ROBERT HUDEC (Eds. Daniel Kennedy and James Southwick), forthcoming Cambridge University Press 2001.

[2] Amendments to Brazil's patent law were enacted in 1996 and became effective on January 1, 1997. These amendments did not authorize retroactive patent protection to drugs on the market and not under patent at the time the legislation became effective. Law No. 9,279, of May 14, 1996, Regulating rights and obligations regarding industrial property, notified to WTO Council on Trade-Related Aspects of Intellectual Property Rights, IP/N/1/BRA/I/1,19 Sept 2000.

[3] The Indian Parliament continues to debate amendments to its patent legislation, which currently does not protect pharmaceutical products. *See* Bill No. XLIX of 1999, The Patents (Second Amendment) Bill, 1999, to further amend the Patents Act, 1970, as introduced in the Rajya Sabha, 20 Dec. 1999.

The United States and some other Members have pressured developing and least developed Members to accelerate the adoption of patent protection on pharmaceutical products. In its submission to the TRIPS Council on access to medicines, the United States promotes the adoption of strong patent protection, and discourages an extension of transition timetables. The arguments put forward are: (1) patents encourage research and development on new pharmaceuticals; (2) strong patent regimes encourage foreign direct investment; (3) patents promote disclosure of technical information, and (4) least developed Members should demonstrate that they will be disadvantaged by introducing patent protection before seeking to extend transition timetables. The United States contends:

> "Apart from stimulating innovation, however, a strong IPR regime - particularly a strong patent regime - can also produce other benefits for countries, regardless of whether the countries are developed or developing.
>
> For example, countries that have strong patent regimes are more effective in attracting investments and market entry by innovative companies. The reasons for this are fairly simple - patents provide a greater capacity for the innovator to compete based on the innovation. If the innovator cannot use the innovation to provide a market advantage, there is a disincentive to enter the market, particularly where others in that market can charge lower prices because they do not need to recover the costs of research and development, nor invest in new research and development.
>
> As I have already noted, another important benefit of a patent regime is that, in order to obtain a patent, an innovator must disclose all the technical details of the invention, a requirement embodied in Article 29 of the TRIPS Agreement. This disclosure stimulates a significant flow of information to the public, including competing manufactures, that might otherwise be kept secret. Therefore, patent systems do not impede research and development activities nor do they discourage competition. Patent systems encourage this activity.
> ….
>
> Before discussing the specific articles of the Agreement most commonly associated with access to medicines, I would like to remind delegations that among the most significant flexibilities contained in the TRIPS Agreement are the transition periods provided to developing and least-developed country Members, especially the specific transition period provided to Members which had not established patent protection for pharmaceuticals and agricultural chemicals at the time the Agreement entered into force.
>
> We would like to understand better what impact the TRIPS Agreement could be having on the health care regimes of least-developed country Members given that these Members are not currently obligated to

> implement the Agreement, including its patent provisions. We are particularly interested because certain Members have suggested that these transition periods be further extended, even before these Members have had any experience implementing the Agreement."[4]

The taking off point of the U.S. delegation's justification for encouraging implementation of TRIPS commitments is that a strong patent system results in a greater level of innovation, particularly in the pharmaceutical sector. The most important studies of patents and innovation generally have been inconclusive regarding a correlation between patents and invention.[5] It is demonstrable that as countries have reached higher levels of economic development they have tended to adopt stronger patent protection,[6] but this does not demonstrate a causal link between patents and invention.[7] Over the past several decades, patterns of invention have shifted from individuals working in isolation or in smaller groups, toward large-scale corporate enterprise research and development (R & D) targeted to achieving specific aims.[8] This new invention pattern plausibly is more reliant for invention-stimulus on patent protection than the former pattern.[9] Assuming that the presence of patent protection provides an incentive for increased levels of corporate R& D toward developing new pharmaceuticals, and that increased levels of R & D result in more pharmaceutical inventions, this does not address the interests of developing and least developed countries in stronger patent protection.

The granting of patents involves a balancing between the public interest in access to a larger pool of inventions, and private interests in wealth generation. In the case of medicines, the public interest is in new products for the prevention and cure of disease. The private interest is in generating profits for pharmaceutical industry shareholders and for employee (including executive) compensation. The developing and least developed countries will gain from the TRIPS implementation bargain to the

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[4] 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.

[5] *See, e.g.,* Fritz Machlup, *An Economic Review of the Patent System*, Subcomm. On Patents, Trademarks and Copyrights, of the Committee on the Judiciary, 85th Cong. 2d. Sess (1958), and J. JEWKES, D. SAWERS & S. STILLERMAN, THE SOURCES OF INVENTION (1958), and references in KEITH MASKUS, INTELLECTUAL PROPERTY RIGHTS IN THE GLOBAL ECONOMY 42-44 (IIE 2000) [hereinafter "Maskus"]. As Maskus reports, pharmaceutical industry sources assert that availability of patent protection plays a significant role in their decisions to develop new drugs. However, this assertion cannot be equated with empirical evidence that new drugs are created because of the availability of patent protection. Maskus is used in this report as a source because he is among the most widely respected economists who study intellectual property rights, and because his views are in the mainstream of theoretical discourse.

[6] Maskus, at 102.

[7] This may indicate that countries reach higher levels of economic development, they tend to shift the allocation of capital toward the development of new technologies, and that as capital is shifted into R & D, investors seek to protect their capital investments with patents.

[8] *See* discussion by Lord Hoffmann in *Biogen v. Medeva*, House of Lords (UK), [1997] RPC 1, 31 Oct. 1996 regarding calculated enterprise invention in the biotechnology sector.

[9] Jewkes, et al., *supra* note 5, found that most great inventors acted out of scientific interest and curiosity, though not entirely unmotivated by the prospects for financial gain. Corporate investor-inventors are presumably more interested in invention as a means to an economic end than sole inventors

extent that they (a) can afford more expensive medicines and (b) will obtain access to new medicines that they would not otherwise obtain.

1. Price

Pharmaceutical patents by design and function increase the price of medicines to consumers. Patents enable pharmaceutical manufacturers to sustain prices higher than their marginal costs of production by discouraging the emergence of competitors. The United States and the OECD pharmaceutical industry have argued that price is only one factor in determining access to medicines in developing countries, and infrastructure and professional support must also be addressed. Yet this is hardly an argument against measures that would lower the price of patented pharmaceuticals. It is difficult to conceive of products as to which price matters more than life-saving drugs, and as to which price reductions would be more welcomed by those who need them. The author of this report has analyzed this specific point in Annex A hereto, "The Economics of Public Health".

For a developing or least developed country, the grant of pharmaceutical patent protection almost certainly means increasing payments to U.S., European or Japan-based pharmaceutical companies.[10] As a general proposition, the United States will be by far the largest beneficiary of the patent provisions the TRIPS Agreement.[11] As a consequence of TRIPS implementation, there will be large rent transfers from the developing and least developed to wealthier developed countries.

The TRIPS Agreement does not expressly promote the affordability of medicines, other than by allowing WTO Members to grant compulsory licenses when they consider that prices being charged by patent holders are contrary to the public interest, by permitting the authorization of parallel importation and by recognizing the right of Members to enforce competition law.[12] The United States has threatened trade sanctions against WTO Members when they have proposed to grant compulsory licenses or authorize parallel importation. It has attempted to make the use of these policy instruments as difficult as possible.

2. Access

So far the developing and least developed countries have enjoyed access to new medicines that have not been protected by patent. The pharmaceutical industry in the developed countries has devoted very limited attention to diseases of particular

[10] The vast preponderance of patents worldwide are held by individuals and enterprises based in the OECD countries. *See* UNDP Human Development Report 1999, *Globalization with a Human Face*, at 69.
[11] *See* Maskus, at 183-86.
[12] The TRIPS Agreement does not restrict the right of Members to adopt price control measures, and such measures may be used to enhance the affordability of patented medicines. Price control measures do not, however, assure that drugs will be made available in contrast, for example, to compulsory licensing measures.

prevalence in the developing countries,[13] and there is nothing in the TRIPS Agreement that obligates this industry to use the increased patent rents obtained from developing countries for research on diseases prevalent in those countries.[14]

There is no public interest constraint imposed on the pharmaceutical companies in regard to the increased rents that will be generated from patents extended by the developing and least developed WTO Members. There is nothing to prevent the increased income from being spent on R & D for lifestyle drugs that appeal mainly to OECD consumers, and there is no constraint on what portion of income may be spent on advertising and promotion. There is no limit on the level of executive compensation. The pharmaceutical industry is the beneficiary of an extremely valuable public policy instrument -- the TRIPS Agreement -- and has not been made accountable for its use of the benefits.

The TRIPS Council reviews the legislation adopted by Members to meet its obligations. It does not review income statements of the pharmaceutical companies, R & D expenditures in the pharmaceutical sector, or the direction of these expenditures (and other budget items such as advertising and promotion expenditure). The pharmaceutical sector does not make public specific information on R & D, invention and profits that would allow the type of evaluation that the TRIPS Council might usefully perform.

It is well-known that U.S.-based pharmaceutical companies benefit substantially from research supported by federal government funding, and that many important new drugs were developed with material subsidies from the government.[15] Patents deriving from federally funded research are granted or licensed to private firms. Developing and least developed WTO Members, by providing patent protection for drugs developed in the United States under government subsidy, only indirectly encourage innovation. They mainly aid the U.S. government to support its domestic pharmaceuticals sector. This is not to underestimate or to devalue the critical contributions of the U.S. scientific community to the development of new drugs, but rather to pose the question why developing countries should make their contributions to industry, when they might instead directly subsidize the development of new drugs through contributions to researchers?

By providing patent protection, developing and least developed Members may also provide some additional incentive to their local research communities. While not

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[13] *See* Maskus, at 156; UNDP Human Development Report 2001, *Making New Technologies Work for Human Development*, at 109-10, and; Carlos M. Correa, *Some Assumptions on Patent Law and Pharmaceutical R&D*, manuscript July 2001.

[14] To the extent that Article 7, TRIPS Agreement, might be construed to impose such an obligation, it certainly has not been operationalized in this context.

[15] *See* U.S. National Institutes of Health, *NIH Contributions to Pharmaceutical Development* (February 2000), detailing the substantial dependence of the U.S. pharmaceutical sector on publicly funded research, and noting that "Advances in cellular and molecular biology have created the new biotechnology industry, which is based on an entirely new concept of drugs and medicines. Biotech drug and medicine development is, if anything, even more based in and interrelated with public sector research than drug development in the big pharmaceutical firms" (*id*.); *also see* Affidavit of James Packard Love, April 2001, In the Matter of Pharmaceutical Manufacturers' Association of South Africa v. The President of the Republic of South Africa and Others, High Court of South Africa, Case No. 4183/98.

wishing to discount the value of this incentive, the quantum of innovation that is likely to be stimulated is very unlikely in terms of economic return to offset the level of rent transfer from the developing to the developed countries.[16]

Research-based pharmaceutical companies in the developed countries have made important discoveries that contribute to global public health. Patent protection in the OECD countries may well have played a constructive role in this process. Experts in the patent and trade fields are in substantial agreement, however, that the role of patent protection in a country will vary depending on a variety of factors, including level of economic development, capacity for innovation and local market size. The United States is pressing a one-size-fits-all approach to patents.

3. Foreign direct investment

The U.S. delegation's assertion that strong patent protection encourages higher levels of foreign direct investment developing countries is unsupported by empirical evidence.[17] The delegation asserts that the correlation is simple. Yet the most talented economists in the United States have reached differing conclusions in this area even at the theoretical level.[18]

4. Conclusion

A survey by Keith Maskus of the important economics literature on introducing pharmaceutical patent protection in developing countries yields this conclusion:

> "It is remarkable how little is known about the potential effects of changing global policy regimes in this fundamental manner, despite the fact that the pharmaceutical sector is the most extensively studied of all IPR-sensitive industries. This information gap results from a scarcity of data to support estimation of key elasticities and market-structure parameters, and from uncertainty about the potential effects on prices, profitability and innovation. However, several articles may help us understand the issues and get a sense of their tentative conclusions. The preponderance of conclusions is pessimistic about the net effects of drug patents on the economic welfare of developing countries (or, more accurately, of net importers of patented drugs)."[19]

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[16] *See* Maskus, at 165.
[17] *See, e.g.,* Carlos A. Primo Braga and Carsten Fink, *The Relationship between Intellectual Property Rights and Foreign Direct Investment*, 9 DUKE J. INT'L & COMP. L. 163 (1998).
[18] *See* presentation of various studies reaching different conclusions in Maskus, at ch. 4. The U.S. asserts that developing Members will benefit from the disclosure afforded by a patent system. In fact, patent grants are already disclosed in the developed countries, and the developing countries will gain little incremental benefit from additional local disclosure. The reason that companies seek patents is that they are not otherwise able to protect their technology against reverse engineering. Countries seeking to maximize access to existing pharmaceutical technologies would not grant patents.
[19] Maskus, at 160.

Regardless whether enhanced patent protection for pharmaceutical products may at some point in the future provide benefits to developing countries, there is no sound empirical basis for the United States to demand immediate introduction of such protection by developing countries, or to stand in the way of extending transition timetables for least developed countries.

Although there may be an exceptional case in which a least developed country will develop a new drug for which patent protection might be useful, as a general proposition least developed countries have no reason to provide patent protection for pharmaceutical products other than to pay higher prices to OECD-based pharmaceutical companies.[20] OECD-based companies do not generally invest in diseases principally affecting least developed countries, so that higher prices paid for drugs will benefit the least developed countries only in a remote sense. The preponderant effect of introducing patents on pharmaceuticals in the least developed countries will be to reduce the number of individuals who can afford to buy them.

The U.S. delegation has not explained why the situation demanded by the TRIPS Agreement is that best suited to the developing and least developed Members.

Recommendation:

In light of the existing situation, no developing or least developed country that wishes to have access to low-price medicines under patent elsewhere should provide patent protection for pharmaceuticals (if they have not already done so) until they are mandated to do so by the TRIPS Agreement (at earliest, January 1, 2005).

The TRIPS Council should be directed to undertake an objective in-depth study, in cooperation with the World Health Organization, of the effects of the TRIPS Agreement on the prices of pharmaceuticals, the identity of the beneficiaries of pharmaceutical patent protection, and the level and direction of research (and other expenditures) by those beneficiaries

B. The changed situation in 2005/2006

A substantial change to the TRIPS-imposed legal conditions in developing and least developed countries will occur on January 1, 2005 and January 1, 2006.

[20] The U.S. delegation requested that the least developed countries provide information on the effects that the TRIPS Agreement could be having on them since they are not as yet obligated to implement the agreement, including patent protection. Without such information, according to the U.S., it cannot determine whether it would be useful to extent transition timetables. It is odd for the U.S. to ask for evidence of effects from governments that are not implementing the agreement. The U.S. might well look to the experiences of Thailand and Brazil for evidence that the introduction of market exclusivity and patent protection increases the price of essential medicines, with significant negative local effects. *See, e.g.*, Susannah Markandya, *Draft Timeline for trade disputes involving Thailand*, Consumer Project on Technology, July 22, 2001.

On January 1, 2005, developing countries that did not have patent protection for pharmaceutical products in place when the TRIPS Agreement became effective will be required to have such protection in place. This rule will apply to least developed countries on January 1, 2006. Also on January 1, 2005 and January 1, 2006, "mailbox" applications that were submitted during the transition periods will be operationalized such that patent protection will become effective for those applications as to which the relevant criteria of patentability are met.[21] For convenience, this report refers to the date of the new situation as 2005, except as the context indicates otherwise.

Just as Brazil, China, India and other developing countries presently manufacture medicines that are not under patent because they were not subject to patent protection in those countries when invented, so many medicines will remain off-patent when the situation changes in 2005. Just as producers of off-patent drugs produce and export them (to countries where there is no patent protection) today, they will be able to do so in 2005. The change will affect medicines already in the mailbox application pipeline, and those medicines invented on or after 2005.

Among the important consequences of this changed situation will be that developing countries with the present capacity to export off-patent medicines (including ARVs) will lose that capacity in regard to drugs in the mailbox pipeline and newly-developed patented drugs. These consequences will be addressed in the sections following that deal with compulsory licensing and parallel trade.

It is important to stress here, however, that least developed Members will lose substantial flexibility to import drugs that may be off-patent in some developed and developing Members if they implement patent protection for pharmaceutical products on January 1, 2006, and if those drugs were in their mailbox pipelines during the transition period (and are granted patent protection). The least developed Members will loose flexibility to manufacture and distribute on-patent pharmaceuticals once they have put patent protection in place. In addition, least developed Members that elect to cooperatively adopt compulsory licenses and produce patented pharmaceuticals may lose their capacity to pool and share resources once they have adopted pharmaceutical patent protection, unless Article 31 of the TRIPS Agreement is interpreted to allow this. Finally, very few least developed Members have the technical resources to effectively implement a patent system, and to the extent such systems are implemented, they are likely to provide only a conduit for decisions taken by patent offices in the OECD countries. The decisions of these patent offices are likely to reflect OECD patent holder interests. On the whole, there is no reason that least developed should be required to implement patent protection for pharmaceutical products in 2006, and they should seek to extend the transition time periods.

Recommendation:

Least developed WTO Members should seek a minimum five-year extension on implementing patent protection for pharmaceutical products, with the possibility of additional extensions.

[21] The extent to which there may be some time lag between the effective date of patent protection and the grant of a patent as to a previously filed mailbox application is not entirely clear, but to the extent that exclusive distribution rights may have been established, this issue may not be pressing.

III. Compulsory Licensing

A. Local manufacturing and importation

Developing countries that provide patent protection for pharmaceuticals may obtain low-price drugs by authorizing their local manufacture or importation under compulsory license. A compulsory license may be issued on any grounds, including to address public health needs. There is a requirement that adequate compensation under the circumstances be paid to the patent holder, but this is a flexible standard that would allow a royalty to be based on the local wholesale selling price, which should result in a manageable amount.

There may be significant costs associated with establishing a local manufacturing capacity for exploitation of a compulsory license. There is nothing in the TRIPS Agreement to preclude the holder of a compulsory license from meeting demand by importation.[22] Therefore, a developing country such as South Africa could grant a compulsory license to a producer from Brazil, China or India that could export from its established place of production, certainly in the case that the drug is not under patent to another party in Brazil, China or India.[23] The right of a WTO Member to satisfy a compulsory license through importation is implicit in article 27:1, TRIPS Agreement, providing that patent rights shall be enjoyable without discrimination as to whether products are imported or locally produced. The holder of a compulsory patent license should be entitled to work that license by importation.

Although the TRIPS Agreement has from the outset authorized countries to grant compulsory licenses for medicines under patent, no developing WTO Members has yet to do so.[24] It is important that developing countries seek to identify and address the reasons for this. One reason is that some governments may fear that potential foreign direct investors will react negatively to an environment in which compulsory licensing is authorized. Another important reason is that the United States and European Union initially adopted a highly threatening posture *vis a vis* Members that signalled a potential willingness to do so. A third reason is that internal administrative procedures for issuing compulsory licenses may not have been established, or if established may be bureaucratically cumbersome. If the process is too difficult, time-consuming or expensive, potential applicants for licenses may not proceed.

Each of these concerns should be addressed. Regarding foreign direct investors, it should be apparent that commercial investors recognize the risks posed by public health threats such as the HIV/AIDS pandemic, and should not perceive a compulsory license granted to redress such a crisis as evidence of a risk to general commercial investment. Investors in the automobile and mining sectors in South Africa, for example, have expressed increasing concern regarding the future of their employee

[22] *Accord* EU Commission, Compulsory Licensing and Data Protection, Legal Issues related to Compulsory Licensing under the TRIPS Agreement (referenced in para. 13 of Communication to TRIPS Council), *infra* note 29, at II.B.4.
[23] The situation in which the drug is under patent in Brazil or India will be addressed further on.
[24] Note, however, that Brazil has announced its intention to issue a compulsory license regarding the ARV Nelfinavir. *See* M. Petersen with J. Rich, *Roche Asks for Meeting With Brazil Health Minister*, NY TIMES, Aug. 24, 2001.

base as a consequence of the HIV/AIDS pandemic. It seems highly unlikely that these industrial investors would view government action to provide low-price ARVs in a negative manner.

The situation regarding U.S. and EU pressure is more difficult to address. Though the U.S. government publicly professes to be interested in addressing public health issues, its representatives to the TRIPS Council continue to exert pressures against constructive interpretation of the TRIPS Agreement, and U.S. government economic pressure – reflecting the interest of its pharmaceutical producers -- realistically remains a problem for developing countries.[25] The EU appears to have assumed a more neutral stance.

Overcoming procedural or process obstacles requires governments to adopt legislation that makes the granting of a compulsory license to address public health crises fast and inexpensive. The WHO and other multilateral organizations committed to addressing access to medicines issues should provide concrete advice to developing Members regarding the appropriate formulation of legislation.

Recommendation:

Suggestions for Doha may include a statement that developing countries are encouraged to issue compulsory licenses to lower the acquisition costs of medicines, and to adopt legislation that will permit such action to be taken expeditiously. Developing countries should seek a firm commitment that no Member will be penalized for taking this step.

B. External Manufacturing and Importation

As noted earlier, a substantial change to the TRIPS-imposed legal conditions in developing and least developed countries will occur on January 1, 2005 and January 1, 2006. Among the important consequences of this changed situation will be that developing countries with the present capacity to export off-patent drugs will lose that capacity in regards to newly-developed patented drugs (and drugs in the mailbox pipeline that come under patent). At this juncture, affordable access to on-patent medicines in developing and least developed countries will become increasingly dependent on compulsory licensing. If the prices of medicines offered by patent holders are too high, or if sustainable access is otherwise restricted or threatened, relief will be sought through the issuance of compulsory licenses.[26]

Certain developing countries will have capacity to manufacture under compulsory license, but there will certainly be developing and least developed countries without

[25] *See, e.g.,* Susannah Markandya, *Draft Timeline for trade disputes involving Thailand*, Consumer Project on Technology, July 22, 2001.

[26] At the outset of this discussion, parallel importation and discussed *infra*, and compulsory licensing should be distinguished. If a WTO Member follows a policy of international exhaustion of patent rights, and medicines under patent have been lawfully marketed in another Member, they may be imported without the grant of a compulsory license.

that capacity. Moreover, developing countries will require a variety of medicines, and it may be important that production of different medicines be allocated among countries. Finally, it may well be that certain developed countries will wish to aid developing and least developed countries by producing under compulsory license to satisfy import requirements.

In the foregoing circumstances, it is foreseeable that developed and developing WTO Members may wish to grant compulsory licenses for export, and this raises legal issues under the TRIPS Agreement.

Article 28 provides patent holders with the enumerated rights regarding the making, selling, using and importing of products. A manufacturer for export will be "making" a product prior to exporting it, and if it does this without the consent of the patent holder, it will arguably be interfering with the patent holder's exclusive right to "make". It might be argued that an authorization solely for purposes of export would not interfere with the rights of patent holders, since the right to export is not an enumerated right.[27] This, however, appears strained from a textual standpoint if a product is in fact made before it is exported. (Note, however, that there is flexibility in the term "make" such that intermediate components of a patented product may be made and exported without contravening Article 28). If Article 28 is interpreted to preclude production for export, then such production might be authorized under compulsory license.

Article 31(f) provides that a compulsory license "… shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use." Although there may be circumstances in which a country such as India will grant a compulsory license that will predominantly (i.e., more than 50%) supply its domestic market, and still allow for substantial exports, there are circumstances in which this will not be the case. Some developed WTO Members may, for example, wish to continue providing protection to the patent holder for their domestic market, but allow third parties to export for humanitarian reasons. Some developing Members may wish to pool productive resources and create regional supply facilities operating under compulsory license, with no single predominant market.

From the standpoint of developing and least developed WTO Members, a restriction on compulsory license for export will frustrate their capacity to effectively address access and affordability issues.

1. Recognition of an Article 31 license and application of Article 30

There are several possible approaches to addressing this problem from the legal standpoint. As the European Union noted in its communication to the TRIPS Council in connection with the first meeting on access to medicines,[28] and elaborated in a cross-

[27] The U.S. Supreme Court in 1972 interpreted the U.S. Patent Act not to preclude a manufacturer in the United States from exporting component parts of a patented product for assembly abroad, *Deepsouth Packing v. Laitram*, 406 U.S. 518 (1972), though this holding was later substantially reversed by an amendment to the Patent Act.

[28] 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.

referenced document,[29] the TRIPS Agreement might be interpreted to allow one WTO Member to recognize and give effect to a compulsory license issued by another WTO Member, and to authorize local production for export to that other Member. This may overcome the legal obstacle posed by Article 31(f) in that a compulsory license would be issued predominantly for the supply of the domestic market, with that market supplied by importation (which is generally accepted as permitted under the TRIPS Agreement).

As the EU observed, the recognition by one Member of another Member's compulsory license should be voluntary in order to avoid potential problems raised by Article 4bis (independence of patents) of the Paris Convention.[30] A legal basis for voluntary recognition of the compulsory license may be found in the concept of "comity".[31] Under the principle of comity, the authorities of one country may choose to give effect to the decision of authorities in another country if that decision does not conflict with a strong public policy of the country where the decision is to be given effect.[32]

However, as the EU has also observed, the recognition by the Member giving effect to the compulsory license would still potentially conflict with the rights of the patent holder in its territory, and a basis for authorizing the making and exporting of an on-patent medicine by a compulsory licensee would still need to be found. In this regard, Article 30 of the TRIPS Agreement may provide a basis for allowing local production and export of an on-patent pharmaceutical, provided that such production and export is understood to meet the three Article 30 criterion of being (1) limited, (2) not unreasonably conflicting with the normal exploitation of the patent, and (3) not unreasonably prejudicing the interests of the patent holder, taking into account the legitimate interests of third parties.

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[29] EU Commission, Compulsory Licensing and Data Protection, Legal Issues related to Compulsory Licensing under the TRIPS Agreement (referenced in para. 13 of Communication to TRIPS Council), *id*.

[30] Although the language of the Paris Convention rule on independence of patents is ambiguous, it is at least arguable that a rule of automatic recognition by one country of another country's decision to grant a compulsory license may be in conflict with that rule. Generally, under the rule of independence, determinations by the patent authorities in one country regarding the validity of a patent are not binding as to the validity of the patent in another country.

[31] *See Hilton v. Guyot*, 159 U.S. 113 (1894) for classic formulation of doctrine in U.S. law, and Restatement of the Law, Third, Foreign Relations Law of the United States (1987), §101, comment e, quoting that case, stating:

> "e. Comity distinguished. Comity has been variously conceived and defined. A well-known definition is: 'Comity, in the legal sense, is neither a matter of absolute obligation, on the one hand, nor of mere courtesy and good will, upon the other. But it is the recognition which one nation allows within its territory to the legislative, executive or judicial acts of another nation, having due regard both to international duty and convenience and to the rights of its own citizens or of other persons who are under the protection of its laws.' Hilton v. Guyot, 159 U.S. 113, 163-64, 16 S.Ct. 139, 143, 40 L.Ed. 95 (1895)."

[32] This principle presently provides the basis for cooperation among competition law authorities in the EU and the United States.

In an important U.S. antitrust enforcement decision, *United States v. Imperial Chemical Industries*, (SDNY 1952), 105 F. Supp. 215, 227-31, the judge issued an order intended to restrict the enforcement of British patents, acknowledging the absence of power to make that order effective in the U.K., and that only "comity" on the part of a British judge might give it effect.

If a WTO Member adopts legislation allowing it to recognize and give effect to compulsory licenses for export in reliance on Article 30, it will presumably need to do so in a manner that takes into account the "limited" nature of the exception, such as by taking into account public health and nutrition needs as identified in Article 8:1 of the TRIPS Agreement.

Because Article 30 of the TRIPS Agreement has no direct counterpart in the Paris Convention or the common law of WTO Members predating the Uruguay Round negotiations, there is substantial uncertainty regarding how its criterion will be applied. Although the panel in the *Canada – Generics* case provided some guidance on the interpretation of Article 30,[33] it was dealing with a context substantially different than that suggested here, and it is difficult to predict how the precedent of that case would be applied in these circumstances. Furthermore, the Appellate Body has not yet addressed Article 30, and it is more difficult to predict how the Appellate Body might approach these circumstances.

2. Article 31 or Article 30 standing alone

As discussed earlier, a developed or developing WTO Member invoking only Article 31, TRIPS Agreement, as the basis for granting a compulsory license for export or medicines would face a potential conflict with the express text of Article 31(f). This leads to a paradox. The WTO Members that are able to take advantage of the compulsory licensing provisions of the TRIPS Agreement to supply essential medicines are the countries with the capacity to manufacture medicines under patent, and this may exclude the countries most in need of medicines from taking advantage of compulsory licensing.

As an alternative to invoking Article 31, a WTO Member wishing to grant a compulsory license for export could invoke Article 30 without reliance on the recognition of a compulsory license granted by another Member. The EC has suggested,[34] and the panel in the *Canada – Generics* case intimated,[35] that Articles 30 and 31 might not be used for an equivalent exception from Article 28. However, it does not follow that Article 30 may not, standing alone, be used to provide an exception for a compulsory license for export that is not permitted by the express text of Article 31(f). If a compulsory license for export is not permitted under Article 31, then an exception for export may constitute a limited exception under Article 30,

[33] Canada – Patent Protection of Pharmaceutical Products, Report of the Panel, WT/DS114/R, March 17, 2000 (hereinafter "Canada – Generics").

[34] The EU Commission paper on compulsory licensing, *supra* note 29, states: "It is important to note that the footnote to Article 31 ('other use refers to use other than that allowed under Article 30') indicates that Articles 31 and 30 are mutually exclusive: a WTO Member can not invoke both Article 31 and Article 30 to justify the same practice."

[35] The panel said: "Articles 30 and 31 are linked together by the opening words of Article 31 which define the scope of Article 31 in terms of exceptions not covered by Article 30."[footnote 429] Footnote 429 states: "Article 31 is titled 'Other Use Without Authorization of the Rights Holder', and footnote 7 to Article 31 defines 'other use' as 'use' (derogations from exclusive patent rights) other than that allowed by Article 30." Canada-Generics, *supra* note 33, at para. 7.91.

without reliance on Article 31.This would be a "limited" exception from the exclusive rights conferred by Article 28.[36]

The counter-argument is that WTO Members in prescribing the conditions for the grant of compulsory licenses "occupied the field" in terms of regulating that form of exception, and specifically acted to disapprove compulsory licensing predominantly for export.

It is difficult to predict how the Appellate Body would define the relationship between Articles 30 and 31, and whether it would permit Article 30 to be used for what is in essence a compulsory license.

2. Frustration of Purpose

The purpose of allowing WTO Members to grant compulsory licenses is to allow them to elevate public interests over private interests when circumstances call for such action. If developing and least developed WTO Members are effectively precluded from addressing public interests because of lack of local manufacturing capacity, the purposes of Article 31 are frustrated. As noted above, the WTO would face the paradox that its most well-off Members would be able to take advantage of its public interest exceptions, but its least well-off would not. There are compelling public policy grounds for WTO Members to address this situation.

2. Solutions

The solution to the interpretative issues discussed above may lie in express recognition by WTO Members that the scope of limited exceptions under Article 30 is not constrained by the terms of Article 31. This interpretation would appear permissible since it does not contravene the express terms of the TRIPS Agreement, but rather clarifies that footnote 7 to Article 31 is not intended to create a situation of mutual exclusivity.

A second and somewhat more legally and administratively cumbersome solution would be to interpret the TRIPS Agreement to permit Members to recognize and give effect to compulsory licenses granted in other Members, and to interpret Article 30 to permit an exception to the patent holder's right in the country of export under these circumstances.

A third solution would be to interpret Article 31(f) to allow a predominant portion of products made under compulsory license to be exported when failure to allow this would frustrate the purposes of Article 31 (by denying access to medicines and other necessities on the part of those requiring them).[37]

[36] If the subject product is under patent in the country of importation, a compulsory license for importation should be granted.

[37] It may be argued that international human rights law provides a basis for interpreting Article 31 to give meaningful effect to the right to grant compulsory licenses to meet public health needs. *See* F.M. Abbott, *TRIPS and Human Rights: Preliminary Thoughts*, conceptual outline/paper presented at

Recommendation:

Developing countries should press for formal recognition that compulsory licenses for the making and export of medicines may be granted under Article 30 and/or Article 31 under appropriate conditions.

III. Parallel Importation

A. The basic right of Members

Developing countries that provide patent protection may authorize parallel importation of medicines, that is importation from markets where drugs under patent have lawfully been first sold or marketed (*i.e.,* where the patent holders' rights have been exhausted). Parallel importation is an extremely important policy instrument for mitigating patent price effects and promoting competitive worldwide markets in pharmaceutical products, and developing country Members of the WTO are strongly encouraged to authorize parallel importation of patented drugs. Parallel importation should be pursued along with other policy instruments, such as compulsory licensing, to encourage the lowest-cost availability of drugs.

B. Responding to the U.S. Intervention

In its submission to the TRIPS Council, the United States submission refers to article 6 of the TRIPS Agreement[38] as standing for the undisputed proposition that Members may not invoke the WTO dispute settlement mechanism "in relation to questions involving parallel imports, except when those questions involve national or most-favoured-nation treatment."[39]

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conference on Human Rights and International Trade, World Trade Institute, Berne, Switzerland, August 12-14, 2001.

[38] Article 6, TRIPS Agreement, states: "For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."

[39] It is perhaps worthwhile to begin by noting that article 6, TRIPS, refers only to dispute settlement "under this Agreement", and that at least two leading authorities on the TRIPS Agreement and participants in the Uruguay Round TRIPS negotiations, Thomas Cottier (then head of the Swiss delegation) (s*ee* Thomas Cottier, *The WTO System and the Exhaustion of Rights*, draft of November 6, 1999, for Conference on Exhaustion of Intellectual Property Rights and Parallel Importation in World Trade, Geneva, Nov. 6-7, 1998, Committee on International Trade Law, and Remarks of Thomas Cottier, in Frederick M. Abbott, Second *Report (Final) to the Committee on International Trade Law of the International Law Association on the Subject of the Exhaustion of Intellectual Property Rights and Parallel Importation***,** presented in London, July 2000, at the 69th Conference of the International Law Association, rev. 1.1 (hereinafter "Second Report") (posted at http://www.ballchair.org), and Adrian Otten (then Secretary to the TRIPS Negotiating Group) (s*ee* Remarks of Adrian Otten in Second Report) take the position that article 6 does not preclude application of the GATT 1994 or GATS to issues involving parallel importation. This view is challenged by other leading commentators on the TRIPS Agreement (s*ee* Marco C.E.J. Bronckers, *The Exhaustion of Patent Rights under World Trade Organization Law*, 32 J. WORLD TR. L. 32 (1998) and Remarks of Marco Bronckers and Remarks of William Cornish, Second Report). Resolution of this issue is not of immediate importance

The United States takes the position, however, that article 6 does not alter the substantive obligations of Part II of the TRIPS Agreement, and that "Article 6 of the TRIPS Agreement does not, in our view, authorize parallel imports."

Viewed from a benign or positive perspective, these statements of the United States could be understood as asserting only that article 6, standing alone, does not authorize parallel importation for each WTO Member. In other words, the United States could be interpreted as saying that article 6 and article 28 of the TRIPS Agreement (on patents) taken together, for example, allow each Member to establish its own policy on parallel importation of patented medicines, but that article 6 does not alone establish a particular policy or rule. Understood this way, the United States position is consistent with the TRIPS Agreement. However, in light of past U.S. assertions on this subject, it is doubtful that this is the interpretation the United States intends. Instead, what the United States probably means is that for at least some fields of intellectual property provided for in Part II of the Agreement, parallel importation is prohibited. This interpretation is not consistent with the TRIPS Agreement.

Pharmaceutical industry spokespersons and the United States Trade Representative's Office have at various times asserted that article 28, TRIPS Agreement, regarding the rights of patent holders prohibits WTO Members from allowing parallel importation of patented products, including medicines. Article 28:1 states:

> "A patent shall confer on its owner the following exclusive rights:
>
> (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing[40] for these purposes that product;"

Article 28 of the TRIPS Agreement requires each WTO Member to grant to patent holders a right to exclude others acting without their consent from importing products that would infringe their patents. Article 28 does not, however, establish the conditions upon which that right of importation may be "exhausted", just as its does not establish the conditions upon with the patent rights to "make", "use", "offer for sale" or "sale" may be exhausted. In other words, article 28 does not establish the conditions upon which the holder of the patent right no longer may exercise a right to exclude others from performing the listed acts.

In most countries,[41] the right of patent holders to control the patented product traditionally has been extinguished or exhausted by the "first sale" (*e.g.*, U.S.) or "putting/placing onto the market" (*e.g.*, EU) of the product.[42] When a patented

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since none of these commentators have asserted that TRIPS precludes each WTO Member from allowing parallel importation.

[40] "This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6."

[41] Some IPRs commentators indicate that in a few countries (France is argued to be one) the rights of a patent holder are not subject to a local rule of exhaustion. Though this seems improbable from a practical standpoint, the point is mentioned here for sake of completeness.

[42] The EU "putting onto the market" formulation appears to contemplate that intra-corporate sales may not exhaust patent holder control.

product has been lawfully sold (or made available on a public market) the purchaser of the product may resell, transfer or use the product without permission from the patent holder. The United States does not contend that article 28 interferes with the general operation of the first sale doctrine in respect to patent rights.

Some countries have adopted and operated under a rule of "international exhaustion", and some have operated under a rule of "national (or regional) exhaustion". Under a rule of international exhaustion, local patent holders are considered to have exhausted their rights of consent to importation and disposal when their products have lawfully been placed on the market anywhere in the world. A rule of international exhaustion provides the basis for parallel importation.

In a number of national legal systems, including that of the United States and Japan, the rights of a patent holder to control subsequent disposition of a product are exhausted when the patented product is first put on the market anywhere in the world, subject to the right of the patent holder to restrict the subsequent movement of the product by contract. This was clearly and recently decided by the Japanese Supreme Court in the *BBS* case,[43] in which the court held that the right under the Japanese Patent Act of a patent holder in Japan to block importation of a patented product were exhausted when the product was first sold abroad, subject to the possible imposition of contractual restrictions to the contrary.

Although there is some contrary opinion among commentators in the United States, the most comprehensive study of this issue finds the weight of authority to establish the principle of international exhaustion of patent rights, again subject to the possibility of contractual modification. Prof. Margreth Barrett states:

> "Notwithstanding assumptions and arguments to the contrary in some of the literature, a close examination of United States case precedent demonstrates that this country has tended to apply the doctrine of exhaustion to patentees' sales both inside and outside of the country, though in both cases it permits patentees to contract to avoid the effects of the doctrine. Absent a ruling to the contrary, from either the Supreme Court or the Court of Appeals for the Federal Circuit, this rule, which authorizes parallel importing in the absence of enforceable contractual restrictions, should be deemed the prevailing rule in the United States. The legislative history of the Uruguay Round Agreements Act suggests that Congress intended to maintain the status quo with regard to parallel imports, so that the Act's provision of an express importation right for patentees did not alter the general legality of parallel importing."[44]

[43] *BBS Kraftfahrzeugtechnik AG and BBS Japan, Inc. v. Rasimex Japan, Inc.,* Supreme Court Heisei 7 (o) No. 1988 (July 1, 1997), J. of S. Ct., No. 1198 (July 15, 1997).

[44] Margreth Barrett, *The United States' Doctrine of Exhaustion: Parallel Imports of Patented Goods*, 27 N. KY. L. REV. 911, 984 (2000). See also, Frederick M. Abbott, *Political Economy of the U.S. Parallel Trade: Toward a More Thoughtful Policy*, 4 WORLD TRADE FORUM (THOMAS COTTIER AND PETROS MAVROIDIS EDS. 2001). The leading case on this issue in the United States is Curtiss Aeroplane v. United Aircraft, 266 F. 71 (2d. Cir. 1920).

Although the United States restricts the importation of patented medicines, its does not do so on the basis of the Patent Act or a rule against parallel importation. Instead, this restriction is imposed by the rules of the Food and Drug Administration (FDA) that impose restrictive regulatory requirements with respect to drug imports.

The Federal Supreme Court of Switzerland, in *Kodak v. Jumbo-Markt*,[45] has expressly held that the TRIPS Agreement allows that country to adopt the rule of exhaustion with respect to parallel importation of patented products that it considers appropriate.[46] While the Supreme Court decided in favor of national exhaustion (rather than international exhaustion) for patents in Switzerland, its decision expressly rejects the argument suggested by the United States in its TRIPS Council submission. It should be noted, moreover, that while Switzerland has decided in favor of national exhaustion in respect to patents, it has adopted a rule of international exhaustion for copyright and trademark.

In addition, the International Law Association at its 69th Conference in London (July 2000) adopted Resolution 2/2000, including a "Declaration Regarding the Exhaustion of Intellectual Property Rights and Parallel Trade" (the "Declaration"), based on the recommendation of its Committee on International Trade Law. The Committee is composed of a number of the world's leading authorities on trade law and intellectual property law, including present and former members of the WTO Appellate Body and legal divisions (acting in their private capacities). The Declaration expressly acknowledges the right under the TRIPS Agreement of WTO Members to adopt their own policies with respect to parallel importation. The Declaration:

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[45] *Kodak SA v. Jumbo-Markt AG*, 4C.24/1999/rnd, December 7, 1999.

[46] In the *Kodak* case, the Swiss Supreme Court found:

> "3 b) Pursuant to Art. 28 of the TRIPs Agreement, the patent holder has inter alia the right to prevent third parties selling patented objects and importing such for this purpose. This provision with its protection of imports merely lays down that the import of products that infringe the patent must be prohibited, without itself laying down a prohibition on parallel imports. This follows not only from Art. 6 of the TRIPs Agreement but is also clarified in a reference to Art. 6 in a footnote to Art. 28 of the Agreement (GATT Message 1, 1994 Federal Gazette IV, p. 301/2; cf. also Bollinger, Die Regelung der Parallelimporte im Recht der WTO, sic! 1998, p. 548; Alesch Staehelin, Das TRIPs-Abkommen, 2nd ed., Bern 1999, p. 57 et seq. and 148/9; Cottier & Stucki, loc. cit., p. 52; Cohen Jehoram, International Exhaustion versus Importation Right: a Murky Area of Intellectual Property Law, 1996 GRUR Int., p. 284). The claim expressed occasionally in the literature that the substantive protection of importation practically requires national exhaustion through the TRIPs Agreement is not, on the other hand, convincing (argued by Straus, Bedeutung des TRIPs für das Patentrecht, 1996 GRUR Int., p. 193/4); for the attempt to derive the exclusive application of national exhaustion from this agreement ignores and misinterprets the objectives of the agreement to establish the World Trade Organisation dated April 15, 1994, one element of which is the TRIPs Agreement, namely to eliminate all kinds of trade restrictions. On the contrary, TRIPs is intended to balance two sets of interests, namely the demand for the freedom of trade on the one hand and an increased protection of intellectual property rights on the other hand (Bronckers, The Exhaustion of Patent Rights under WTO Law, Journal of World Trade 1998, p. 144). Exhaustion, and hence the question of whether in particular parallel imports can be prohibited by the party entitled to the patent, is not, however, regulated by Art. 28 of TRIPs, but expressly reserved to national law pursuant to Art. 6 of the Agreement (cf. also Kunz-Ballstein, Zur Frage der Parallelimporte im internationalen gewerblichen Rechtsschutz, 1998 GRUR, p. 269/70)."

> "13. *Recommends* that WTO Members continue to inquire into the approach to parallel trade in patented inventions that is best suited to protecting the interests of consumers and producers, *recognizing that Members may adopt their own national and regional approaches to parallel trade in patented inventions consistently with the terms of the TRIPS Agreement*." [emphasis added]

In light of (1) the express language of article 28 that does not purport to regulate the question of exhaustion; (2) article 6 that is cross-referenced by article 28 to make clear that Members may not assert a claim based on article 28 in TRIPS dispute settlement; (3) the fact that the two largest industrial economies in the world (and WTO Members) provide for the international exhaustion of patent rights; (4) the decision of the Swiss Supreme Court expressly rejecting the view that article 28 establishes a rule for parallel importation, and; (5) the weight of scholarly authority on this issue, it is manifestly clear that the TRIPS Agreement permits each WTO Member to adopt its own policy and rule with respect to parallel importation of patented medicines. To the extent that the United States has suggested otherwise, it is wrong.

Recommendation:

The right of the developing countries to authorize parallel importation is established under the TRIPS Agreement. Nevertheless, because it is costly and time-consuming for developing country governments to engage in litigation over the right to authorize parallel importation, an explicit acknowledgement of this right in a Ministerial Declaration or interpretation

C. Parallel Importation, Tiered Pricing and Safety

The United States questions the policy behind the authorization of parallel imports on two grounds.[47] First, it suggests that a policy allowing parallel imports may interfere with proposals for tiered pricing by limiting the willingness of drug producers to sell to developing country markets at low prices. Second, it suggests that parallel imports create risks to the public health because of difficulties governments face in monitoring those imports.

Parallel importation plays an extremely important role in assuring price competition among world markets, and in the pharmaceuticals context in assuring that WTO Members will obtain the lowest world market price for available drugs. It is interesting that the U.S. position paper refers to "middle men" who buy drugs at low prices in one country and sell them in another country as somehow engaged in socially harmful activity. These "middle men" are the "traders" who are at the foundation of an open world trading system, and who act to assure that consumers in each country have access to products at the lowest world market price. The U.S. delegation does not complain when grain brokers, or "middle men", in the United States buy wheat from U.S. farmers at low prices and sell it for higher prices in

[47] Intervention of the U.S. delegation, *supra* note 4.

developing countries. As noted below, tiered pricing arrangements do not require that pharmaceutical producers be insulated from competitive pricing in world markets.

Allowing parallel importation and providing for tiered pricing are by no means legally inconsistent. First, the TRIPS Agreement does not prevent a WTO Member from agreeing by contract with a company that provides low-priced drugs that those drugs may not be exported. Private parties may similarly contract to provide that patented drugs will not be resold outside a particular national market. If a WTO Member were to pass legislation that authorized restrictions on exports of patented drugs to address *bona fide* public health needs, and if such legislation were considered to otherwise be inconsistent with GATT article XI (prohibiting import and export quotas), then article XX(b) of the GATT provides an exception for such export restriction in the interests of protecting public health. There is adequate flexibility under present TRIPS Agreement and GATT rules to permit the implementation of tiered pricing programs.

The second argument made by the United States is that parallel imports present monitoring difficulties, and may endanger public health. There is, however, no correlation between patents and the monitoring of imports, and this argument is unrelated to intellectual property issues. Every WTO Member is capable of establishing a parallel importation program that provides for regulatory approval and monitoring of imports. This is a matter for the legal and regulatory authorities of each WTO Member.

Recommendation:

Developing Members should firmly resist any proposal that would limit their discretion to authorize parallel importation. Tiered pricing programs may be implemented without relinquishing such discretion.

III. Exceptions to Rights Conferred

Article 30 of the TRIPS Agreement establishes the bases for exceptions to exclusive patent rights. Three criteria are established: (1) that exceptions be "limited"; (2) that they "not unreasonably conflict with a normal exploitation of the patent", and (3) that they "not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."

The panel in the *Canada – Generics* case took a fairly narrow approach to evaluating exceptions under Article 30.[48] The most significant restriction was its decision that exceptions under Article 30 are subject to the rules of non-discrimination set out in Article 27:1. Thus, an exception under Article 30 may not discriminate as to place of invention, field of technology or whether products are imported or locally-produced. Absent the panel's further clarification regarding the meaning of Article 27:1, this restriction might have severely curtailed the capacity of developing Members to address specific concerns relating to public health.

[48] *Supra* note 33.

The panel went on to explain that "discrimination" in Article 27:1 meant something other than "differentiation", and that Members may well treat different fields of technology differently, provided that they have a legitimate reason for doing so. A developing Member might therefore adopt regulatory measures affecting pharmaceutical patents that do not also affect software patents if there is a sound basis for the differential treatment.

Nonetheless, the express text of Article 30 does not indicate that it is limited by Article 27:1, and since Article 30 specifically addresses "limited" exceptions to patent rights, the panel's decision to subject Article 30 to Article 27:1 is not entirely persuasive. One of the panel's principal reasons for reaching its conclusion was evidence that Article 31 on compulsory licensing was accepted to be bounded by Article 27:1, and in the view of the panel there was no reason to conclude that Article 30 might be construed otherwise. This did not take into account that Articles 30 and 31 address substantially different subjects, and that Article 30 expressly encompasses "limited" exceptions (and so quite plausibly exceptions limited to a field of technology), while Article 31 contains no such restrictive language.

Article 30 may play a significant role in establishing the scope of application of TRIPS patent provisions as they apply to pharmaceuticals, and developing Members might consider proposing an interpretation of Article 30 that effectively overrules the decision of the panel in *Canada – Generics* on the subject of its relationship to Article 27:1. Because the potential areas of application of Article 30 are difficult to predict, it may not he particularly helpful to attempt to enumerate measures that would fall within the range of limited exceptions, since to do so might imply the exclusion of other exceptional measures.

Recommendation:

Developing Members might consider proposing an interpretation of Article 30 of the TRIPS Agreement establishing that it is not subject to Article 27:1, since exceptions allowed by Article 30 are defined to be limited, and limited exceptions may be addressed to particular fields of technology.

VI. TRIPS Article 7

Article 7 of the TRIPS Agreement provides:

> "Objectives
>
> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner

> conducive to social and economic welfare, and to a balance of rights and obligations."

A number of developing country delegations have noted that so far there is little evidence that the TRIPS Agreement is contributing to the transfer and dissemination of technology in a manner that is conducive to their social and economic welfare, particularly in the field of public health.

Developing Members might choose to challenge the continued enforcement of the TRIPS Agreement or specific provisions on grounds that it is not meeting its stated objectives. They might demand that transition timetables be extended until evidence of benefits to them has emerged. Alternatively, they might demand that developed country Members use better efforts to operationalize the statement of objectives.

Article 7 and Article 8:1 of the TRIPS Agreement speak very strongly against the practice of the United States, the European Union and other developed Members of threatening to impose trade sanctions and to take other economically disadvantageous measures against developing Members that chose to employ the flexibility afforded by the TRIPS Agreement. The threat and/or realization of economic sanctions could hardly be more inconsistent with the objective of promoting social and economic welfare, and might well be characterized as a breach of the founding principles of the TRIPS Agreement as reflected in its statement of objectives. The threat and/or realization of trade sanctions create substantial economic and political insecurity, and such insecurity increases investment costs throughout an economy. Economic sanctions against developing countries jeopardize the livelihood of individuals who can ill-afford to bear the costs of such sanctions.

Recommendation:

Developing country Members might request a review of the TRIPS Agreement from the standpoint of demanding that developed Members objectively demonstrate the benefits that have accrued to developing Members in the field of public health and access to medicines. This might be set in the context of comparing the benefits that have accrued to private stakeholders in the developed Members so that a sense of the balance of rights and obligations can be derived.

VII. General Public Health Flexibility and Technology Transfer

A. TRIPS Article 8:1 ("Principles")

Article 8:1 of the TRIPS Agreement ("Principles") provides that "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement." Article 8:1 of the TRIPS Agreement establishes a basis for the adoption of internal measures in

language similar to that used in Article XX(b) of the GATT 1994. However, Article XX(b) of the GATT 1994 is used to justify internal measures which are necessary yet otherwise inconsistent with the GATT 1994. Article 8:1 of the TRIPS Agreement, by way of contrast, provides that necessary measures must be "consistent" with the Agreement.

Since language of a treaty is presumed not to be surplus, it would appear that Article 8:1 is to be read as a statement of TRIPS interpretative principle: it advises that developing country Members were expected to have the discretion to adopt internal measures they consider necessary to protecting public health. The constraint is that the measures they adopt should not violate the terms of the agreement. This suggests that measures adopted by developing and least developed Members to address public health should be presumed to be consistent with the TRIPS Agreement, and that any Member seeking to challenge the exercise of discretion should bear the burden of proving inconsistency. Discretion to adopt measures is built in to the agreement. Challengers should bear the burden of establishing that discretion has been abused.

This statement of principle in Article 8:1 should also prove important in limiting the potential range of non-violation nullification or impairment causes of action that might be pursued under the TRIPS Agreement. Developing countries might be challenged in respect of measures such as pharmaceutical price controls, generic substitution laws or trademark fair use determinations. Article 8:1 indicates that they were reasonably expected to adopt such TRIPS-consistent measures. In this regard, developed Members may not succeed with claims that their expectations as to the balance of concessions have been frustrated.

Although it would be of considerable aid to developing Member interests if the language of Article 8:1 tracked the language of Article XX(b), GATT 1994, and authorized necessary measures that were otherwise inconsistent with the TRIPS Agreement, this would fall outside the scope of an interpretation of the existing terms of the Agreement, and so might most realistically be considered in the context of a longer term review of the TRIPS Agreement.

Recommendation: Developing Members should seek to affirm that the TRIPS Agreement provides complete regulatory discretion in the adoption of measures taken to address public health interests, and that Members seeking to challenge the exercise of that discretion bear the burden of proving inconsistency with the terms of the agreement.

VIII. Granting of Patents

It is important that developing country governments recognize that while the TRIPS Agreement requires them to provide patent protection for pharmaceutical products and processes, it establishes only general rules regarding the criteria for patentability, i.e. newness, inventive step, commercial application, and adequate disclosure (enablement). These criteria are flexible, and may be interpreted restrictively so as to limit the number of patents on pharmaceuticals that are granted. Many or most developing countries grant patent protection based on applications that have been

reviewed and approved in one of the OECD country patent offices, or that have not been reviewed by any authority. OECD country patent offices have been very lax in granting patents on pharmaceutical products and processes, and this laxity may reflect conditions of industrial policy that are inappropriate to developing countries. As an example, developing countries might insist that patents be granted only for new drugs that represent major (or breakthrough) developments – significant therapeutic advances – and that patents not be granted for lower level improvements, for example, for new methods of dosage delivery of existing therapeutic compounds.

The technical flexibility inherent in patent law has been explored in depth from a developing country perspective.[49] Applying more demanding standards to patent applications requires putting in place technical capacity for reviewing applications, as well as putting in place administrative frameworks for adjudicating disputes. Such technical and administrative capacity may be beyond the existing capacity of many developing countries, and most least developed countries.

An important component of reducing the adverse effects of the TRIPS Agreement on public health is to create administrative mechanisms that require patent holders to meet strict standards, and to create adequate infrastructure. Regrettably, in the current institutional climate, if this task is pursued with the assistance of WIPO and the WTO, the recommended standards are not likely to reflect the public health interests of developing and least developed countries. UNCTAD is presently engaged in a project that seeks to approach this problem from a developing country perspective. Developing countries may also strongly consider pooling their resources toward the creation of regional patent offices that approach patenting from a developmental perspective.

Developing countries may seek to establish the principle that technical assistance in the development of patent infrastructure should be specifically designed to accommodate their interests, and not those of industrialized country patent applicants.

Recommendation:

Developing WTO Members should administer their patent systems in a manner suited to their specific interests. They should be cautious in relying on determinations regarding patentability made by the developed country patent offices, for example under the Patent Cooperation Treaty system. To the extent feasible, developing countries should attempt to pool their technical resources to enable a thorough review of patent applications. Developing WTO Members should be cautious in accepting technical assistance on the implementation of patent systems, depending on the source of the assistance.

IX. Trademarks and Copyrights

[49] *See* CARLOS CORREA, INTEGRATING PUBLIC HEALTH CONCERNS INTO PATENT LEGISLATION IN DEVELOPING COUNTRIES, SOUTH CENTRE (2000), AND J.H. Reichman, *From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement,* 29 N.Y.U. J. INT'L L. & POL. 11, 26-85 (1996).

Patents are not the only form of intellectual property regulated by the TRIPS Agreement with effects on access to and affordability of medicines. Pharmaceutical producers have also used trademark and copyright protection to inhibit parallel importation and to limit producers of generic (or off-patent) drugs from entering the market.

A. Trademarks

Trademark holders have attempted to restrict access to pharmaceuticals in several ways. They have asserted that governments may not allow or require pharmacists to dispense generic drugs in response to prescriptions for trademarked drugs, and that governments may not require that prescriptions be written in generic terms. They have asserted that parallel importers may not use local trademarks for drugs that have been put on the market by trademark holders in other markets under different names. They have claimed trademark and trade dress rights in the colors of tablets and capsules, and that generic producers may not use identical colors for identical drugs.

Article 16 of the TRIPS Agreement establishes the basic rights of trademark holders. These holders are protected against the use of their marks without their consent when such use is likely to result in consumer confusion. There is no affirmative market access right connected to a trademark. Trademark rights are limited in the sense that the public is entitled to fair use of trademarked terms.

So far, trademark holders do not appear to have successfully attacked generic substitution laws, which are common throughout the states of the United States. The European Court of Justice has held that parallel importers may, in the intra-Union context, change the trademark on a drug to reflect the locally-recognized mark. Otherwise, trademark holders would be able to partition the EU market by adopting different brand names in the different EU member states.[50]

The situation regarding colors of drugs is less certain. The issue is important because drug users, and particularly those with limited reading skills and the elderly, are prone to identifying medications by their capsule or tablet color, and drug therapy is facilitated when generic producers are able to use the same color capsule or tablet as the branded producer. The U.S. Supreme Court has permitted a single color to be trademarked if it has acquired sufficient secondary meaning, but strictly conditioned on grounds that the single color at issue did not serve a functional purpose.[51] Although at least one court in Canada has rejected protection of the color of a drug, it did so on grounds that there was inadequate proof of secondary meaning.[52]

Even assuming that a single color of a drug capsule acquired secondary meaning and was found to be non-functional, a court might still allow a generic producer to use that color on grounds of fair use.

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[50] *See* Pharmacia & Upjohn v. Paranova, European Court of Justice, Case C-379/97, 12 Oct. 1999.
[51] *See* Qualitex v. Jacobson, 514 U.S. 159 (1995).
[52] *See* Eli Lilly (Prozac), Canadian Federal Court, docket A-391-97, http://www.fja.gc.ca/en/cf/2000/orig,html/2000fca27986.o.en.html.

B. Copyright

Pharmaceutical manufacturers have argued that package labels and inserts that contain physician and consumer information and instructions are protected by copyright, and as such that generic producers may not include the same information with their products. This claim is among the major misuses of intellectual property in connection with medicines since copyright is well understood to protect only creative expression, and not idea or method of operation. This limitation on the scope of copyright protection is expressly incorporated in TRIPS Agreement Article 9:2.[53] Despite the apparent overreaching in arguing that "Take two tablets every four hours" is the subject of copyright protection, the pharmaceutical manufacturers do not hesitate to delay the introduction of generic drugs with litigation over this question.[54]

C. Summary

Although each of the foregoing issues, standing alone, may not be as critical to access as the scope of patent protection, when pharmaceutical producers attack generic manufacturers on multiple legal grounds, these attacks can substantially inhibit the willingness and capacity of generic producers to supply affordable medicines. It would be useful for the TRIPS Council to make clear that the Agreement grants to each Member regulatory flexibility to address the manner in which pharmaceuticals are marketed within its territory.

Recommendation:

Developing Members might suggest that the TRIPS Council indicate that the TRIPS Agreement does not seek to limit the regulatory discretion of developing country Members in addressing the manner in which trademark and copyright law can be used to affect the introduction of generic drugs, or parallel importation

X. Data Protection

Developed country WTO Members have increasingly turned their attention to measures affecting regulatory agency and third party use of clinical test and other data submitted during regulatory approval processes. The United States and EU each have suggested that Article 39:3 of the TRIPS Agreement should be interpreted to impose a bar against regulatory authority reliance on test data submitted during an initial applicant's regulatory approval procedure.[55]

[53] Article 9:2 states: "Copyright protection shall extend to expressions and not to ideas, procedures, methods of operation or mathematical concepts as such."
[54] *See, e.g.*, Smithkline Beecham v. Watson Pharmaceuticals, (2d Cir. 2000), 211 F. 3d 21, disposed of on grounds that U.S. FDA rules mandated that the generic producer use essentially identical materials, so no need to decide scope of copyright protection.
[55] In its submission to the TRIPS Council, the U.S. stated: "With respect to Article 39.3, we concur with the EC's observation that the most effective way of protecting test data against 'unfair commercial

Article 39:3 of the TRIPS Agreement provides:

> "Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."

In this instance, it is perhaps adequate to rely on the express TRIPS text to refute the argument that it "mandates" that regulatory authorities not rely on previously submitted data in evaluating third party submissions, including those of generic producers seeking to introduce off-patent versions of drugs that have been patented.[56] The text prohibits only "unfair commercial use", and the question of what is unfair commercial use is capable of differing good faith interpretations.

Requiring generic producers to conduct identical trials on equivalent compounds is socially wasteful and imposes additional costs on the public. Pharmaceutical patent holders are granted a period of market exclusivity, and to preclude regulatory agency and generic producer reliance on patent holder test data is to effectively extend the term of the patent. If patent holders are anxious to avoid regulatory agency and

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use' in a manner consistent with the TRIPS Agreement is to ensure that regulatory authorities do not rely on such data for a reasonable period of time, such as five years, as is the case in the United States."

The EU stated in its pre-meeting submission to Members:

> "Further clarification of Article 39.3 could also be useful in the context of the debate on access to drugs. This provision obliges WTO Members to protect undisclosed test or other data against unfair commercial use, when those WTO Members require submission of such data, the origination of which involves considerable efforts, as a condition of approving the marketing of pharmaceutical products.
> "Indeed, a new medicine normally has to go through a series of safety tests before it is granted marketing approval. The question then arises as to whether the resulting test data can be relied on by the regulatory authority years later when reviewing an application for marketing approval for a generic version of the medicine, thus avoiding the need for the applicant to submit new data and speeding up commercialisation of the generic medicine in, for example, developing countries.
> "The view taken by the EC and their member States is that the Agreement does contain an obligation to protect test data against 'unfair commercial use', and that the most effective method of doing so is to deny the regulatory authorities the possibility of relying on such data for a reasonable period of time. Furthermore, data protection should be available whether or not the product subject to regulatory approval is protected by patent or not, since data protection is quite a different issue from patent protection." (The Relationship Between the Provisions of the TRIPs Agreement and Access to Medicines, Communication from the European Communities and their member states, IP/C/W/280, 12 June 2001)

[56] As Maskus has noted: "TRIPS sets no clear requirement to avoid relying on prior test data for subsequent applications; nor does it mandate a fixed period of market exclusivity." (Maskus, at 23).

generic producer use of test data, then perhaps the term of patent protection can be shortened while a period of data exclusivity is tacked on. This would be "fair" to the public in the developing countries. It is perhaps "unfair" to require consumers in developing countries to pay the costs of patent protection and the additional costs of data exclusivity.

This is not to suggest that developed Members lack the regulatory discretion to evaluate fairness in another way, and to require data exclusivity in their own jurisdictions.

Developing country Members of the WTO are not likely to seek an interpretation of the TRIPS Agreement that mandates regulatory data exclusivity since this would in the vast preponderance of cases work against their economic interests. It may be in the interests of developing Members to secure an interpretation of the TRIPS Agreement making clear that there is no obligation to bar regulatory authorities from relying on previously submitted test data. Since the text of the Agreement does not mandate the US/EU proposed interpretation, there is no apparent urgency to pursuing this, except in the context of resisting extra-legal pressures to adopt TRIPS-plus standards of protection.

Recommendation:

Developing country Members should resist pressures to adopt an interpretation of the TRIPS Agreement that limits their flexibility to determine what constitutes "unfair commercial use" of data submitted to regulatory authorities.

XI. Emergence of the HIV/AIDS pandemic

A. Changed circumstances

While it was foreseeable that the Agreement would impose substantial costs on developing Members, and that its effects on public health interests would at the least be ambiguous, the scale or magnitude of the HIV/AIDS pandemic was not contemplated by any party to the negotiations. In the early 1990s, it was not foreseen that by 2001 over 35 million individuals would be infected with HIV and that virtually all those infected, absent treatment with antiretroviral medicines (ARVs), would die from AIDS within a decade. It was not foreseen that the epicenter of the pandemic would be sub-Saharan Africa, and that the pandemic would be spreading rapidly in parts of Asia, Central and Eastern Europe and Latin America.

The HIV/AIDS pandemic is one of several critical public health problems facing the international community. In addition to addressing the HIV/AIDS crisis, there is a compelling need to address issues associated with the development and distribution of drugs to combat other diseases principally affecting developing country populations.[57]

[57] *See*, e.g.,B. Pécoul, et al., *Access to essential drugs in poor countries: A lost battle?* JAMA (1999) 281,361-67.

The people living in the developing Members require access to medicines, and governments in developing Members must be able to purchase or manufacture those medicines at prices within the limits of their budgets. Even assuming that large-scale financial assistance is made available by developed Members to address the immediate consequences of the HIV/AIDS pandemic, access to low-price medicines must be assured over the long term, and without local capacity to make and distribute medicines it will be difficult for developing Members to assure such access. Access to low-priced medicines must be sustainable and secure.

B. A possible waiver approach

One approach to addressing the HIV/AIDS pandemic from a TRIPS/WTO standpoint would be to acknowledge that this situation was not contemplated when the Agreement was negotiated, and to recognize that urgent and fundamentally changed circumstances demand an immediate waiver of TRIPS obligations to permit Members to take whatever measures are appropriate to address the situation. This would be a matter of deciding that ordinarily applicable rules, to the extent they may otherwise constrain Member actions, simply would not apply. Since developing and least developed Members are not required by the TRIPS Agreement to implement patent protection for pharmaceutical products until 2005/2006, in many Members there would be little or no impact on private stakeholders (other than in the sense of affecting their longer-term expectations).

Such a waiver should be viewed as fulfilling the commitment in Article 7 of the TRIPS Agreement to contribute to the dissemination of technology, and the commitment in Article 66:2 to provide incentives to encourage technology transfer to least developed Members.[58] If any developed Member seeks a rebalancing of concessions as a consequence of authorizing a waiver, this request should be approached consistently with the objective set forth in the preamble of the WTO Agreement that speaks of "positive efforts" in favor of developing Members.[59]

Drawbacks of a waiver approach based on fundamentally changed circumstances are that: (1) it would not resolve TRIPS-related issues in regard to other critical public health and access to medicines issues, and (2) it would not provide a secure foundation for setting in place a sustainable approach to access to medicines issues. For these reasons, it is important to address the specific features of the TRIPS Agreement that may have negative consequences for public health.

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[58] Article 66:2 provides:

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

[59] The WTO Agreement Preamble states:

> *"Recognizing* further that there is need for positive efforts designed to ensure that developing countries, and especially the least developed among them, secure a share in the growth in international trade commensurate with the needs of their economic development".

The possible advantage of a waiver approach is that by limiting Member consideration to a particular context, support from Members with strong pharmaceutical industry interests might be easier to secure.

Recommendation:

Developing country Members should consider requesting a waiver of TRIPS obligations that will enable them to take whatever steps are appropriate to address the HIV/AIDS pandemic, without prejudice to further discussions and interpretations of the TRIPS Agreement.

XII. Declaration, Interpretation and Amendment

There are three institutional mechanisms generally available for addressing developing Member concerns regarding the application and potential application of TRIPS Agreement provisions: Ministerial Declaration, interpretation and amendment. The interpretation and amendment mechanisms are expressly addressed by Articles IX and X, respectively, of the WTO Agreement. The Ministerial Declaration is not expressly addressed, but some indication of its potential legal effect is found in the decision of the Appellate Body in the *Shrimp-Turtles* case.[60]

A. Ministerial Declaration

As just noted, the WTO Agreement makes no specific reference to a Ministerial decision in the form of a "declaration". A declaration by its express terms might incorporate a binding interpretation, and it would then be considered an interpretation, provided that the requisite voting super-majority was met. We would otherwise expect that there would be a legal distinction intended between a "declaration" as such, and an "interpretation".

In its *Shrimp-Turtles* decision, the Appellate Body ("AB") interpreted the meaning of Article XX of GATT 1994. In the course of its interpretation, the AB referred to the decision taken by Ministers at Marrakesh to establish a permanent Committee on Trade and Environment ("CTE"). In that decision, the Ministers referred to the Rio Declaration on Environment and Development, and certain other non-binding instruments, in establishing the terms of reference of the CTE. The principles enumerated in the Rio Declaration, and particularly the stated preference for reaching multilateral solutions to environmental problems, were used by the AB to interpret the chapeau of Article XX, and ultimately to conclude that the United States had unjustifiably discriminated among Members in the application of environmental measures. The AB also made reference to a CTE Report to the Ministers at the Singapore Ministerial Conference in support of its interpretation of Article XX, GATT 1994.

[60] *United States - Import Prohibition of Certain Shrimp and Shrimp Products*, AB-1998-4, WT/DS58/AB/R, 12 October 1998 (commonly referred to as the "Shrimp-Turtles" case).

We might distill from the AB decision in *Shrimp-Turtles* that, in the face of ambiguity in the text of the TRIPS Agreement, the AB would use a Ministerial Declaration as a supplementary means of interpretation of the Agreement. We might further presume that since the Ministerial Conference is the highest level decision-making body of the WTO (*see* Article IV:1, WTO Agreement), that a Declaration would be given substantial weight in the interpretative process.

Nonetheless, a declaration would not constitute a binding legal instrument in the sense of definitively interpreting the TRIPS Agreement. In the application of Articles 31 and 32 of the Vienna Convention on the Law of Treaties, the AB would likely regard a declaration to be part of supplementary means of interpretation, if for no other reason than (1) the WTO Agreement makes specific provision for interpretation, (2) the Vienna Convention makes specific provision for interpretation, and (3) if WTO Members opted for a mechanism other than interpretation they presumably intended that mechanism to have a different effect. In this context, if the AB found other substantial evidence – such as state practice – with a higher priority in the interpretative hierarchy than supplementary means, it might not follow the line set out in a Ministerial Declaration.

B. Interpretation

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."

Article 31 of the Vienna Convention 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;"

Article IX:2 of the WTO Agreement and Article 31 of the Vienna Convention, 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.

The meaning of this is relatively clear. An interpretation can resolve textual uncertainty. If the language of the TRIPS Agreement leaves room for interpretation, the Ministerial Conference or General Council can resolve uncertainty. An interpretation may not, however, do violence to the text of the Agreement. It cannot change "yes" to "no" or "no" to "yes".

There may well be dispute regarding how far an interpretation may go in adjusting the nuances of language.

The principal advantage of an interpretation over an amendment is that the former may be undertaken by vote of the Ministerial Conference or General Council, without further approval of national legislative bodies. A precondition of the adoption of an interpretation of the TRIPS Agreement is a recommendation by the TRIPS Council.

C. Amendment

Although the WTO Agreement makes provision for expedited amendment of the TRIPS Agreement, that provision applies only in regard to agreements to raise levels of intellectual property rights protection to which all Members are party, and does not apply in the present context.[61]

Amendment of the TRIPS Agreement would be a time-consuming undertaking, and for present purposes discussion may usefully be limited. Essentially, pursuant to Article X:1 of the WTO Agreement, either a consensus on amendment must be reached, or a two-thirds majority vote achieved, following which the proposed amendment would be referred to Members for approval. An amendment would take effect for Members that had accepted it once a two-thirds majority had notified their acceptance (Article X:3).

One factor making amendment time-consuming is that in many or most constitutional systems, treaty amendment generally requires legislative consent (since an amendment is in effect a new agreement). The legislative assent process is usually rather deliberative. A main reason GATT Contracting Parties adopted the mechanism of the negotiating "round" was to allow a substantial number of issues to be dealt with in a package, and therefore limit the number of occasions on which the legislatures of all Parties would be asked for consent to new rules.

Although it is certainly possible to envision an amendment process limited to the TRIPS Agreement, from a practical standpoint an amendment process is more likely to be linked to a new round of negotiations, and a new round of negotiations would not likely be completed for some years.

In sum, while developing Members may well wish to place amendment of the TRIPS Agreement on the table at Doha in the context of a new negotiating round, this would involve a medium- to long-term enterprise.

[61] Article X:6, WTO Agreement and Article 71:2, TRIPS Agreement.

Recommendation:

On the whole, an interpretation of the TRIPS Agreement would be the most effective near-term mechanism for addressing developing Member concerns. A Ministerial Declaration may well be useful, but it will not carry the same weight in dispute settlement. The only pre-condition of an interpretation is recommendation by the TRIPS Council. This should not be an obstacle if Ministers or the General Council are otherwise prepared to act. Although it seems doubtful that developing Members would wish to force a vote on an interpretation, a three-quarters majority vote of the Members of the WTO would

ANNEX A

The Economics of Public Health

Frederick M. Abbott
August 31, 2001

"Patents are not the problem," says Harvey Bale of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA). Financial Times (London), June 20, 2001, p. 12.

Harvey Bale, director general of the International Federation of Pharmaceutical Manufacturers Associations, … said it would be a mistake to alter TRIPs. "Access to medicines isn't about patents, but about investing in health services so the drugs get to the people that need them," he said. Poor WTO states and pharma clash over TRIPS, IAC (SM) Newsletter Database, July 2, 2001.

"Health experts inform us that the cost of drugs is only one of many important issues that must be addressed in any health crises….
…
"We must recognize that even if enough drugs to treat every single HIV-positive person were provided, free of charge, an adequate infrastructure to deliver them and monitor their use does not appear to exist in many areas most in need. To ensure that health care is available, particularly to those unable to afford basic medical care, health experts tell us that each country must also develop its medical and public health infrastructure, increase the resources allocated to health care, and take other appropriate steps.[62]" From the United States the 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 (Intellectual Property and Access to Medicines) JOB(01)/97/Add.5, Council for TRIPS, 28 June 2001

"Mr. Zoellick wrote that he was troubled by the reasons that Mr. Lamy's colleagues had offered for tiered pricing, including the

[62] At the Norway conference, Dr. Brundtland closed with the following statements:

'We have heard quite clearly that the price of drugs matters, it matters to poor people, and it matters to poor countries. But little progress will be possible without a significant investment in building effective health systems", and

"There were other important lessons that came out of our review of current experience. It reinforced the point that just making drugs available - even at no cost - does not guarantee that they will be utilized. All other pieces of the picture have to be in place as well: the distribution systems, the partnerships between public and private providers; the agreements between governments and development agencies; and clear and explicit goals and objectives."

> argument that cheap drugs were still not available in Africa. Repeating an argument often made by spokesmen for the drug industry, he wrote that it was 'more likely the result of the enormous infrastructure problems plaguing this region, rather than drug prices.'" NY Times, July 20, 2001 (McNeil, U.S. at Odds With Europe Over Rules on World Drug Pricing)

The United States intervention to the TRIPS Council session on access to medicines takes up the line that is repeatedly used by the International Federation of Pharmaceutical Manufacturer's Associations (IFPMA) that patent protection and the high price of patented pharmaceuticals do not determine the extent of access to medicines in developing countries, and in particular in relationship to the HIV/AIDS pandemic. The logic of this argument is that lowering the price of pharmaceuticals by decreasing the level of patent protection or encouraging the use of safeguard measures would not standing alone establish improved health care treatment, or even materially improve levels of treatment.

Yet it is exceedingly difficult to understand the rationale for the U.S. observation to the TRIPS Council. There are few products on the world market that are useful without some form of infrastructure, but that does not mean that lowering the price of those products does not make them more accessible to a greater number of consumers. There are, in fact, very few products for which price matters more than life-saving drugs, because price is the major obstacle to most potential consumers who otherwise have an intense demand for the product. It is indeed rather strange that the leading proponent of market economics, when the subject turns to pharmaceuticals, abandons the basic principles upon which markets function.[63]

1. Supply, Demand and Price

The quantity of a product that is placed on the market by a producer is determined by the price that consumers are willing to pay for that product. In a competitive market, a producer will supply a product so long as the price that consumers are willing to pay exceeds its marginal cost of production; that is, so long as it can profit from the sale of an incremental unit of product. On the other hand, the quantity of products that are purchased by consumers on the market is determined by its price and its desirability. Assuming that a product is desirable, as its price falls additional consumers enter the market to purchase it, up until the point that consumer demand for the product is satisfied. Conversely, as a consequence of income and spending constraints, as the price of a product increases consumers exit the market, and demand falls. The level of supply of a product to any given market is determined by the willingness of producers to furnish that product as determined by whether the consumers will pay a price that exceeds the producers' marginal cost of production.

[63] *See* PAUL A. SAMUELSON AND WILLIAM D. NORDHAUS, ECONOMICS, PART IV (13th ed. 1989), for a basic explanation of supply, demand and price. *See* Alan O. Sykes, *Comparative Advantage and the Normative Economics of International Trade Policy*, 1 J. INT'L ECON. L. 49 (1998), for an explanation of the role of price adjustments in international trade.

2. Competitive markets and patents

In a competitive market, a producer cannot for a sustained period of time charge a price for a product significantly over the marginal cost of production because this encourages new producers to enter the market, eventually bringing down the price of the product. By charging high prices in a competitive market, a producer undermines its own long-term well-being by encouraging additional supply from new market entrants.

A patent protects a producer from competition by blocking the entry of competitive products onto the market. It allows the producer to charge a price in excess of its marginal cost of production for a sustained period. The extent of protection from competition, and the consequent ability to charge a non-competitive price, is affected by factors such as the availability of substitute products, and the extent to which consumers are able to shift demand to alternative non-patented products. Holders of patents are insulated from competition to the extent their product is unique and desired by consumers.

3. Price elasticity

For every product, there is "price elasticity" of supply and demand. This refers to the degree of change in supply or demand that occurs when there is a change in the price. On the demand side, some product markets are very sensitive to price changes; that is, lowering the price of the product brings a substantial number of new buyers into the market, and raising the price causes a substantial number of former buyers to exit the market. Some products, on the other hand, are rather insensitive to price changes. Whether the price rises or falls, the same number of consumers will buy it. Similarly on the supply side, there are differences in the extent to which producers will enter or exit the market depending on changes in price.

The "equilibrium price" of a product is established when supply and demand are in balance.

4. The pharmaceuticals market

The U.S. submission to the TRIPS Council suggests that the laws of supply and demand do not function in respect to pharmaceutical products. In other words, that lowering the price of those products will not bring additional consumers into the market to purchase them, or that producers will not furnish incremental units of the product if the price exceeds the marginal cost of production, if the producers are not barred from entering the market as a consequence of a patent. There is no explanation offered for this apparent paradox that would defy basic market principles, except that there are other factors that determine the level of demand in addition to price. In other words, that there are other factors that make pharmaceuticals more or less desirable – thus affecting the price elasticity of demand.

Before a discussion of pharmaceuticals, it may be useful to illustrate the U.S. point by analogy to a less controversial product, for example, the automobile.

Is the level of market demand for automobiles determined by price alone? No. Although some automobiles are usable without roads, for the most part purchase of an automobile is dependent on whether there are roads. Similarly, most automobiles are run with gasoline, so that the demand for autos is dependent on the availability of a supply of petroleum products. In addition, there is training and government regulation. Most or all countries require that a potential driver of an auto have a license, and obtaining the license is dependent upon passing a qualifying examination. The potential pool of automobile buyers is therefore largely restricted to those who can qualify for a government-regulated license.

The level of demand for automobiles is therefore not wholly determined by price. The other factors just mentioned form part of the "price elasticity" function. No matter how far the price is lowered, persons without roads, gasoline and driver's licenses are not going to purchase many automobiles. Yet while price alone does not determine the number of consumers who have access to automobiles, this does not prevent automobile companies from engaging in vigorous price competition to sell more of them, including in markets where roads are poor.

Having made this basic point, is there any reason to believe that potential consumers of pharmaceuticals are not affected, or are affected only in immaterial measure, by changes in price?

To begin with, if we are considering a life-saving or essential pharmaceutical, it is logical to assume that any person who could afford to pay the price for the drug, and who needed it, would buy it. The desirability of the product is so great to the consumer who needs it that consumers with unlimited resources are likely to be very insensitive to price. There is no price above which someone with unlimited resources, who would otherwise die, will refuse to buy the drug.

However, for those with limited resources, the ability to enter the market is strictly determined by price. As the price of the life-saving pharmaceutical decreases, all potential consumers with adequate resources will purchase it, or otherwise die.

Would any person with adequate resources refuse to buy a life-saving drug? In limited cases, those who would perhaps chose not to sacrifice the well-being of their family by depleting all asset reserves to stave off death. This might, however, constitute a limited pool of potential consumers.

If a life-saving drug is within the ability of a person to pay, would the lack of a road to the pharmacist deter demand? Would the person or a family member be willing to walk along an unpaved path? One would logically think yes. It is in fact exceedingly difficult to imagine a product that is more sensitive to price on the downside than a life-saving drug.

Reducing the price of a pharmaceutical will not allow every person who might benefit from the drug to acquire it. As the price moves progressively downward, additional

consumers are progressively enabled to pay the price. There may well be obstacles other than price that will deter different classes of potential consumers. The fact that not every potential consumer will be able to benefit from a price reduction is not an argument against lowering the price.

A patent on a pharmaceutical product prevents a competing producer from entering the market with an identical product. The price which the producer is able to charge for the drug does not depend on its marginal cost of production because the producer does not face potential competitors for the same product. The main constraints on price for the holder of a pharmaceutical patent are the presence of potentially substitutable drugs that can be offered by other companies, the available income of prospective consumers and government intervention in the market (for example, in the form of price controls).

The holder of a patent on a unique life-saving drug is in a position to charge a high price without fear that competitive products will enter the market, although it still must account for the ability of consumers to pay, and for potential government intervention. These factors explain why, until quite recently at least, pharmaceutical companies charged very high prices in poor developing country markets for patented life-saving drugs that could be afforded only by a small segment of the population. It was not necessary to lower the price to avoid provoking competitors to enter the market, while lowering the price would not attract a sufficiently large number of consumers to offset the loss of income from the wealthy segment of the population. The only meaningful constraint on price was the potential for government intervention, which would vary from country to country.

5. Research and Development

The argument in favor of providing patents for new pharmaceutical products and processes is that patents allow producers to recover research and development expenditures that they would be unable to capture if potential competing producers could copy their innovations and begin production without similarly incurring R & D expenses. Competitors will incur substantially lower costs because copying is inexpensive compared to conducting original research, and will effectively be able to sell at their cost of manufacturing.

There is economic justification for allowing research-based producers to recover their R & D expenditures, but granting a patent monopoly is a very imprecise instrument for achieving this objective because there is no direct correlation between the income that is obtained on the basis of the patent and the amount of R & D undertaken. A research company may spend very little to develop an important new drug – for example, in reliance on the work of a university laboratory or under a government subsidy – but it may charge a price for the resulting drug that earns a very large amount of income.

The lack of direct correlation between research expenditures and patent-based income has become more significant as the world market has become more integrated (or "globalized"). R &D conducted in a single country can today be exploited by an

effectively worldwide patent, so that income to the patent holder is generated from a far larger consumer base than was formerly possible.

There is a very strong policy argument for requiring precise disclosure by pharmaceutical patent holders (and independent auditing) of the amount actually expended in creating new drugs. Absent a concrete basis for determining R & D expenses, it is exceedingly difficult to draw a conclusion about whether the system of patent protection established by the TRIPS Agreement is "fair".

Integrated pharmaceutical producers expend more on advertising and promotion than on R &D. There is no apparent justification for allowing patent-based pricing to generate income for advertisements. This is particularly apparent in the case of life-saving drugs such as antiretrovirals that are necessities, and require no advertisement

Moreover, there is no constraint as to where pharmaceutical companies elect to concentrate their R & D budgets. If the highest potential return is likely to be generated by hair-regeneration drugs, the profits from antiretroviral sales may be invested there.

There are a variety of policy mechanisms other than patents that allow research-based companies to recover costs, including tax credits, subsidies, prizes and so forth.

6. Patents and price revisited

In South Africa, local private industry is facing a crisis as workers miss work because of AIDS-related opportunistic infections, and die in increasingly large numbers. As private industry confronts this crisis, major corporations are planning to offer antiretroviral treatment to their workers. Does it matter to these corporations whether the cost of treatment is $7,000 per employee per year or $300 per employee per year? Of course it does. Assuming that the corporations will need to invest in health facilities to administer and monitor drug treatment, the money that is saved in drug costs will allow for related health expenditures. If the $300 price for antiretroviral drugs is not available because of local patent protection, should the South African corporations be satisfied that price is only one factor in HIV/AIDS treatment? No. They should bargain with the patent holders to match the low prices offered by generics producers, and if their demands are not met, they should arrange through compulsory licensing or other TRIPS-safeguards to acquire the lower price drugs.