

Commission on Intellectual Property Rights

Study Paper 2a

**WTO TRIPS Agreement and Its Implications
for Access to Medicines in Developing
Countries**

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Executive Summary

This study accepts the consensus of experts that developing countries should make use of policy options such as compulsory licensing and parallel importation to increase the supply of low-price medicines and vaccines. The interests of the OECD and its consumers will not be undermined by such action since, *inter alia*, Pharma is not significantly dependent on profits from developing countries to pursue its research mission.

The Doha Declaration on the TRIPS Agreement and Public Health mandates that the agreement be interpreted in a manner that supports public health interests and promotes access to medicines for all. This study analyzes the TRIPS Agreement in light of that mandate.

As of January 1, 2005, developing countries (excluding least developed) will be required to implement and enforce pharmaceutical product patent protection and operationalize patents based on mailbox applications that were submitted during the TRIPS transition period. At that time, the world supply of low-price off patent medicines will decrease. Not only will supplies of low-price medicines within developing countries decrease, but supplies available for export by these countries will gradually diminish.

The Doha Declaration provides to least developed countries (LDCs) an extension until January 1, 2016, to implement or enforce pharmaceutical product patent protection. That extension will have a limited effect on supplies since LDCs will remain dependent on low price imports from developing countries that may no longer be available. LDCs might best take advantage of the transition period by increasing their intra-LDC capacities to make and trade medicines and vaccines, but there are practical obstacles to accomplishing this.

When the developing country transition period ends, the restriction imposed by Article 31(f) of the TRIPS Agreement on exports under compulsory license is likely to have a significant effect on the world supply of low price medicines and vaccines. If a predominant part of compulsory licensed production must supply the local market, the quantity of available exports will be limited. To remedy this problem, the TRIPS Agreement should be amended to delete Article 31(f).

If Article 31(f) is not deleted, Article 30 of the TRIPS Agreement regarding exceptions to patent rights must be interpreted so as to permit making and export of pharmaceutical products and other public health related inventions to meet public health needs. The adoption of a formal interpretation by the WTO Ministerial Conference or General Council would provide legal security for countries following this approach. This study provides a detailed analysis of Article 30 indicating that such exception from the rights of patent holders is permitted, and suggests criteria on which implementation of this exception may be evaluated.

Article 8:1 of the TRIPS Agreement authorizes the adoption of necessary public health measures provided they are “consistent” with the terms of the TRIPS Agreement. There is no justification for the TRIPS safeguard to be more restrictive than the safeguards applicable to goods and services. Article 8:1 should be amended to

permit the adoption of necessary public health measures inconsistent with the TRIPS Agreement.

Developing countries may consider revisiting the position many of them advocated during the GATT Uruguay Round, and propose amendment of Article 27:3(a) of the TRIPS Agreement to allow exception from patenting of public health related inventions, including medicines and vaccines.

Developing countries should implement the TRIPS Agreement recognizing that its provisions do not demand excessive levels of protection promoted by only a few OECD countries.

Knowledgeable observers agree that meeting the public health needs of developing countries requires substantial subsidization from OECD countries and international organizations such as the IMF and World Bank. The Global Fund does not to date evidence that it will be adequately funded so as to address urgent developing country needs for public health supplies. Developing countries must be prepared for self-reliance, and this self-reliance requires increased capacity to produce low price medicines and vaccines, whether or not such products are under patent by Pharma enterprises. This intensifies the importance of interpreting and amending the TRIPS Agreement to reinforce developing country capacity to act in their own best interests.

Increasing attention must be devoted to research and development on medicines and vaccines of particular relevance to developing countries. Neither the market nor the TRIPS Agreement provides a solution for the lack of attention to this R & D. An option to be further explored is increasing the level of funding for publicly undertaken R & D.

Study Paper for the British Commission on Intellectual Property Rights on the WTO TRIPS Agreement and Its Implications for Access to Medicines in Developing Countries

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I. Industrial Policy and Public Health

The WTO Agreement on Trade Related Aspects of Intellectual Property Rights (“TRIPS Agreement”) provisions relating to medicines resulted from the pursuit of an industrial policy directed toward maintaining and increasing the dominance of OECD-based pharmaceutical companies in the world market for innovative drugs. There is little mystery surrounding the GATT Uruguay negotiations on TRIPS during which this industrial policy was pressed upon developing countries. The most seasoned participants and observers in the negotiating process are in accord that developing countries were essentially given no choice but to accept the terms on TRIPS demanded by the EU-Japan-US negotiating block.¹

The use by governments of industrial policy instruments to secure and maintain trade and investment advantages is a factor today in many sectors of the international economy. Europe subsidizes Airbus Industries² while the United States funds defense procurement programs that enhance aircraft R & D.³ Japan invests in supercomputers⁴ while Korea invests in the steel export sector.⁵ In each case, the exercise of an industrial policy option has an effect on the international economy. In each case, the strengthening of a sector in one country may have adverse effects in other countries, resulting in shifts in patterns of employment, perhaps with a social effect adverse to some citizens in the affected countries.

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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 2002.

² See, e.g., *Superjumbo Launch Provokes Diplomatic Dispute*, 10 WORLD AIRLINE NEWS No. 50, December 22, 2000 (reporting remarks of President Clinton to French President Chirac regarding non-commercial loans); *U.S. Concern Over Subsidies to European Plane Maker*, AIRWISE NEWS, June 18, 2001 (reporting speech of U.S. Commerce Secretary Evans expressing concern over Airbus subsidies).

³ See John Birkler, et al., *Assessing Competitive Strategies for the Joint Strike Fighter: Opportunities and Options* (Rand 2001) (describing government financial support to Boeing and Lockheed Martin during research phase for Joint Strike Fighter). Ultimate acquisition costs for JSF are anticipated in \$300 billion range. Boeing is the leading U.S. commercial aircraft producer, and research spillover into the commercial arena would be expected.

⁴ Asian Technology Information Program, *High Performance Computing Research: Japan's Real World Computing Partnership (RWC)*, ATIP97.081 (1997) (describing government-sponsored R & D program). The United States has objected to allegedly discriminatory supercomputer procurement practices that are said to reinforce the research program.

⁵ See *AK Steel v. U.S.*, (CAFC 1999), 192 F. 3d 1367 (describing various aspects of steel subsidies program).

While industrial policy measures are not always consistent with the ideal of a liberal world economy, they are a fact of economic and political life that governments and policy planners must accommodate. The question to be addressed by this Commission is whether, in the particular case of the WTO TRIPS Agreement, OECD industrial policy is likely to cause harm to other important international interests and objectives sufficient such as to recommend amendment or redirection of its implementation.

A review of the currently available literature by independent researchers on the TRIPS Agreement and access to medicines, including vaccines, in developing countries reveals a striking level of agreement on the essentials. These are:

1. Present TRIPS Agreement standards will principally benefit commercial pharmaceutical enterprises located in the OECD countries, and more specifically in the United States, Japan, Switzerland, Germany and the United Kingdom.⁶
2. Increased developing country R & D on medicines and vaccines brought about by adoption of strong patent protection is highly unlikely for the foreseeable future to yield the development of new pharmaceutical products, the income from which would offset increased patent rents that will flow from the developing to the developed countries based on the introduction of such protection.⁷
3. Developing countries should take advantage of the policy options afforded by the TRIPS Agreement including the granting of compulsory licenses and authorization of parallel importation.⁸ Price controls may be effective in specific contexts.⁹ Restrictions on exports of tiered-priced drugs may be useful in specific contexts.¹⁰
4. Substantial subsidization of developing country purchases of medicines is necessary if highly active antiretroviral (ARV) treatment (HAART) is to be provided to address the HIV/AIDS pandemic.¹¹
5. Funding for R & D on medicines and vaccines of particular relevance to developing countries is inadequate. Private enterprise will not undertake such research as a consequence of lack of perceived market incentives. Mechanisms to facilitate R & D on medicines and vaccines of particular relevance to developing countries should urgently be developed and put into operation.¹²

This study principally focuses on the third area of consensus: that is, that developing countries should take advantage of policy options available under the terms of the TRIPS Agreement to address public health needs.

The preliminary draft of this study was written prior to the WTO Doha Ministerial Conference. The study has been revised to take into account the adoption of the Doha Declaration on the TRIPS Agreement and Public Health. One aspect of the Doha Declaration concerned a future work program for the WTO Council for TRIPS ("TRIPS Council"). This study analyzes the subject matter of that work program, and makes certain recommendations.

⁶ See Gambardella, Alfano, Orsenigo, Luigi & Pammoli, Fabio 2000; Maskus 2000; OECD 2000, and; World Bank 2002.

⁷ See Barton 2001; Lanjouw 2001; Maskus 2000 & 2001; Scherer and Watal 2001, and; World Bank 2002.

⁸ See Abbott 2001, Correa 2000 & 2001, Fink 2001, Maskus 2001, Scherer and Watal 2001, WHO 1998-2001 and World Bank 2002.

⁹ Fink 2001, Maskus 2001 and Scherer and Watal 2001.

¹⁰ Barton 2001, Maskus 2001, Scherer and Watal 2001.

¹¹ Nagelkerke, N, et al. 2001; UNAIDS, Transnational Working Group, The Global Fund to Fight AIDS, Tuberculosis and Malaria (<http://www.GlobalFundATM.org/>), and; WHO Macroeconomics Commission, draft recommendations 2001.

¹² Correa 2001; Lanjouw 2001, and; Maskus 2001.

This study recommends that developing countries use the policy options of granting compulsory licensing and authorizing parallel trade. To improve the effectiveness of the compulsory licensing option, this study recommends that Article 31(f) of the TRIPS Agreement that limits exports of licensed products be deleted. If Article 31(f) is not deleted, a formal interpretation of Article 30 should be adopted to make clear that WTO Members may authorize an exception to the rights of patent holders to make and export medicines and vaccines to countries that need them.

The TRIPS Agreement should be amended to make its basic safeguard provision, Article 8:1, compatible with the safeguard provisions of the GATT 1994 and GATS, and allow acts inconsistent with the TRIPS Agreement necessary to protect public health. There is no valid reason why intellectual property should be accorded a higher level of protection in the WTO hierarchy of norms than goods and services, particularly since IPRs rules may be the most likely to have an adverse effect on public health.

Developing Members of the WTO should take particular care not to accept at face value the claims by pharmaceutical enterprise IPRs holders that the TRIPS Agreement requires the application of exceedingly restrictive rules regarding the marketing and sale of drugs. The TRIPS Agreement does not require harmonization at the most restrictive level of protection.

Developing Members may wish to consider revisiting the position many of them took during the GATT Uruguay Round negotiations: namely, that public health related inventions may be excluded from the scope of patent protection. This could be accomplished by amending Article 27:3(a) of the TRIPS Agreement.

While there is consensus that meeting the immediate public health needs of developing countries requires substantial subsidization, there is little present evidence that such subsidization will be forthcoming. This study examines the apparent impasse, and offers a few suggestions regarding how funding for purchases of medicines and R & D on diseases of relevance to developing countries might be improved. Nonetheless, present evidence strongly suggests that developing countries may need to rely on their own efforts and resources to deal with their public health needs, and increasing capacity to make and distribute generic medicines and vaccines may be their only and best way to accomplish this. This conclusion is highly relevant to an analysis of the TRIPS Agreement because it emphasizes the importance of assuring that the agreement does not inhibit the use of IPRs-related policy options.

II. The World Market for Pharmaceuticals, TRIPS, and Technology Rents

A. Patent Holder Concentration

The world pharmaceutical sector is divided among a small number of research-based producers based in a few OECD countries (hereinafter referred to as “Pharma”), and a fairly large number of generic drug manufacturers located in the OECD countries and in a number of developing countries.¹³ Pharma is concentrated in the United States, Japan, Switzerland,

¹³ See OECD 2000, stating:

“The pharmaceutical sector is a high-technology and knowledge-intensive industry. The industry has a two-tier structure. The largest firms account for the majority of the R & D investment in the industry and hold the majority of patents. A large number of smaller firms manufacture off-patent products or under license to a patent-holder.” at 7.

See, e.g., Lanjouw 1998 describing structure of Indian pharmaceutical sector. See USITC 1999, Table A-2, for China’s increased exports to the U.S. of bulk medicinal chemicals. Argentina and Brazil have substantial pharmaceutical industries.

Germany and the United Kingdom.¹⁴ Pharma and other research institutions based in the OECD hold the vast preponderance of patents on pharmaceutical products.¹⁵ U.S.-based inventors hold about 45% of these patents, and 18.5% are held by Japan-based inventors.¹⁶

B. Developing Country Markets

The TRIPS Agreement is structured such that pharmaceutical product patent protection will be mandatory for all developing countries as of January 1, 2005.¹⁷ As discussed later in this study, least developed countries have now been granted an extension until January 1, 2016 (from the previous deadline of January 1, 2006) to implement and enforce patent protection with respect to pharmaceutical products. At least for developing countries, under the “mailbox” provisions, patent protection will be provided following the transition period with respect to applications submitted during the period, and exclusive marketing rights will be available during the transition period.¹⁸ Although developing countries were entitled to take advantage of transition periods, largely as the result of pressure from OECD trade policy officials, many have already implemented pharmaceutical product patent protection.

Patents are used to restrict competition and sustain prices higher than would be available in a competitive market.¹⁹ On a static economic basis, the introduction of pharmaceutical patent protection in countries where such protection formerly was not available will (a) redirect production and sales from generic producers to on-patent producers (b) increase prices of pharmaceuticals to consumers, and (c) result in transfers of patent rents to OECD-based producers.²⁰ This is the explicit purpose of introducing patent protection. The introduction of generic versions of patented products is delayed, and trade in generic pharmaceuticals is reduced. The aggregate effects on developing countries might be calculated by examining price differentials between patented and off-patented versions of the same drugs, examining present rates of consumption and the ways in which demand patterns shift upon transition to reliance on patented drugs, examining the effects of reduced drug demand (resulting from higher prices) on various aspects of local health care systems, and a variety of other factors.²¹ While estimates of the overall effects of the TRIPS Agreement on

¹⁴ See Gambardella, Alfonso, Orsenigo, Luigi & Pammoli, Fabio 2000, at Tables 14-16.

¹⁵ *Id.*, at Table 16.

¹⁶ Indian inventors appear to hold less than .2% of pharmaceutical patents at the EPO, and about .5% at the USPTO. *See* Lanjouw 2000, at Table 3. Subsequent to entry into force of the Brazilian Industrial Property Act that provided for protection of pharmaceutical products, residents of Brazil have filed 2.6% of the pharmaceutical patent applications, U.S. applicants have filed 38% and German applicants have filed 11.5%. *See* Bermudez, et al., at 82.

¹⁷ Pharmaceutical process patent protection was required to be in place as of January 1, 2005.

¹⁸ *See* detailed discussion of TRIPS provisions *infra*.

¹⁹ *Accord*, World Bank 2002.

²⁰ *See* Fink 2001; Scherer and Watal 2001; Scherer 2000, and; Maskus 2001.

²¹ Maskus has noted that the present lack of data on factors such as elasticities of demand has so far made objective analysis of the aggregate impact of introducing pharmaceutical patent protection in developing countries difficult. Maskus 2000, at 160.

Fink’s modeling analysis of the effects of the TRIPS Agreement patent provisions in India illustrates the complex range of factors that influence the welfare effects of introducing patent protection. Regarding India, Fink’s general conclusion is:

“From the viewpoint of Indian consumers, the simulated welfare losses in this study were quite large – in part due to a loss of brand variety implied by the CES sub-subutility function. However, it needs to be emphasized that, as of 1993, the patented segment in India accounted for only 10.9% of the total sales values of the Top-500 pharmaceutical producers in India. Moreover, the Indian government will have some flexibility in restraining high prices by granting compulsory licenses and directly controlling prices – as long as these regulations are in compliance with the TRIPS Agreement.” Fink 2001, at 120.

developing countries have been made,²² there is yet to be a comprehensive systematic investigation of the overall effects in economic terms on developing country access to medicines and health care.²³

Access to essential medicines has been substantially inhibited by patent protection. The most striking evidence is from sub-Saharan Africa where prices of patented antiretroviral medicines (ARVs) were maintained at OECD levels until large scale international pressure forced Pharma to move toward approximating prices offered by generic producers in India and Brazil.²⁴ OECD-based pharmaceutical manufacturers have actively opposed introduction of generic ARVs in South Africa,²⁵ Kenya,²⁶ Uganda²⁷ and elsewhere.²⁸ The world political situation has most recently made it more difficult for Pharma to aggressively attack sub-Saharan African plans to market generic versions of HIV-related medicines, but current political circumstances are not an appropriate basis upon which to base multilateral trade and IPRs policy. Moreover, the political pressure pertaining to actions in sub-Saharan Africa does not necessarily pertain in other parts of the world. Reliance on voluntary restraint by Pharma is not an adequate basis upon which to analyze and frame TRIPS Agreement rules.

C. Patent Rents and R & D

To analyze the role of Pharma patents in developing countries it would be useful to be able to identify the extent to which Pharma profits derive from patent rents from these countries, whether from direct or indirect sales of patented pharmaceutical products, from patent licensing royalties and otherwise. If reasonably objective approximations of these profits at an aggregate level are publicly available, this author has not yet discovered the source.²⁹ Inquiries have been made to leading economists, and a request was made in the preliminary draft of this study for information that might be available among those participating in its review (including industry participants). For present purposes, the author

²² See Maskus 2000, at 181-91, and; World Bank 2002.

²³ A study of the results of the WHO Commission on Macroeconomics and Health does not indicate an overall number reflecting the potential results of TRIPS implementation. Bermudez notes that between the entry into force of Brazil's Industrial Property Act in 1996 and 1998, the negative balance of trade in pharmaceutical products in Brazil rose from negative \$417 million to negative \$1.018 billion. Bermudez et al., at 83.

²⁴ See WHO Medicines Strategy 2001, graph on reduction of prices over time (Advocacy, corporate responsiveness, & market forces have reduced anti-retroviral prices 95%) and Medecins Sans Frontieres, *A Matter of Life and Death: The Role of Patents in Access to Essential Medicines* (2001).

²⁵ This author, who serves from time to time as a WHO technical consultant to the Department of Health of the Republic of South Africa, advised the government in the course of the litigation initiated by 39 pharmaceutical companies against the government, and has consulted in the process of implementing medicines regulations following withdrawal of the litigation by the pharmaceutical companies. See further discussion of South Africa *infra*.

²⁶ Author's discussions with Kenya patent office officials.

²⁷ Author's interview with WHO Essential Medicines personnel responsible for Uganda.

²⁸ See e.g., Susannah Markandya, *Timeline of disputes over pharmaceutical patent protection in the Dominican Republic*, July 23, 2001 and *Timeline for trade disputes involving Thailand*, July 23, 2001 (<http://cptech.org>), and M. Petersen with J. Rich, *Roche Asks for Meeting With Brazil Health Minister*, NY TIMES, Aug. 24, 2001. See also, Raymond Li, *Firms may be allowed to copy Aids drugs*, SOUTH CHINA MORNING POST, Nov. 2, 2001, at 10, suggesting that Chinese health officials will soon initiate discussions with patent holders seeking sharp price reductions, with potential for compulsory licensing as alternative.

²⁹ When this author was attempting to analyze the potential economic impact of the TRIPS Agreement in the 1980s, he was surprised by the absence of reasonably reliable data or projections by economists, and (as here) assumed that someone must have developed projections even if he could not find them. As it happens, even today, the aggregate impact of the TRIPS Agreement on rent flows remains an uncertain and somewhat controversial enterprise, though not from the absence of best efforts. See generally KEITH MASKUS, INTELLECTUAL PROPERTY RIGHTS IN THE GLOBAL ECONOMY 160 (IIE 2000).

assumes that hard aggregate data is either confidential or unassembled, and has made some informal calculations based on publicly available data to suggest some “order of magnitude” approximations.³⁰

Pharma appears to earn profits in the range of several billion dollars per year from its operations in and sales to developing countries. If those profits are in the range of \$5-7 billion, and half of those profits derive from sales of patent-protected products,³¹ Pharma may earn in the range of \$2.5 - \$3.5 billion from developing country patent-based operations. Pharma enterprises appear to spend one-third to one-half the amount of their net profits on R & D. This suggests that perhaps \$1.25 to \$1.75 billion per year in OECD research and development (R & D) expenditures might be at risk on an aggregate worldwide basis if profits based on patent protection in developing countries were foregone. All profits would obviously not be lost if patent protection were foregone, and it seems reasonable to conclude that less than \$1 billion per year in OECD R & D might be affected by the loss of patent protection in developing countries.

Available data raises questions regarding Pharma’s contention that lower standards of patent protection in developing countries will impede the “research mission” of its members. It seems unlikely that a shortfall of less than one billion dollars in R & D finding would undermine the basic mission of an industry with an aggregate market size of \$337.2 billion in 1999,³² and OECD company R & D expenditures of ECU 22 billion in 1995.³³

A concern expressed by Pharma is that exports of drugs by developing countries to OECD markets would seriously affect Pharma’s profitability, research mission, and so forth. This concern might be more realistic than concern over loss of profits within developing country markets. However, OECD patent laws generally prevent the importation of drugs produced without the consent of patent holders. If developing country generic producers that are not operated by Pharma seek to export to OECD markets, the firms are able to block imports of those drugs under existing patent legislation.

D. Dynamic Offsets

The dynamic effects of introducing patent protection on pharmaceutical products are difficult to predict. There is no substantial evidence to suggest that introduction of patent protection will result in a substantial increase in pharmaceutical product R & D in the developing countries.³⁴ Assuming that there is some dynamic movement to researched-based industries in the developing countries,³⁵ it is highly unlikely that for the foreseeable future the

³⁰ Data from SEC filings was extrapolated and examined in light of government import-export data. The methodology for this extrapolation is set forth in Annex 1 to this paper. The main suggestion of the approximation is that profits from developing country sales of patented pharmaceuticals are not in the tens of billion range, but are in the billions.

³¹ The other half being returns on sales of non-prescription and more widely used drugs, such as common pain relievers.

³² Gambardella, et al., at Table 1.

³³ *Id.*, Table 5.

³⁴ See Lanjouw 2000. Bermudez, et al., (regarding Brazil) and Supakankunti, et al. (regarding Thailand) observe that an increase in foreign ownership of local manufacturing facilities does not result in an appreciable increase in local R & D, but rather increasing returns for R & D conducted in the OECD. See World Bank 2002.

³⁵ Fink 2001 and Lanjouw 1999 note the possibility of some increase in local pharmaceutical invention in India, but each cautions that this is largely a matter of speculation.

rents accruing to local developing country pharmaceutical companies will offset the increased rents flowing to OECD-based companies.³⁶

E. OECD Effects

Pharma's most serious concern appears to be that consumers in OECD markets will rebel against paying high prices for patented pharmaceuticals if they are aware that developing country consumers pay substantially less for the same products. Of course, it has long been the case that OECD consumers effectively subsidize R & D on medicines and vaccines sold and used in developing countries. Up until now that has not been a problem. Presumably, OECD consumers that were aware of price differentials attributed this to differences in standards of living and purchasing power, and did not regard it as troubling that distinctions between rich and poor markets were made.

The social disruption caused by the TRIPS Agreement in developing countries has widely publicized the effects of patents on price, and the means by which consumers support Pharma R & D. The reaction by Pharma so far has been to insist on maintaining the position initially staked out in the TRIPS Agreement, regardless of evidence that the effects may be counterproductive to developing country consumers and to the industry itself. It is not beyond peradventure that Pharma could elect to change tactics and instead focus public relations efforts on why there may be price differences between developed and developing country markets, and why OECD consumers should continue to subsidize globally useful pharmaceutical R & D.

Increasing emphasis on publicly supported research in the OECD might be effective in generating new medicines and vaccines, thereby reducing the importance of protecting Pharma profits to support R & D. Many of the new chemical entities marketed by Pharma are initially discovered in university or hospital research laboratories operating with substantial government funding. This is evident in the United States.³⁷ The European Commission-backed study of EU competitiveness in the pharmaceutical sector attributes much of the success of the U.S.-based pharmaceutical companies to close cooperation between the federal government, public institutions such as university research laboratories, and the private sector.³⁸ Since much of today's research is performed at universities and in research hospitals under government subsidy, what is mainly at issue is the mix of research mechanisms. The clinical trial sub-industry may still be employed by additional public research entities. However, assuming that Pharma will continue to serve its current role in the OECD, it is a matter for that industry to educate the public regarding the necessity for paying higher prices to fund R & D.

³⁶ See Scherer and Watal 2001. At a recent international conference, the former head of Canada's competition authority advised that spending on pharmaceutical industry R & D in that country has increased only regarding clinical trials, and not basic research, following amendment of its patent law to eliminate permissive compulsory licensing. Remarks of Lawson Hunter, President of IBA Committee on Antitrust and Trade Regulation and Panel Chair, at International Bar Association Conference, Cancun, Mexico, Nov. 1, 2001, panel on international protection and enforcement of industrial property rights. Industry has pointed to Canada for evidence that higher levels of patent protection result in increased R & D (see IFPMA, *TRIPS, Pharmaceuticals and Developing Countries: Implications for Health Care Access, Drug Quality and Drug Development* (2000), at 9), even though Canada had in fact reached agreement with industry that R & D funding would be increased in exchange for amendment of its legislation.

³⁷ See NIH and Gambardella, et al.

³⁸ Gambardella, et al.

It may indeed be a paradox of the TRIPS Agreement process that its imposition on developing countries to extract patent rents generates a backlash against pharmaceutical patent protection in the OECD.

F. Infrastructure and Non-Patenting

Pharma spokespersons frequently suggest that patents are not impeding access to medicines in developing and least developed countries, and that the principal impediments to access are in the area of health care infrastructure and medical personnel. Public health and IPRs experts have not questioned the importance of improved infrastructure, personnel recruitment and training, and related factors in addressing disease burdens.³⁹ However, the fact that there are important additional considerations in effectively addressing disease does not diminish the importance of addressing the fundamental element of pharmaceutical costs. Most patented products are dependent for their usefulness on additional elements of infrastructure.⁴⁰ The price of medicines directly affects the ability of prospective consumers to obtain them, and this is especially true in the case of life-saving medicines for which demand is highly price elastic among poorer populations (in the sense that lowering prices substantially enhances effective demand).⁴¹

Pharma has also suggested that because potentially patentable medicines have not always been patented in certain African countries, this demonstrates that patenting is not a significant obstacle to access.⁴² Yet inventing enterprises have always patented selectively, strategically targeting those countries with the greatest sales potential, and those countries where they are most likely to confront competitive production capacity and other commercial threats.⁴³ The patenting pattern in Africa represents strategic planning that was deemed appropriate by Pharma in its specific time-frame, emphasizing South Africa as the principal potential source of competitive production, and countries such as Kenya, Nigeria and Zimbabwe as markets with comparatively high income. Major new commercial threats from generic producers in Brazil and India form the backdrop of Pharma's aggressive efforts toward accelerated implementation of the TRIPS Agreement.

II. The TRIPS Agreement

A. The Doha Declaration

The WTO Council for TRIPS held sessions in June and September 2001 specifically devoted to issues concerning access to medicines. A substantial group of developing countries submitted a detailed proposal for a Declaration on TRIPS and Public Health to be adopted at the Doha Ministerial.⁴⁴ The United States and a small group of like-minded countries submitted an alternate proposal. Following extensive negotiations based on a compromise text prepared by the WTO Secretariat, Ministers in Doha adopted a Declaration on the TRIPS Agreement and Public Health.⁴⁵

³⁹ See, e.g., WHO Medicines Strategy 2000-2003, at chpt. 5.

⁴⁰ See Abbott, *The Economics of Public Health*, Annex A to 2001 QUNO paper.

⁴¹ *Id.*

⁴² This argument first surfaced in a report by IPI that was referenced in the South Africa pharmaceuticals litigation. International Intellectual Property Institute, *Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa* (2000).

⁴³ See, e.g., EC Commission, *Green Paper on the Community patent and the patent system in Europe* (June 1997), noting high concentration of patent designations for major market countries.

⁴⁴ Issues raised by developing countries in regard to the TRIPS Agreement and access to medicines were identified and analyzed in Abbott, QUNO Occasional Paper 7, *supra* * note.

⁴⁵ WT/MIN(01)/DEC/2.

The Doha Declaration on the TRIPS Agreement and Public Health is comprised of 7 paragraphs. Three of these are preambular, and indicate the importance that WTO Members ascribe to effectively addressing public health concerns, especially epidemic disease. The fourth paragraph includes a strong decision in support of Member's rights to take measures to protect public health and provide affordable access to medicines. The fifth paragraph clarifies provisions on compulsory licensing and exhaustion of IPRs. It affirms, *inter alia*, that the TRIPS Agreement does not limit the grounds on which Members may grant compulsory licenses, that each Member has discretion to determine the existence of a public health emergency, and that the TRIPS Agreement permits each Member to adopt its own policies and rules regarding the exhaustion of IPRs and parallel trade. The sixth paragraph places the issue of compulsory licensing for export on the agenda of the TRIPS Council, requiring that a proposal be furnished to the General Council by the end of 2002. The seventh paragraph extends until 1 January 2016, the transition period for least developed Members to provide or enforce pharmaceutical product patent protection.

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

“4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.”

Paragraph 4 is stated in terms of an agreement among WTO Ministers acting on behalf of Members. This agreement is most reasonably considered a “decision” of WTO Members under Article IX:1 of the WTO Agreement.⁴⁶ This decision of WTO Members would appear to constitute an agreement on the method of application of the agreement within the meaning of Article 31(3)(a) of the Vienna Convention on the Law of Treaties (“VCLT”), and to be the substantive equivalent of an interpretation of the TRIPS Agreement.

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

Notwithstanding the political and legal success it represents for developing WTO Members, the Doha Declaration did not address and resolve many of the significant obstacles the TRIPS Agreement creates regarding access to medicines and vaccines. The following part of this study examines the provisions of the TRIPS Agreement and, where relevant, discusses the impact of the Doha Declaration.

B. Changing Circumstances

1. Present situation

⁴⁶ Article IX:1 of the WTO Agreement provides in relevant part.

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

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. 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.

Absent extension, least developed Members had until January 1, 2006 to provide patent protection. As a consequence of the Doha Declaration, the transition period will be extended regarding pharmaceutical products until January 1, 2016.

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 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 Brazil⁴⁷) or are not yet patentable (*e.g.*, in the case of India⁴⁸). 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 and India because there is no TRIPS-mandated export or import restriction, unless exclusive marketing rights under Article 70:9 are granted.

2. Developing countries in 2005

A substantial change to the TRIPS-imposed legal conditions in developing countries (excluding the least developed) will occur on January 1, 2005. On that date, 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. Also on January 1, 2005, “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.⁴⁹

Just as Brazil, 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

⁴⁷ 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.

⁴⁸ 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.

⁴⁹ 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.

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.

3. Extension of LDC transition period

The Doha Declaration at paragraph 7 directed the TRIPS Council to authorize the extension until January 1, 2016 of the transition period for least developed Members (hereinafter “LDCs”) to implement or enforce pharmaceutical patent protection. The terms of this extension are somewhat ambiguous in that it is not clear from the express text whether LDCs are required to implement mailbox and exclusive marketing rights provisions prior to the end of the transition deadline.⁵⁰ There is some indication that paragraph 7 was understood by negotiators in Doha not to require that mailbox and exclusive marketing rights requirements be implemented or enforced.

If an LDC is required to implement mailbox protection, it must establish a procedure under which it will accept for filing pharmaceutical product patent applications filed abroad. Until the LDC establishes patent protection, the patent application remains dormant. However, during the period of dormancy, the LDC is required to grant exclusive marketing rights to the patent holder for a maximum period of five years following marketing approval of its drug.⁵¹ For almost all intents and purposes, the grant of exclusive marketing rights will be as effective as granting a patent in preventing generic drugs from entering the LDC market. Beyond that, however, when the dormancy period of the mailbox application ends, the drug covered by the application will be patented (assuming it meets relevant criteria). An entire “pool” of drugs that may be generic in an LDC during the mailbox transition period will come under patent at the end of the period. If, however, there is no mailbox system in place, holders of patents outside the LDC will not be able to obtain patents after the transition period has ended because the inventions covered by the patents will no longer be novel in the

⁵⁰ The express text of paragraph 7, second sentence, exempts LDCs from the obligation to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement, and the obligation to enforce rights provided for under those sections. By its express terms, paragraph 7, second sentence, does not address obligations under Article 70:8 and 70:9 of Part VII of the Agreement. In the absence of some contrary understanding reached at Doha, Article 70:8 would appear to continue to apply, and require least developed Members to maintain “mailbox” application mechanisms that allow for the receipt and retention of pharmaceutical patent applications until coverage is provided under local law. Pharmaceutical patent applications received before January 1, 2016 would have priority dates preserved and be reviewed under patentability criteria as of the priority dates. Patent protection would be available for the remainder of the patent term counted from the priority date.

Absent a contrary understanding reached at Doha, Article 70:9 also appears to apply. If so, exclusive marketing rights should be granted to the patent applicant for a maximum period of five years following marketing approval of the pharmaceutical product in the least developed country, provided that a pharmaceutical patent has been granted and marketing approval has been obtained by the patent applicant in another Member. A pharmaceutical patent applicant with exclusive marketing rights in a least developed Member has the effective equivalent of patent rights because, while it may not have exclusive rights to make or import the covered drugs, it presumptively will be able to prevent the marketing of generic equivalents, and it may thereby control the local market.⁵¹ Exclusive marketing rights may be even more burdensome to LDCs than patents if they are understood not to be subject to the same exceptions (*e.g.*, Article 30, TRIPS Agreement) to which patents are subject, or to compulsory licensing (Article 31, TRIPS Agreement).

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

⁵¹ Provided also that a patent has been granted and marketing approval obtained in another WTO Member.

patenting sense. Thus, if there is no mailbox system in place, drugs that are generic (off-patent) during the transition period will remain generic after the transition period ends.

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

In a limited set of circumstances, the transition period extension in favor of LDCs will allow them additional access to generic medicines. This is when a medicine is off patent in a developing Member such as India (and may be exported), but prior to the extension would be on patent in the LDC. The transition period extension relieves the LDC from the obligation to enforce local patents, so the LDC will be able to import the drug for so long as it remains off-patent in India.⁵² For drugs that go on-patent in India (and other developing Members) after January 1, 2005, either because applications filed during mailbox period are converted to patents, or because of newly-filed applications, no relief will be provided for LDCs that otherwise wish to import drugs. Those drugs will be on-patent in the country of export and more expensive.

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

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

Also, paragraph 7 of the Doha Declaration is somewhat ambiguous regarding whether LDCs are relieved from implementing and enforcing pharmaceutical process patent protection during the extended transition period.⁵³ If LDCs are not so relieved, then under

⁵² There is an additional complication in that the drug in India may be subject to exclusive marketing rights, and it is not clear whether such rights would entitle the mailbox application holder to block exportation as well as local supply.

⁵³ The relevant part of paragraph 7 reads:

“We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016...”

This language might be construed to cover pharmaceutical process patents if those patents are considered issued with respect to pharmaceutical products, such that the exemption from implementing or enforcing patent

TRIPS Agreement Article 66:1, pharmaceutical process patent coverage must be implemented by January 1, 2006. This may limit the capacity of LDCs to initiate production. In giving effect to paragraph 7, the TRIPS Council should clarify that it extends to pharmaceutical process patents.

C. Compulsory Licensing

Compulsory licensing has long been recognized as the most important tool for addressing the adverse effects of the patent grant on public welfare.⁵⁴ Exploiting compulsory licensing may involve the actual grant and implementation of a license. It may also involve the threat of a license that results in a patent holder revising its own pricing or supply strategy.

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.

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

1. Capacity to exploit

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

- There must be a party within the country granting the license that is able to exploit it, either by manufacturing the subject invention or importing it. This requires, *inter alia*, technical expertise and financial capital;
- If local manufacturing is to be undertaken, there must be sufficient purchasing power among the population to justify investments undertaken by the party exploiting the license (or export opportunities must be available). If the local population is small and/or poor, there may not be a consumer base adequate to provide an adequate return on investment;
- The government may act as the party exploiting the compulsory license (e.g., for government use), and/or it may act as purchasing agent on behalf of the

protection with respect to pharmaceutical products is considered to encompass processes involved in their making. The patent “rights provided for” in Article 28:1(b) of Section 5, Part II of the TRIPS Agreement are rights in respect to process patents, and those may be construed to be related to the subject matter of “pharmaceutical products”.

⁵⁴ See EDITH TILTON PENROSE, THE ECONOMICS OF THE INTERNATIONAL PATENT SYSTEM, Ch. XI (1951: Johns Hopkins Press)

population acquiring the exploited invention. In either case, the government will require technical expertise and financial resources.

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

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

2. Need to exploit

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

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

- The price of goods is a more significant determinant of market demand in low-income countries because consumers have fewer resources to allocate among goods. Compulsory licensing is an instrument for obtaining lower prices on goods protected by patent.
- Although countries are at substantially different stages of technology capacity development, in general there is a wide disparity between the research and development capacities of developing and developed countries. The vast preponderance of patented technology is owned and controlled by enterprises based in developed countries. Developing countries on the whole are in a position of reliance on technological development in the developed countries, and are in the position of systemic net payers for technology. For a variety of reasons, the technology needs of developing countries often may not be met by acquisition of technology licenses on voluntary terms. Compulsory licensing provides a means for developing countries to obtain technology necessary for development and social welfare.
- A weak industrial base implies dependence on imports for goods. Suppliers based outside the territory of a country are less sensitive than local suppliers to internal economic and political pressures to provide goods at prices affordable within the country.

3. The pharmaceutical sector

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

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

“At the other end of the pharmaceuticals market, a relatively small number of firms have limited monopolies (limited in time and subject to therapeutic competition) for complex drugs (such as anti-retrovirals), available only on prescription. This sub-market is characterised by information problems, and legal barriers to entry posed by patent protection. Here price is commonly several times the marginal cost of production, particularly in the early years of patent life. Profits generated under patent protection are a reward for risk-taking and innovation - in the form of research and development expenditures - by the patent-holding company.

“Competition is perhaps the most powerful policy instrument to bring down drug prices for off-patent drugs. In the United States, when a patent expires the average wholesale price falls to 60% of the branded drug’s price when there is just one generic competitor, and to 29% with 10 competitors. The concept of marginal cost is important because it reveals the value of resources used in making a product. In a competitive environment, marginal cost is close to the market price of the product. However, determining marginal cost is difficult. So other approaches to determining a price for a particular drug, including using the price of unpatented therapeutic equivalent drugs, and pharmacoeconomic analysis, have been proposed. With price at, or close to marginal costs, some essential drugs may still remain unaffordable to poor people. In these instances additional international financing should be considered.” [footnotes omitted]⁵⁵

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

4. Post transition period

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, 2016. 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

⁵⁵ Working paper by Andrew Creese and Jonathan Quick, *Differential Pricing Arrangements and Feasibility: Context Setting Paper*, World Health Organization, 21 Jan. 2001.

otherwise restricted or threatened, relief will be sought through the issuance of compulsory licenses.⁵⁶

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

5. A multi-dimensional problem set

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

To date, developing countries have made limited use of compulsory licensing as a tool to address public health issues.⁵⁷ This stems from a number of causes: (1) the TRIPS Agreement has only recently begun to increase the incidence of patent protection; (2) use has been opposed by developed country WTO Members and interested industry groups within them, and a strong political commitment to act in the face of this opposition is required; (3) some developing countries have expressed concern regarding a potential backlash from foreign direct investors; (4) developing country enterprises may find it easier to reach accommodation with foreign patent holders than to challenge them through the compulsory licensing process for various economic and administrative reasons and, as noted earlier; (5) effectively implementing compulsory licensing requires that certain preconditions relating to administrative, financial and technical capacity be met, and these conditions are often not met in developing countries.

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

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

⁵⁶ At the outset of this discussion, parallel importation as 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.

⁵⁷ See Abbott, QUNO Occasional Paper 7, *supra* * note.

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

6. Article 31(f)

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

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

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

The word “predominantly” would generally appear to refer to the major part or majority,⁵⁸ and would generally suggest that more than fifty percent of the production by a compulsory licensee should be intended for supply of the domestic market of the Member granting the license.

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

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

1. By restricting the availability of export drugs made under compulsory license, it limits countries that are not in a position to support manufacturing under compulsory license (or where patent protection is not in force) in the availability of supply of generic import drugs, and;
2. By requiring compulsory licensees to supply a predominant part of their production to the domestic market, it limits the flexibility of countries to authorize the export of compulsory-licensed drugs and thereby to exploit economies of scale.

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

The demand side problem is self-evident. If a developing Member lacks manufacturing capacity for a particular drug, and there are no Members that are able to

⁵⁸ “Predominant” is defined as an adjective as: “(1) Having supremacy or ascendancy over others; predominating. (2) Constituting the main or strongest element; prevailing. (3) Rising high over.” NEW SHORTER OXFORD DICTIONARY, at 2329.

supply it by export under compulsory license (or exception), there may be no affordable supply of the drug.

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

a. Implementation by importation

Neither Article 31 in general, nor Article 31(f) in particular, state or imply that a compulsory licensee must produce the invention within the territory of the Member granting the license. Under Article 31, a compulsory licensee may import products in the implementation of its license.⁵⁹

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

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

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

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

The patent holder in the country of export may consent to the exportation, perhaps because that patent holder is different than the patent holder in the country of import.⁶⁰ There would be no infringement in either country if the importer also acted under compulsory license.

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

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

c. Potential infringement in the country of export

⁵⁹ Imports into country A might be exported to country B. A compulsory licensee that imported to implement the license, but exported a predominant part of the imports, would be acting inconsistently with Article 31(f).

⁶⁰ The patent holder may be the same in both Members, and in theory it might consent to export to the Member that has issued the compulsory license regarding its own patent. It is difficult to foresee the circumstances in which this might occur.

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

From the standpoint of TRIPS Agreement obligation, the issuance of a compulsory license in the country of import does not constitute non-compliance with TRIPS obligations, even if prospective imported products are under patent in a country of export.⁶¹ If exports originate in another Member in a manner inconsistent with the exporting country’s obligations under Article 28 of the TRIPS Agreement, it is the obligation of the exporting country to take steps in regard to its obligations.

7. Article 31-based solutions

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

a. Parallel compulsory licensing

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

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

1. A request for issuance of a parallel compulsory license might be triggered by a request from a country that had previously issued a compulsory license.
2. If the license request is based on a national emergency in the importing country, that might result in the prompt issuance of the parallel license to fulfill import requirements without negotiations with the patent holder, with compensation in the exporting country presumptively based on established guidelines.

⁶¹ In the U.S. paper submitted to the TRIPS Council in advance of the Doha Ministerial, there is some suggestion of liability on the part of the importing Member, though the reasons for this are not clear. 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.

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

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

(a) As noted in a prior report, the concept of “comity” provides a basis for one WTO Member to recognize the grounds of grant of a compulsory license in another Member as the basis for its own grant of a parallel license.⁶² The determination of the first Member would not be “binding” on the second Member, but would rather provide the basis for voluntary recognition.

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

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

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

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

b. Regional market arrangements

One important potential solution to the Article 31(f) problem is the creation of integrated regional patent regimes that would allow for the grant of regional compulsory licenses. The European Union is a regional organization Member of the WTO and would presumably be entitled to consider its member states to constitute a single domestic market from the standpoint of Article 31(f). Although neither the European Patent Convention (in force, though not a Union legal instrument) nor the Community Patent Convention (not in force), provide for the grant of a Union-wide compulsory license, it is difficult to see an objection as a matter of legal principle to such a mechanism.⁶³

⁶² See Abbott, QUNO Occasional Paper 7, *supra* * note.

⁶³ The individual EU member states may be resistant to recognizing a right of one member state to grant a license that is effective for all EU markets. That is, however, a political issue.

The WTO legal instruments foresee and allow the formation of customs unions and free trade areas (GATT Article XXIV), and regional services arrangements (GATS Article V). The WTO legal instruments do not generally impose restrictions on the capacity of such arrangements to jointly adopt and implement regional legislation.⁶⁴ It would not appear necessary for such an arrangement to be a Member of the WTO (as is the European Union) in order to be considered a single domestic market in the sense of Article 31(f) of the TRIPS Agreement. The EU, it should be recalled, was traditionally considered a Contracting Party to the GATT 1947 even though not formally a party to the agreement.

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

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

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

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

Under existing GATT rules, foreign trade zones have been tolerated as areas within the territory of a Member that are considered outside the customs territory of the Member for tariff assessment purposes,⁶⁵ with the consequence that goods may be imported into and worked upon in the zone without being subject to the payment of customs duties. In the United States, for example, the foreign trade zone (FTZ) concept is used quite extensively.⁶⁶ Imported goods may be brought into an FTZ, worked into a product in a different tariff classification, and exported with no tariff consequences, or imported into the U.S. at the lowest applicable tariff rate. The FTZ is within the physical geographic boundaries of the United States. From the standpoint of non-application of tariffs, the FTZ is a legal fiction.⁶⁷

⁶⁴ Article 4(d) of the TRIPS Agreement requires that intellectual property rights related privileges be granted on a most favored nation (MFN) basis. The creation of a regional patent arrangement should generally comply with MFN requirements; that is, be non-discriminatory. Allowing for the grant of region-wide compulsory licenses would not appear to be discriminatory *vis-à-vis* Members not party to the arrangement, but the MFN requirement is noted here for the sake of completeness.

⁶⁵ From a GATT 1994 standpoint, the legal fiction of the FTZ is presumably justified on the basis that goods in the FTZ are part of “traffic in transit” within the meaning of GATT Article V:1. However, to the extent that goods are worked within the FTZ, this pushes the limits of the “in transit” concept. FTZs may also in some cases provide exemption from certain tax obligations, but that aspect is not considered here. See note 68 *infra* as to subsidy aspects.

⁶⁶ See 19 USC § 81a, et seq. , and US International Trade Administration, Foreign Trade Zones (June 2000), <http://ia.ita.doc.gov/ftzpage/tic.html>, visited January 9, 2002.

⁶⁷ Although at early stages a U.S. manufacturer needed to be located within a particular geographic area in order to qualify for FTZ treatment, in later stages the law provides for subzones that may be established for individual company manufacturing sites where specifically approved.

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

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

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

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

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

A key issue regarding the concept of the PPEZ is whether the legal fiction may be established without reliance on Article 30 (discussed in the Section VIII), or the adoption of a waiver. The principal grounds for suggesting that neither an Article 30 exception nor a waiver may be required is that FTZs are in use by WTO Members to authorize importing, working and exporting goods without payment of tariffs, and this common practice is accepted among Members. By operating FTZs, WTO Members provide preferential tariff treatment to certain manufactured goods, namely those destined for export markets. This acts as a subsidy of exports (reducing the cost of exports by the extent of the waived customs duties). It may also result in differential treatment of imports and exports of like products, and constitute derogation from MFN tariff obligations. WTO Members may at least implicitly have removed certain duty drawback or remission schemes (including those manifested in FTZs) from challenge as export subsidies by reference in Annexes to the Subsidies Agreement.⁶⁸ If this is so, it may be more the result of recognition of the need to tolerate a widely used practice than a neutral policy determination that such schemes do not constitute export subsidies. Members might, by the

⁶⁸ The Agreement on Subsidies and Countervailing Measures appears to assume that a duty drawback or remission scheme that does not provide for remissions or drawbacks of charges in excess of those paid on inputs consumed (including incorporated) in the exported product will not be considered to have benefited from a subsidy. *See* Subsidies Agreement, Annex 1(i) and Annex II. For a recent analysis of export subsidization in the tax treatment context, *see* United States – Tax Treatment For “Foreign Sales Corporations”, AB-1999-9, WT/DS108/AB/R, 24 Feb. 2000, and; United States Tax Legislation (DISC), Report of the Panel presented to the Council of Representatives on 12 November 1976, (L/4422 - 23S/98).

same token, decide that PPEZs should be tolerated even if to do so requires the acceptance of a legal fiction.

d. Anticompetitive practices remediation

Article 31(k) of the TRIPS Agreement⁶⁹ exempts compulsory licenses issued to remedy anticompetitive practices from the Article 31(f) requirement. A WTO Member that determined the existence of anticompetitive conduct on the part of a patent-holding pharmaceutical company might well grant one or more licenses regarding that company's patents that could be used to supply the markets of any number of developing Members. Whether the grant of a parallel compulsory license would be required in importing Members would depend on the presence or absence of local patent protection, and the rule of international exhaustion followed in the importing Member. The latter issue is discussed in Section XII of this study.

Since major research-based pharmaceutical companies have recently been found by OECD country authorities to have engaged in systematic anticompetitive conduct,⁷⁰ there is reason for developing countries to explore joint investigation into the business practices of these companies.

e. Article 31(f) conclusion

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

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

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

The restrictions imposed by Article 31(f) will limit the available supply of generic drugs for developing countries, a condition that will be increasingly problematic, as developing countries are required to implement pharmaceutical patent protection in 2005.

⁶⁹ Article 31(k) reads in part: "Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive."

⁷⁰ See, e.g., remedial measures regarding the vitamin price-fixing conspiracy, referenced in Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements, Prepared Testimony of James M. Griffin Deputy Assistant Attorney General Antitrust Division, Before the Senate Judiciary Committee, FED. NEWS SERV., May 24, 2001.

Interpreting the express text of Article 31(f) in a way that relaxes its restrictions presents serious difficulties. Alternative approaches should be considered.

8. Article 30-based solutions

Authorization of the export of public health related inventions without the consent of the patent holder is not dependent on Article 31(f). Article 30 of the TRIPS Agreement expressly authorizes Members to provide limited exceptions to patent rights under certain conditions. Members should be able to authorize exports of products under patent in their territories as an exception to the rights of patent holders when local producers are able to provide low price products, and when such products are needed by importing Members. Use of the Article 30 exception for exports would be most consistent with implementing the TRIPS Agreement in a manner supporting public health and promoting access to medicines for all as decided by Ministers in paragraph 4 of the Doha Declaration.

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

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

a. Interpretation of express text

Article 30 of the TRIPS Agreement provides:

“Exceptions to Rights Conferred

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

The express text of Article 30 establishes three basic criteria for establishing exceptions to the Article 28 enumerated rights of patent holders.⁷¹

⁷¹ In this subsection, I have deliberately avoided reference to decisions by WTO panels since the decision of panels do not restrict interpretations by the Ministerial Conference, General Council, and Members not party to a particular dispute. However, the Canada-Generics panel report is discussed *infra*.

i. “Limited exceptions”

Article 30 of the TRIPS Agreement states that Members may provide “limited exceptions to the exclusive rights conferred by a patent”. The common meaning of “limited” is that the subject matter is bounded by constraints.⁷² Standing alone, the term “limited” does not indicate that the established boundaries should be narrow. Subject matter that is “limited” is differentiated from subject matter that is “unlimited”, or not subject to boundaries.

An “exception” is a deviation or derogation from a rule or principle.⁷³ As with the term “limited”, the term “exception” standing alone does not connote a particular degree. Exceptions to rules may be infrequent and minor, or they may be frequent and substantial.

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

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

ii. “provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent”

The term “unreasonably” is flexible.⁷⁴ The term combines the root “reasonable”, with the prefix “un”. Something that is “reasonable” appeals to logic or is equitable. Something that is “un-reasonable” does not appeal to logic, or is inequitable. A party or subject matter acts “unreasonably” if it acts in a way that does not appeal to logic, or inequitably.

“Conflict” means to stand in opposition.⁷⁵

“Normal” means to be within the generally accepted parameters of conduct.⁷⁶

“Exploitation” means use.⁷⁷

⁷² “Limited” as an adjective is defined as “(1) Appointed, fixed. (2) Confined within definite limits; restricted in scope, extent, amount, etc.; (of an amount or number) small; (of an income) low; (of monarchy, government, etc.) exercised under limitations of power prescribed by a constitution.” NEW SHORTER OXFORD DICTIONARY, at 1592.

⁷³ “Exception” is defined as a noun as “(1) The action of excepting someone or something from a group, the scope of a proposition, etc.; the state or fact of being so excepted.” “Except” is defined as a verb as “(1) Specify as not included in a category or group; exclude (from).” *Id.*, at 872.

⁷⁴ “Unreasonable” is defined as an adjective as “(1) Not endowed with reason; irrational. (2) Not based on or acting in accordance with reason or good sense. (3) Going beyond what is reasonable or equitable; excessive.” *Id.*, at 3503. “Reason” as a noun is defined as “(1) The mental faculty (usually regarding as characteristic of humankind, but sometimes also attributed in a certain degree to animals) which is used in adapting thought or action to some end; the guiding principle of the human mind in the process of thinking.” *Id.*, at 2495.

⁷⁵ “Conflict” as a verb is defined as “(1) Fight, struggle (with). (2) Engage in battle, assault. (3) Of principles, interests, etc.: clash, be incompatible.” *Id.*, at 476.

⁷⁶ “Normal” is defined as an adjective as “(3) Constituting or conforming to a type or standard; regular, usual, typical; ordinary, conventional. Also, physically or mentally sound, healthy.” *Id.*, at 1940.

⁷⁷ “Exploitation” is defined as a noun as “The action or practice of exploiting something or someone.” *Id.*, at 889. “Exploit” is defined as a verb as “(1) Accomplish, achieve, perform” and “(4) ... utilize for one’s own ends, take advantage of, (a person, esp. an employee, etc.).” *Id.*, at 888.

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

- iii. “and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties”

“Unreasonably” is defined above.

“Prejudice” means to act adversely in relation to the subject matter.⁷⁸

“Legitimate” means within the expectations of law or social custom.⁷⁹

“Interests” refer to that which a party considers themselves affected by, or in some circumstances to that which a person is entitled.⁸⁰

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

“Third parties” are those persons or enterprises that are not directly part of the referenced relation.⁸¹

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

iv. The significance of footnote 7

Footnote 7 to Article 31 of the TRIPS Agreement states that “‘Other use’ refers to use other than that allowed under Article 30.”

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

Article 31 sets forth relatively detailed steps regarding the granting and administration of compulsory licenses, including a requirement that adequate remuneration in the circumstances of the case is paid, and that a predominant part of licensed products be for the

⁷⁸ “Prejudice” is defined as a verb as “(1) Affect adversely or unfavourably; injure or impair the validity of (a right, claim, etc. b. injure materially; damage.” *Id.*, at 2333.

⁷⁹ “Legitimate” is defined as adjective as “(2a) Conformable to, sanctioned or authorized by, law or principle; lawful, justifiable, proper. b. Normal, regular; conformable to a recognized standard type; ... d. Sanctioned by the laws of reasoning; logically admissible or inferable.” *Id.*, at 1563.

⁸⁰ “Interest” is defined as a noun as “(1) The fact or relation of having a share or concern in, or a right to, something, esp. by law; a right or title, esp. to (a share in property or a use or benefit relating to property ... (2) A thing which is to the advantage of someone; a benefit, (an) advantage (3) The relation of being involved or concerned as regards potential detriment or (esp.) advantage.” *Id.*, at 1393.

⁸¹ “Third party” is defined as “(a) a party or person besides the two primarily concerned; (b) a bystander” *Id.*, at 3283.

supply of the local market. Article 30, by way of contrast, does not specify procedures for the authorizing of exceptions, does not address the issue of remuneration, and does not include geographic limitations.

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

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

b. Application of interpretation based on express text

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

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

i. Normal exploitation of the patent right

(a) Right to export

It must first be observed that a right to consent to “export” is not an enumerated right of patent holders under Article 28 of the TRIPS Agreement. There is an enumerated right of “import”, making evident that TRIPS negotiators considered the movement of patented articles in international trade. This author is not aware of national or regional patent laws that specifically enumerate a right of “export” (although the U.S. Patent Act addresses this subject indirectly).⁸²

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

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

(b) Higher income market conditions

A patent grant confers rights within the territory of the country granting the patent. The patent serves several purposes from the standpoint of the patent holder. It precludes

⁸² See 19 USC §271(f), as discussed in Abbott, QUNO Occasional Paper 7, *supra* * note.

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

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

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

(c) Lower income market conditions

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

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

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

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

(d) Developing country requirements as criteria

Recall that paragraph 4 of the Doha Declaration states:

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

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

The appropriate base criterion for an Article 30 exception is whether it would address a legitimate need in the importing country, not whether there is manufacturing capacity in that country, or whether it would be desirable to create manufacturing capacity in that country.

This suggests criteria such as:

1. Whether the importing country is confronting an unaddressed health need;
2. Whether the importing country has the financial resources to pay for on-patent drugs or other public health related inventions, whether locally produced or imported, to supply the needs of “all” those in need of treatment;
3. Whether the exporting country has the capacity to supply low-price pharmaceuticals or other public health related inventions.

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

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

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

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

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

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

c. Additional interpretative factors

- i. The Vienna Convention on the Law of Treaties

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

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

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

Article 32 of VCLT provides, in relevant part:

“Supplementary means of interpretation

Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of article 31, or to determine the meaning when the interpretation according to article 31:

- (a) leaves the meaning ambiguous or obscure; or
- (b) leads to a result which is manifestly absurd or unreasonable.”

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

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

ii. The Doha Declaration

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

“4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.”

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

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

iii. Negotiating history

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

limit an interpretation within the express text, context, and object and purpose of the agreement.

Article 30 of the TRIPS Agreement was adopted as a compromise solution following the inability of negotiators during the Uruguay Round to agree on a list of exceptions to patent holder rights that might be recognized by Members.⁸³ Negotiations concerning such a list proceeded contemporaneously at WIPO, and no agreement was reached in that forum.⁸⁴

The most that may be said about the negotiating history of Article 30 is that it does not resolve uncertainty regarding the meaning of the express text. The draft on exceptions in

⁸³ In his July 23, 1990, report on the status of work in the TRIPS Negotiating Group, the Chairman (Lars E. R. Anell) presented a draft composite text on the analogue to Article 30 that was completely reworked by the time the Dunkel Draft text was distributed in late 1991. The July 1990 draft included alternative “A” (developed country supported) and “B” (developing country supported) proposals. It provided:

“2.2 Exceptions to Rights Conferred

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

2.2.1 Rights based on prior use.

2.2.2 Acts done privately and for non-commercial purposes.

2.2.3 Acts done for experimental purposes.

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

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

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

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

⁸⁴ The corresponding provision under negotiation at WIPO provided:

“Article 19(3)(a). Notwithstanding paragraphs (1) and (2), any Contracting Party shall be free to provide that the owner of a patent has no right to prevent third parties from performing, without his authorization, the acts referred to in paragraphs (1) and (2) in the following circumstances:

(i) where the act concerns a product which has been put on the market by the owner of the patent, or with his express consent, insofar as such an act is performed after that product has been so put on the market in the territory of that Contracting Party, or, in the case of a group of States constituting a regional market, in the territory of one of the member States of such group;

(ii) where the act is done privately and on a non-commercial scale, provided that it does not significantly prejudice the economic interests of the owner of the patent;

(iii) where the act consists of making or using for exclusively experimental purposes, provided that it does not significantly prejudice the economic interests of the owner of the patent;

(iv) where the act consists of the preparation for individual cases, in a pharmacy or by a medical doctor, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared.

Article 19(3)(b). The provisions of paragraphs (1) and (2) shall not be interpreted as affecting the freedom that Contracting Parties have under the Paris Convention for the Protection of Industrial Property to allow, under certain circumstances, the performance of acts without the authorization of the owner of the patent.”

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

the 1990 Anell text is wholly different than the final text that emerged as Article 30 in the Dunkel Draft text in late 1991.⁸⁵ There was no agreement on the Anell text.

The list of exceptions set out in the Anell text included several that would have significant economic consequences, including a right in favor of prior users and a right of experimental use.⁸⁶ The extent of an exception and the conflict with normal exploitation of the patent is a matter of degree.

iv. The Canada-Generics panel report

To date, there has been one DSU panel report regarding interpretation of Article 30, the decision in *Canada-Generic Pharmaceuticals*.⁸⁷ As this author has discussed in depth in a related paper, the General Council and Ministerial Conference are not bound to follow the jurisprudence of a panel report in the adoption of an interpretation of the TRIPS Agreement.⁸⁸ While Members that are parties to a specific dispute are obligated to comply with a decision of the DSB, that decision does not bind other Members in their development of TRIPS-compatible interpretations. Moreover, the Appellate Body (AB) has yet to address interpretation of Article 30. The history of WTO DSU proceedings so far is that the AB often disagrees with legal analysis by panels, and it cannot be assumed that the analysis in *Canada-Generics* would be sustained at the AB level.⁸⁹

The panel in *Canada-Generics* interpreted the phrase “limited exception”:

“7.30 The Panel agreed with the EC that, as used in this context, the word ‘limited’ has a narrower connotation than the rather broad definitions cited by Canada. Although the word itself can have both broad and narrow definitions, the narrower being indicated by examples such as ‘a mail train taking only a limited number of passengers’, the narrower definition is the more appropriate when the word ‘limited’ is used as part of the phrase ‘limited exception’. The word ‘exception’ by itself connotes a limited derogation, one that does not undercut the body of rules from which it is made. When a treaty uses the term ‘limited exception’, the word ‘limited’ must be given a meaning separate from the limitation implicit in the word ‘exception’ itself. The term ‘limited exception’ must therefore be read to connote a narrow exception - one which makes only a small diminution of the rights in question.

7.31 The Panel agreed with the EC interpretation that ‘limited’ is to be measured by the extent to which the exclusive rights of the patent owner have been curtailed. The full text of Article 30 refers to ‘limited exceptions to the exclusive rights conferred by a patent’. In the absence of other indications, the Panel concluded that it would be justified in reading the text literally, focusing on the extent to which legal rights have been curtailed, rather than the size or extent of the economic impact. In support of this conclusion, the Panel noted that the following two conditions of Article 30 ask more particularly about the economic impact of the exception, and provide two sets of

⁸⁵ The “Dunkel Draft” refers to a draft text prepared by the WTO Secretariat under the direction of then-GATT Director General, Arthur Dunkel Trade Negotiations Committee, Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, MTN.TNG/W/FA, 20 Dec. 1991.

⁸⁶ Quotation and citation in note 83, *supra*. The “Anell” text refers to the draft composite text prepared by the Chairman of the TRIPS Negotiating Group.

⁸⁷ The panel in *U.S.-Copyright Act* also considered interpretation of Article 9(2) of the Berne Convention from which the text of Article 30 is partly derived. United States – Section 110(5) of the Us Copyright Act, Report of the Panel, WT/DS160/R, 15 June 2000.

⁸⁸ See Abbott, QUNO Occasional Paper 9, *supra* *, at Section V.

⁸⁹ The Chair of the *Canada-Generics* panel was Prof. Robert Hudec, a leading authority on international trade law.

standards by which such impact may be judged. The term ‘limited exceptions’ is the only one of the three conditions in Article 30 under which the extent of the curtailment of rights as such is dealt with.”

The panel interpreted “normal exploitation” of the patent right:

“7.54 The Panel considered that ‘exploitation’ refers to the commercial activity by which patent owners employ their exclusive patent rights to extract economic value from their patent. The term ‘normal’ defines the kind of commercial activity Article 30 seeks to protect. The ordinary meaning of the word ‘normal’ is found in the dictionary definition: ‘regular, usual, typical, ordinary, conventional’. As so defined, the term can be understood to refer either to an empirical conclusion about what is common within a relevant community, or to a normative standard of entitlement. The Panel concluded that the word ‘normal’ was being used in Article 30 in a sense that combined the two meanings.

7.55 The normal practice of exploitation by patent owners, as with owners of any other intellectual property right, is to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity. The specific forms of patent exploitation are not static, of course, for to be effective exploitation must adapt to changing forms of competition due to technological development and the evolution of marketing practices. Protection of all normal exploitation practices is a key element of the policy reflected in all patent laws. Patent laws establish a carefully defined period of market exclusivity as an inducement to innovation, and the policy of those laws cannot be achieved unless patent owners are permitted to take effective advantage of that inducement once it has been defined.”

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

“7.68 ... Although the European Communities' definition equating ‘legitimate interests’ with a full respect of legal interests pursuant to Article 28.1 is within at least some of these definitions, the EC definition makes it difficult to make sense of the rest of the third condition of Article 30, in at least three respects. First, since by that definition every exception under Article 30 will be causing ‘prejudice’ to some legal rights provided by Article 28 of the Agreement, that definition would reduce the first part of the third condition to a simple requirement that the proposed exception must not be ‘unreasonable’. Such a requirement could certainly have been expressed more directly if that was what was meant. Second, a definition equating ‘legitimate interests’ with legal interests makes no sense at all when applied to the final phrase of Article 30 referring to the ‘legitimate interests’ of third parties. Third parties are by definition parties who have no legal right at all in being able to perform the tasks excluded by Article 28 patent rights. An exceptions clause permitting governments to take account of such third party legal interests would be permitting them to take account of nothing. And third, reading the third condition as a further protection of legal rights would render it essentially redundant in light of the very similar protection of legal rights in the first condition of Article 30 (‘limited exception’).

7.69 To make sense of the term ‘legitimate interests’ in this context, that term must be defined in the way that it is often used in legal discourse - as a normative claim calling for protection of interests that are ‘justifiable’ in the sense that they are supported by relevant public policies or other social norms. This is the sense of the word that often appears in statements such as ‘X has no legitimate interest in being able to do Y’. ...”

The panel’s interpretation of “limited exception” is somewhat more restrictive than that suggested by this author on the basis of the express text. In the panel’s view, a limited

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

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

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

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

9. Compulsory license in importing countries

The use by one WTO Member of an Article 30 exception for making and export is not dependent on the issuance of a compulsory license authorizing importation in another WTO Member. If a product is under patent in the country of import, the patent holder in that country would ordinarily be able to assert an infringement claim regarding prospective imports.⁹⁰ This situation will not pertain in certain important circumstances.

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

⁹⁰ Under a broad definition of exhaustion of rights doctrine, the party (not the patent holder) placing the drug on the market might be construed to exhaust the right of the holder to further interfere with the marketing and sale of the drug in the country of importation. This would assume that placing a patented good on the market under the terms of an exception would exhaust the patent holder's rights. Such an interpretation of exhaustion doctrine might be based on an idea that the exception by definition operated to exhaust any rights of the patent holder in the invention, and there is no "consent" of the patent holder required for the exhaustion doctrine to operate. However, if an exception to the patent holder's right means that the patent holder has no right *ab initio*, perhaps no right could be exhausted in relation to the importing country.

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

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

10. The issue of remuneration

a. Compulsory licensing

Article 31(h) of the TRIPS Agreement provides:

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

Attached as Annex 2 to this report is a general analysis of the remuneration requirement of Article 31(h) authored by the writer of this report. Some of the key points made in regard to the remuneration requirement are:

- The level of remuneration depends on the particular circumstances of the case and may take into account various factors, including (but not limited to) the economic value of the authorization;
- “Adequate” refers to a sufficient amount meeting minimum standards;
- Commercial market royalty rates are one possible benchmark for remuneration, but may be difficult to ascertain or be unreflective of the value of the license for a variety of reasons. Detailed analysis of underlying costs is an alternative, as are government-established guidelines. Factors such as government subsidization of research and development (R & D) and tax treatment are relevant. Royalties may be based on wholesale selling prices, net of tax liabilities.
- Public welfare interests may be taken into account in establishing remuneration. For example, distinction might be drawn between licenses issued to further industrial policy objectives and licenses issued to supply needed medicines;
- Article 31(k) expressly recognizes that “The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases.” If a compulsory license is issued to remedy a situation in which the patent holder has unfairly benefited, the remuneration may be correspondingly diminished.

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

If a developing Member issues a compulsory license that is satisfied by the issuance of a parallel compulsory license in an exporting Member, there will be remuneration obligations arising in both the exporting and importing Members. In such circumstances, compensation in the importing Member should generally be adequate to satisfy the interests of the patent holder

since the importing Member is the primary locus of exploitation of the patent. In any case, cooperation in determining the level of remuneration between authorities in the importing and exporting Members would be foreseen. The patent holder is not entitled to a double-benefit because there are licenses granted in the importing and exporting markets. Rather, a single adequate return based on the production and sale of the subject pharmaceutical would be foreseen.

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

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

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

b. Exceptions

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

WTO Members have taken into account economic effects on patent holders in the establishment of some exceptions. For example, a number of governments that have established regulatory review exceptions have also adopted patent term extensions.⁹¹ In the Canada-Generics proceeding, a number of these Members argued that patent holders would be treated unfairly if subject to effective shortening of the patent term based on their own regulatory review obligations, if second comers to the regulatory review process would be able to enter the market immediately upon expiration of the patent term. Extending the patent term based on the patent holder’s regulatory review was said to redress the economic effects of the exception.

The panel in the Canada-Generics case rejected the argument that a regulatory review exception would fail to meet the requirements of not conflicting with normal exploitation of the patent (or prejudicing legitimate interests) if it did not include a compensatory patent term extension. The panel found that the patent holder did not have a normal expectation of relief from the effects of regulatory review. A regulatory review exception could be granted under Article 30 without a compensatory patent term extension adjustment.

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

⁹¹ This economic issue was argued *in extenso* in the *Canada-Generics* case, and references to relevant national legislation are included in the panel report.

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

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

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

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

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

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

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

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

Based on the express text of the TRIPS Agreement, some have argued that Article 31 (addressing compulsory licensing) is subject to Article 27:1 prohibiting discrimination as to field of technology.⁹² Article 70:6 stipulates the date prior to which Article 27:1 is not

⁹² Article 70:6 (Protection of Existing Subject Matter) states:

“Members shall not be required to apply Article 31, or the requirement in paragraph 1 of Article 27 that patent rights shall be enjoyable without discrimination as to the field of

applicable to compulsory licensing, and the suggestion is that by implication Article 31 is subject to Article 27:1 after that date.

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

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

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

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

12. Amendment and waiver

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

technology, to use without the authorization of the right holder where authorization for such use was granted by the government before the date this Agreement became known.”

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

Agreement. As a temporary measure pending formal amendment, a waiver might be adopted to implement the options that may be used in amendment.

13. Formal interpretation

In anticipation of the Doha Ministerial Conference, developing Members prepared a set of specific recommendations intended to address the problems associated with the restriction on compulsory licensing established by Article 31(f) of the TRIPS Agreement. Those recommendations included that:

“5. A compulsory license issued by a Member may be given effect by another Member. Such other Member may authorize a supplier within its territory to make and export the product covered by the license predominantly for the supply of the domestic market of the Member granting the license. Production and export under these conditions do not infringe the rights of the patent holder.

...

7. Under Article 30 of the TRIPS Agreement, Members may, among others, authorize the production and export of medicines by persons other than holders of patents on those medicines to address public health needs in importing Members.”⁹³

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

In effect, Article 30 must be interpreted so as to allow the making, sale and export of patented products to address public health needs in importing countries as a way to operationalize the capacity of Members to produce for export to meet the compulsory licensing requirements of importing Members. A formal interpretation adopted by the Ministerial Conference or General Council would be useful in providing legal security for Members following this approach. If an interpretation authorizing production for export is adopted, there is no need to adopt an additional specific interpretation of Article 31, unless some Member(s) elects to place in doubt whether a compulsory license may ordinarily be fulfilled by importation. If doubt is expressed on this issue, it may also be prudent to adopt an interpretation of Article 31 making clear that Members may fulfill compulsory licenses granted within their territories by importation.

⁹³ The developing country group non-paper draft declaration submitted to the TRIPS Council on September 18, 2001 included the following additional provisions relevant to the subject matter of paragraph 6:

“ 3. Each Member has the right to allow other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, and to determine the grounds upon which such use is allowed.

...

4. In the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use, Members may grant compulsory licenses without prior efforts on the part of the user to obtain authorization from the right holder.

...

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

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

1. Authorization to make, sell and export patented public health related products is a limited exception to the rights of patent holders;
2. Such authorization does not conflict with the normal exploitation of the patent when:
 - a. Undertaken to address unmet public health needs in countries of import, and;
 - b. Financial constraints in countries of import restrict attention to the public health requirements of all individuals;
3. Such authorization does not prejudice the legitimate interests of patent holders, taking into account the legitimate interests of third parties when:
 - a. The authorization is not directed to supplying a developed importing Member;
 - b. Without prejudgment as to the form such mechanism may take, the country of import accepts to provide the patent holder in the country of export with a reasonable opportunity to prevent the systematic diversion to developed Members of products supplied under exception.
4. Nothing in the foregoing precludes Members from authorizing exceptions regarding developed Members as circumstances justify.

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

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

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

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

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

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

D. Parallel trade

Legislation authorizing parallel importation of patented pharmaceuticals permits developing country consumers to obtain the lowest cost supplies of such products. Important recent economic studies of differential pricing have noted that prices for patented pharmaceuticals do not necessarily reflect the purchasing power of consumers, and that developing countries may benefit from access to parallel imports.⁹⁴ In the preparations for the Doha Ministerial, the United States and Switzerland initially resisted the consensus of WTO Members that the TRIPS Agreement permits each Member to establish its own policy and rules on this subject. Eventually even these two Members reluctantly conceded this point.

1. The Doha Declaration

Paragraph 5(d) of the Doha Declaration provides:

“The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.”

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

The EU and US each proposed to incorporate in the Declaration on the TRIPS Agreement and Public Health a limit on international exhaustion to marketing with the consent of the patent holder.⁹⁵ Such limitation was not included in the Doha Declaration. Instead, paragraph 5(d) leaves each Member “free to establish its own regime for such exhaustion without challenge.” This appears to leave each Member with the discretion to determine whether it will recognize compulsory-licensed marketing or sale of a product in a country of export as exhausting the patent holder’s rights in the country of import to consent to importation and resale.

2. By another authorized party

⁹⁴ See Maskus 2001, and; Scherer and Watal 2001.

⁹⁵ See EU and U.S. (with like-minded) negotiating texts presented during pre-Doha negotiations.

Although the Doha Declaration appears to resolve the issue of exhaustion based on marketing under compulsory license, it may be useful to consider the legal issues in more detail since they are likely to be further discussed by Members.

There are circumstances under which patented products may be first sold or put onto the market under compulsion of government authority. This is typically through the grant to the government itself, or to a third party, of a compulsory license to make and dispose of the product. Such licenses may be authorized because the government determines that public interests will be met by the grants (*see* analysis of TRIPS compulsory licensing rules above), including as a remedy for anticompetitive practices by patent holders.⁹⁶

When patent holders are required to license third parties to produce and dispose of patented drugs, and the licensees put the drugs on the market, buyers are entitled to use or dispose of those drugs just as if the drugs had been put onto the market by the patent holders. In other words, first sales by the licensees have the same effects (in the local market) as first sales by patent holders. The right of the patent holders to control subsequent sales or transfers is extinguished or exhausted by the licensees' acts.

The question has been raised whether drugs (or other patented products) put onto the market under compulsory license in one country may be parallel imported into another country without the consent of the patent holder in that other country. Two textual bases in the TRIPS Agreement suggest a basis for authorizing parallel importation in this context. The first is article 6, TRIPS Agreement, providing that the exhaustion issue may not be subject to dispute settlement. Since "exhaustion" is not a specifically defined term, it would appear that each WTO Member is permitted to adopt the definition it reasonably considers appropriate. This definition might include exhaustion by first sale under compulsory license. The second textual basis is article 31(f), providing that compulsory licenses "shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use". If some drugs produced by compulsory licensees may be exported (*i.e.* the non-predominant portion), then logically they may be imported somewhere, and parallel importation is a mechanism for allowing this without the consent of the patent holder.⁹⁷

The Appellate Body has emphasized that the express language of the WTO Agreement (including the TRIPS Agreement) is its principal source for interpretative guidance, giving terms their ordinary meaning in their context, and in light of the object and purpose of the agreement.⁹⁸ Only if the text is unclear does the Appellate Body resort to supplementary means of interpretation. If "exhaustion" can reasonably be interpreted to take place upon the first sale by a compulsory licensee, then the Appellate Body might well determine that a WTO Member is not subject to WTO dispute settlement for authorizing parallel importation based on sales made by compulsory licensees.

⁹⁶ In the competition law context, to settle government claims patent holders may authorize licensees under so-called "consent" decrees or undertakings. In these undertakings, the patent holder agrees to remedies without a court trial, though often a consent decree will be affirmed and issued by a court in order to provide a basis for enforcement agency supervision.

⁹⁷ The leading expert commentary supporting this position is Carlos Correa.

Some additional support may be found in U.S. and EU copyright legislation that provides compulsory licenses for certain music recording, and does not prohibit local resale of recordings.

⁹⁸ *See* India – Patent Protection for Pharmaceutical and Agricultural Chemical Products, Report of the Appellate Body, WT/DS50/AB/R, Dec. 19, 1997, at *e.g.*, para. 45.

In addition, although (as noted below) there is case law in the developed country WTO Members holding that exhaustion of patent rights is based on the “consent” of the patent holder to placement of goods on the market, the Appellate Body is not under an international legal obligation to interpret the TRIPS Agreement to reflect the traditional practices of developed country Members. Practice in developing Members may well evolve in an alternative direction, provided that such practice is not inconsistent with the express terms of the TRIPS Agreement.

There are, however, arguments that run counter to the suggestion that Members may authorize parallel importation based on the acts of compulsory licensees:

- Though the exhaustion issue is not subject to dispute settlement, the question what constitutes exhaustion might be determined by dispute settlement since there are limits to how the term may be interpreted.⁹⁹
- Article 28, TRIPS Agreement, expressly establishes the rights of patent holders to “consent” to the enumerated acts, including importation. “Consent” to placement on the market anywhere in the world may exhaust the import right under Article 28.¹⁰⁰
- There is a body of case law in the EU, Japan, Switzerland and the United States holding that the notion of patent right exhaustion is based on the consent of the patent holder to first sale. There is a specific holding by the European Court of Justice that intra-Union exhaustion of pharmaceutical patent holder rights does not occur on the basis of a compulsory licensee’s placement of drugs on the market. Although international exhaustion of patent rights is accepted in the United States, the U.S. Supreme Court has barred imports of goods lawfully produced under patent abroad without the consent of the U.S. patent holder (under a so-called prior users’ right).¹⁰¹
- Although article 31(f) allows export of the non-predominant portion of compulsory licensee production, there are at least two contexts in which corresponding importation does not require consent of the patent holder: (a) where the drug is not patented in the country of import,¹⁰² and; (b) where the country of import has issued a compulsory license for importation.

From a practical standpoint, why is the question whether international exhaustion may take place under compulsory license important?

Developing countries that provide patent protection for medicines have limited potential supply of those drugs. They may be purchased locally at on-patent prices, or they may be purchased following placement on the market abroad by the patent holder (or its

⁹⁹ Just as example, a Member could not adopt legislation providing that “exhaustion” is based on piracy of patented products since that would directly defeat the purpose of providing patent protection.

¹⁰⁰ Article 28 does not by its terms refer to compulsory licensing or acts without authorization of the patent holder. Article 28 is specifically cross-referenced to article 6, but article 31 is not. *See also* footnote 14 to article 51 that refers to the consent of the right holder.

¹⁰¹ This view is reflected in the negotiations for the Patent Harmonization Treaty referred to by the WTO panel in *Canada – Patent Protection of Pharmaceutical Products (Canada – Generics)* (WT/DS114/R, 17 March 2000), *see* draft article 19, WIPO, Committee of Experts on the Harmonization of Certain Provisions in Laws for the Protection of Inventions, Eighth Session, Geneva, June 11 to 22, 1990, Draft Treaty on the Harmonization of Patent Laws; Draft Regulations Under the Draft Treaty (Articles 9 to 24; Rule 7), Document prepared by the International Bureau of WIPO, HL/CE/VIII/3, February 15, 1990.

U.S. courts granting compulsory licenses on U.S. patents as remedy for anticompetitive practices have recognized that they are without power to prevent invocation by patent holders of foreign patent rights, although foreign courts may as a matter of “comity” choose to enforce a U.S. court order. *See United States v. Imperial Chemical Industries (ICI)*, (SDNY 1952), 105 F. Supp. 215, 227-31.

¹⁰² In this regard it may be noted that inventors, largely for administrative cost reasons, have rarely sought to patent their inventions in all countries where this might be possible.

agent). Although parallel importation may allow price savings, these savings are not likely to be on the order of magnitude seen in the relationship between on-patent versus off-patent medicines.

A drug produced under compulsory license is effectively an off-patent drug (though payment of an adequate royalty will add to the price). If parallel importation of compulsory licensed drugs is accepted, then in principle a single compulsory licensee in a major market (e.g. Brazil or India) could export a substantial (though “non-predominant”) quantity of low-price drugs, and no action would be required by importing developing countries other than to recognize a broad doctrine of exhaustion and parallel importation. Provided that one or two major market Members were willing to grant compulsory licenses, a worldwide solution to the problem of low-price medicines might be found.

It is clear that WTO Members may authorize parallel importation of patented medicines placed on the market by or with the consent of the patent holder. It is not clear whether the Appellate Body will construe exhaustion doctrine to authorize parallel importation of medicines placed on the market by compulsory licensees. It is likely that developed Members such as the U.S., EU and Switzerland will resist an interpretation of exhaustion doctrine that is not based on the consent of the patent holder. Paragraphs 4 and 5(d) of the Doha Declaration, however, support an interpretation that advances the interests of developing Members in obtaining low cost access to pharmaceutical supplies.

3. Parallel importation, tiered pricing and safety

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. Allowing parallel importation and providing for tiered pricing are not 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.

Parallel importation is argued by Pharma to present monitoring difficulties, and to potentially 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.

As noted at the outset of this report, there is a high volume of pharmaceutical products moving in world trade. There is a substantial interest shared by all governments in assuring the quality of these drugs. The logical extension of Pharma’s arguments on parallel trade and drug safety is that only intra-Pharma trade in pharmaceuticals should be permitted. This would obviously raise very serious competitive concerns, and this approach is fundamentally inconsistent with the liberal trading system.

E. Objectives

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 governments 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.¹⁰³

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.

E. TRIPS Article 8:1 (“Principles”)

1. Interpreting the present text

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

¹⁰³ *Accord* World Bank 2002.

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.

2. Amending Article 8:1

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

F. Granting of patents

1. Discretion within the present terms

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.¹⁰⁴

¹⁰⁴ *Accord* World Bank 2002.

The technical flexibility inherent in patent law has been explored in depth from a developing country perspective.¹⁰⁵ 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.¹⁰⁶

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. The World Bank has pointed out that as a general proposition the costs of putting TRIPS-related administrative infrastructure into place will burden developing countries, and excessively burden least developed countries.¹⁰⁷ One way that costs of administration could be reduced is to increase reliance on the Patent Cooperation Treaty mechanism under which search and preliminary examination are conducted by central authorities.¹⁰⁸ Although this system may generate cost savings, it has the corollary effect of tending to rely on determinations by OECD patent office examiners who are unlikely to evaluate patent applications with the strict views that may be most suitable for developing and least developed countries.

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.

2. Providing a subject matter exception

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

G. Trademarks and Copyrights

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.

1. 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

¹⁰⁵ 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).

¹⁰⁶ *Accord* World Bank 2002.

¹⁰⁷ World Bank 2002.

¹⁰⁸ For a description of the PCT system, see F. ABBOTT, T. COTTIER & F. GURRY, THE INTERNATIONAL INTELLECTUAL PROPERTY SYSTEM, at 1430-67 (1999).

generic drugs in response to prescriptions for trademarked drugs,¹⁰⁹ 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.¹¹⁰ 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.¹¹¹ 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.¹¹²

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.¹¹³ 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.¹¹⁴ Although at least one court in Canada has rejected

¹⁰⁹ In the South Africa pharmaceuticals case, the PMA argued that the mandatory generic substitution provisions of the Medicines Amendment Act are “arbitrary and capricious and amounts to an unwarranted interference with the property rights of the holder of the rights to the prescribed product.” Founding Affidavit, PMA of South Africa, et al. v. Nelson Mandela, President of South Africa, et al., Case No. 4183/98, sworn Feb. 2, 1998, at para. 11.5.5, and that it “interferes with the exercise of the prescribing practitioner’s and pharmacist’s profession whose professional judgments are overridden by the alleged advantages of a purely monetary nature. In particular it creates a situation in which the prescriber’s prescription is to be read differently to what its direct wording conveys.” *Id.* at para. 11.5.6.

In its answering Affidavit to the Amicus Curiae petition in the case, the PMA promised that “Argument will be addressed to the honourable Court with reference to the IFPMA booklets, publications and releases which are Annexed hereto on the effect of section 22F [generic substitution] and 22G [single exit price] on the IP system both nationally and internationally, and on the importance of maintaining the IP system, and in particular the patent and trademark systems.” Applicants’ Answering Affidavit to the Affidavits Filed by the Amicus Curiae, sworn March 29, 2001. Because the lawsuit was withdrawn by the PMA, we do not have the benefit of knowing just how the trademark argument on generic substitution would have been made, since this was not possible to infer from the general reference to IFPMA pamphlets.

¹¹⁰ See *Pharmacia & Upjohn v. Paranova*, European Court of Justice, Case C-379/97, 12 Oct. 1999.

¹¹¹ The following states as having statutes that mandate the substitution of generics for brand name drugs: Florida (Fla. Stat. § 465.025 (2000)); Hawaii (HRS § 328-92 (2000)); Kentucky (KRS § 217.822 (2001)); Massachusetts (Mass. Ann. Laws ch. 112, § 12D (2001)); Minn. Stat. § 151.21 (2000); New York (NY CLS Educ § 6816-a (2001)); Pennsylvania (35 P.S. § 960.3 (2000)); Vermont (18 V.S.A. § 4605 (2001)), and; West Virginia (W. Va. Code § 30-5-12b (2000)). In addition to the states that mandate generic substitution, most (or perhaps all) other states allow generic substitution.

¹¹² See *Pharmacia & Upjohn v. Paranova*, European Court of Justice, Case C-379/97, 12 Oct. 1999.

¹¹³ See discussion in support of the functional characteristic of drug capsule colors in the concurring opinion of Justices White and Rehnquist in *Inwood Laboratories v. Ives Laboratories*, 456 U.S. 844 (1982).

¹¹⁴ See *Qualitex v. Jacobson*, 514 U.S. 159 (1995).

protection of the color of a drug, it did so on grounds that there was inadequate proof of secondary meaning.¹¹⁵

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.

2. 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.¹¹⁶ 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 9:2.¹¹⁷

3. 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.

I. 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.¹¹⁸

¹¹⁵ 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>.

¹¹⁶ 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.

¹¹⁷ Article 9:2 states: "Copyright protection shall extend to expressions and not to ideas, procedures, methods of operation or mathematical concepts as such."

¹¹⁸ 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 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.

It has recently become apparent that the U.S. and EU are seeking to extend the scope of data protection to address situations in which their pharmaceutical companies were unable or neglected to obtain patent protection in developing countries.¹¹⁹ If patent protection was not obtained in a developing country, there will often remain the requirement that a drug obtain regulatory approval prior to marketing. Generic producers and developing country regulatory authorities may seek to rely on data submitted in a developed country market during the regulatory approval process in that country. If generic producers and developing country authorities are unable to rely on that data, there may be substantial delays in the introduction of generic versions of products.

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.”

The express TRIPS text refutes the argument that it “mandates” that regulatory authorities may 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.¹²⁰ 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. The TRIPS Agreement establishes a mailbox system that reflects its negotiated approach to “pipeline” protection. Data protection should not be used as a “back door” to patent protection where such protection was not available at the time an invention was made, or if an enterprise neglected for cost or administrative reasons to seek patent protection.

“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)

¹¹⁹ USTR has designated the Dominican Republic a Special 301 Priority Watch List Country as a consequence, *inter alia*, of alleged failure to provide adequate data protection. Susannah Markandya, *Timeline of disputes over pharmaceutical patent protection in the Dominican Republic*, July 23, 2001 (<http://cptech.org>). Also, author’s discussion with Hungarian public health officials regarding EC Commission pressures.

¹²⁰ 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 2000, at 23).

In addition, pharmaceutical patent holders are granted a period of market exclusivity. If patent holders are anxious to avoid regulatory agency and generic producer use of test data prior to the expiration of patent terms, then perhaps the term of patent protection can be shortened while a period of data exclusivity is tacked on. 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.

IV. Government and Private Operators

A. Invoking Private Rights

The TRIPS Agreement is expressly directed to regulating “private rights” in intellectual property,¹²¹ while the WTO is an intergovernmental organization. Whether the TRIPS Agreement is self-executing (or directly effective) in national and regional law is a question of some complexity, addressed by the European Court of Justice,¹²² by this author and other commentators.¹²³ In the South Africa litigation, pharmaceutical industry lawyers argued that the agreement was not directly effective in the laws of that country.¹²⁴ Generally speaking, the question whether an international agreement is directly effective depends on both the intent of its framers and the constitutional system in the country of application,¹²⁵ and outcomes may vary by country.¹²⁶

Terms of the TRIPS Agreement that are potentially problematic from a public health standpoint create a somewhat greater risk for developing countries if and when they can be invoked directly by private IP holders in national courts. However, even if not directly applicable, these provisions may be invoked in the context of promoting “consistent interpretation”.¹²⁷

The private nature of TRIPS rights has led to their abuse in national legal systems. It is important to emphasize at the outset that the TRIPS Agreement, to the extent it creates problems for developing country public health policies, does not create only “intergovernmental” problems. Pharma invokes IPRs to challenge national government action and private operator conduct in developing countries.

B. The South Africa Medicines Amendment Act

¹²¹ See Abbott, *Technology and State Enterprise* 1998.

¹²² *Parfums Christian Dior v. Tuk Consultancy*, ECJ Joined Cases C-300/98 and C-392/98, Dec. 14, 2000.

¹²³ Abbott, *Intellectual Property Rights Treaties in the Law of the United States: The Direct Application Paradox*, 2 TRANSLEX No. 2:1 (June 1999); Thomas Cottier and Krista Nadakavukaren Schefer, *The Relationship between World Trade Organization Law, National and Regional Law*, 1 J. INT'L ECON. L. 83 (1998).

¹²⁴ Opening statement of PMA counsel before High Court, Pretoria, March 6, 2001.

¹²⁵ See generally, PARLIAMENTARY PARTICIPATION IN THE MAKING AND OPERATION OF TREATIES: A COMPARATIVE STUDY (S. A. Riesenfeld and F. M. Abbott eds. 1994) (Kluwer).

¹²⁶ In *Parfums Christian Dior v. Tuk Consultancy*, the European Court of Justice acknowledged that the question of direct application might be answered differently (on matters not within the scope of the common commercial policy) under different member state constitutions. *Parfums Christian Dior v. Tuk Consultancy*, ECJ Joined Cases C-300/98 and C-392/98, Dec. 14, 2000.

¹²⁷ Although the European Court of Justice has held that the TRIPS Agreement is not directly applicable to the extent that the subject matter is within the Union competence, it has stressed that the EU and its Members should attempt to interpret legislation in a manner consistent with TRIPS obligations. See, e.g., *Parfums Christian Dior*, *supra*.

The most disturbing example of abuse of the TRIPS Agreement occurred in South Africa. Shortly after Nelson Mandela's post apartheid government came into power in South Africa, the government began to take steps to reform its health care sector that had largely been designed to address the problems of the comparatively wealthy white majority, and to address a growing HIV/AIDS crisis. Following adoption of the 1996 National Drug Policy, Parliament approved the Medicines and Related Substances Control Amendment Act, No. 90 of 1997 (hereinafter "Medicines Amendment Act"). This legislation:

- i. Granted the Health Minister the power to prescribe conditions for the parallel importation of drugs;¹²⁸
- ii. Created a mandatory generic substitution obligation requiring pharmacists to dispense a lower-price generic equivalent unless specifically directed otherwise by the prescribing physician or the patient,¹²⁹ and;
- iii. Authorized the Health Minister to adopt regulations to introduce a transparent pricing system that, outside public purchases, would include a single exit price for medicines.¹³⁰

U.S. pharmaceutical industry lobbies persuaded the government to initiate an aggressive campaign to force the South African government to withdraw this legislation, and to threaten trade sanctions if it failed to do so. The U.S. was later joined by the European Union. USTR eventually took the position that it had the right to demand that South Africa comply with U.S.-defined "TRIPS-plus" requirements. In February 1998, the PMA (the South African version of U.S. PhRMA) and pharmaceutical manufacturers brought suit against the government of South Africa alleging various violations of the TRIPS Agreement and the South African Constitution. Just prior to the WTO Seattle Ministerial Conference, the U.S. indicated that it would cease challenging the legislation, provided that South Africa complied with its TRIPS obligations.¹³¹ The pharmaceutical industry did not withdraw its lawsuit.

The legal claims by the pharmaceutical industry were unreasonable. In written submissions and during the first day of the subsequently suspended trial, the industry side (1) argued that the TRIPS Agreement was not directly effective in the law of South Africa¹³² (2) conceded that parallel importation of patented products is permitted under the laws of the United States and Japan,¹³³ and (3) that parallel importation did not violate the TRIPS Agreement.¹³⁴ Since generic substitution laws very similar to those adopted in South Africa are common throughout the states of the United States,¹³⁵ and since price control laws are common throughout the world, it was equally clear there was no plausible TRIPS-based argument against these provisions.

The PMA focused its attention on arguing that the Medicines Amendment Act provisions violated the South African Constitution. The principal attack was against the language of Section 15C of the Act, which industry argued was drafted so broadly as to authorize the Health Minister to abrogate all rights of pharmaceutical patent holders. The

¹²⁸ Section 15C, Medicines Amendment Act.

¹²⁹ Section 22F, *id.*

¹³⁰ Section 22G, *id.*

¹³¹ This history is elaborated in Abbott, *The TRIPS Legality of Measures*, 2001.

¹³² Opening statement by counsel for PMA, High Court, Pretoria, March 6, 2001.

¹³³ Response by counsel for PMA to question from Judge Ngoepe, High Court, Pretoria, March 6, 2001.

¹³⁴ PMA v. President, Applicant's Answering Affidavit to the Affidavits Filed by the Amicus Curiae, Sworn Mar. 28, 2001, at para. 9.1.14.

¹³⁵ See note 112, *supra*.

crux of the argument was that the language referred to permitting the authorization of “acts” in relation to products placed on the market by patent holders, rather than to narrower language such as authorizing only importation and distribution, and was not therefore intended to address parallel importation.¹³⁶ This was despite the fact that the entire legislative history of Section 15C was explicitly directed toward parallel importation, and that the government repeatedly affirmed this in its legal submissions. The PMA said about Section 15C:

“...it is clear that Section 15C grants the Fourth Respondent unfettered powers with no checks and no balances. This amounts to a fundamental denial of democratic government. This Section ... must be deleted in its entirety as it is incapable of rectification. In addition this section represents a fundamental threat to the right to property in general and intellectual property specifically, establishing as it does the principle that these rights may be interfered with or negated in the pursuance of a worthy cause. It has lowered the esteem of our country; its pharmaceutical regulatory system and its willingness to protect the individual for arbitrary administrative interference by the executive. Our international trading partners and co-signatories of international agreements such as GATT and TRIPS have been seriously disturbed by South Africa’s failure to honor its international commitments solemnly undertaken in 1994, resulting in a number of diplomatic protests. Ultimately the very object of promoting public health is seriously endangered by the manner and fashion in which the floodgates for counterfeiting and the dumping of inferior medicines are opened, to say nothing of administrative arbitrariness, ineptitude and corruption.” Para. 10.11, Founding Affidavit, PMA of South Africa, et al. v. Nelson Mandela, President of South Africa, et al., Case No. 4183/98, sworn Feb. 2, 1998.

The language being complained of was taken directly from WIPO Committee of Experts drafts for a Patent Harmonization Treaty (later known as the “Patent Law Treaty”) that had consistently been approved by U.S. and EU delegations,¹³⁷ and that is even today

¹³⁶ This PMA’s position on this point is fully elaborated in PMA v. President, First Applicant’s Replying Affidavit, Sworn May 28, 2000, at section 4, and particularly at paras. 4.2.2.2-4.2.2.3.

¹³⁷ The Medicines Act and Patent Harmonization Treaty provisions differed in the sense that the draft WIPO text recommended a rule of national or regional exhaustion, as contrasted with the Medicines Act preference for international exhaustion. It is the wording of the basic authorization, however, that was challenged by the PMA, and that is essentially the same in both provisions. Section 15C(a) of the Medicines Act provides:

“Measures to ensure supply of more affordable medicines

15C. The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may-

- (a) notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act No.57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent;”

Article 19 of the Committee of Experts draft Patent Law Treaty (1990) provided:

“(3) [Exceptions to Paragraphs (1) and (2)] (a) Notwithstanding paragraphs (1) and (2), any Contracting Party shall be free to provide that the owner of a patent has no right to prevent third parties from performing, without his authorization, the acts referred to in paragraphs (1) and (2) in the following circumstances:

- (i) where the act concerns a product which has been put on the market by the owner of the patent, or with his express consent, insofar as such an act is performed after that product has been put on the market in the territory of that Contracting Party, or, in the case of a regional market, in the territory of one of the members States of such group;”

embodied in WIPO model patent laws recommended to developing countries.¹³⁸ This language was cited to the PMA's lead negotiator in the final negotiations leading to the withdrawal of the lawsuit. The final PMA demand that Section 15C be amended was dropped.¹³⁹

Although the lawsuit brought by the 39 pharmaceutical companies was without merit, it was not legal argumentation that brought about the withdrawal of the lawsuit. The lawsuit was dropped because a coalition of NGOs in and outside South Africa brought public attention to the situation, exposing the public health impact of the industry action. While the principal objective of the complaining companies may have been to force withdrawal of the legislation, delaying its implementation indefinitely would serve the purpose of protecting patent rents.

The result of U.S. and EU government pressure, and the industry lawsuit, was that implementation of the Medicines Amendment Act was suspended, and the implementing regulations are even today not yet in force. This is a period of four years since the legislation was approved by the South African Parliament. Proposed regulations have been objected to by the PMA in South Africa on implausible TRIPS grounds. For example, the PMA has argued that the government should pay its members compensation when drugs are parallel imported, a concept unknown in parallel trade.

Pharmaceutical industry pressure on the government of South Africa, including instigation of pressure from USTR and the EU Commission, may have indelibly altered the way in which the HIV/AIDS pandemic in that country has been addressed. The way that the TRIPS Agreement is implemented, and the manner in which it is used by private operators, are critical aspects of reviewing its impact on developing countries.

V. Ciprofloxacin and TRIPS

Those who have been involved in the controversy surrounding the TRIPS Agreement and access to medicines in developing countries found the reaction in the United States and Canada to the recent and ongoing threat of bioterrorism of particular interest. Both the United States and Canada negotiated very substantial discounts off the patent holder's normal price for a patented essential medicine (ciprofloxacin) under an explicit threat of granting

In explaining this provision, the WIPO International Bureau wrote:

“Paragraph (3)(a) sets out permitted exceptions to the rights established by paragraphs (1) and (2), that is, it sets out the circumstances in which a Contracting Party may provide that the performance by a third party of any unauthorized acts defined in paragraphs (1) and (2) does not constitute an infringement of the rights of the owner of the patent. There are four such circumstances.

Item (i) of paragraph 3(a) contains the so-called principle of exhaustion of rights.” (Underlining added)

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

¹³⁸ See, e.g., Patent Law of Mozambique, distributed at WHO Harare session, August 2001, and WIPO draft patent law for Cambodia.

¹³⁹ It is implausible that the industry position was the result of “innocent mistake”. Bruce Lehman, the former U.S. Commissioner of Patents, produced a paper on the situation in sub-Saharan Africa for the industry-sponsored IPI think tank, and quoted Section 15C. See IPI, note 42, *supra*, at para. 1.3. The former Commissioner of Patents must have known where the language came from, and it is difficult to imagine that someone among the collective patent law talent of PhRMA did not.

compulsory licenses in the event that satisfactory pricing arrangements were not achieved. In both cases, the government acted promptly following the emergence of a medical threat.

In addition to negotiating substantial discounts under threat of compulsory license, the government commission in the United States that is studying the responses to bioterrorism (the “Gilmore Commission”) is recommending that the Department of Defense substantially enhance publicly funded research on vaccines and medicines that might be used in addressing future bioterrorism threats.¹⁴⁰

The TRIPS Agreement provides at Article 31(b) that a government may in a national emergency or for purposes of public non-commercial use grant a compulsory license without prior negotiation with the patent holder, thereby avoiding the potentially time-consuming obligation of attempting to negotiate a license on reasonable commercial terms. Moreover, the TRIPS Agreement article 73(c) permits governments to take measures “which it considers necessary” to protect essential security interests in wartime or international relations emergency. From a technical legal standpoint, the actions by the governments of the United States and Canada can be justified under the terms of the TRIPS Agreement.

However, when developing country governments have proposed to use compulsory licensing legislation to provide more affordable access to medicines to address public health crises within their borders, they have come under intense diplomatic and economic pressure from the government of the United States.

Why was the U.S. government willing to threaten to grant a compulsory license for Bayer’s ciprofloxacin patent when it has so steadfastly opposed similar measures by developing country governments?

A. The Balance of Power

USTR and U.S. PhRMA (the NGO advocating the interests of the major pharmaceutical firms in the United States) consider themselves free to assert heavy political pressure in developing countries with minimal fear of political consequences in the United States. Few people pay attention to foreign trade policies, and the preponderance of those that do are producer groups. The situation is much different when operating within the United States. If PhRMA were perceived as engaging in wartime profiteering, there would be a reaction in the Congress, and in the medium to long term this might shift the balance against industries’ perceived interests. Although PhRMA and Bayer suggested the U.S. government not take measures to grant compulsory licenses in the bioterrorism-ciprofloxacin crisis, the suggestion was measured and non-threatening.¹⁴¹

In the aftermath of the initial bioterrorism threat, PhRMA and the research-based pharmaceutical companies have launched a major lobbying effort in the United States to position themselves as economic beneficiaries of new government efforts to develop vaccines and cures. The levels of financial resources and personnel committed to this lobbying effort are enormous.¹⁴²

¹⁴⁰ Advisory Panel to Assess Domestic Response Capabilities for Terrorism Involving Weapons of Mass Destruction 2001, at 8.

¹⁴¹ See Shankar Vedantam and Terence Chea, *Drug Firm Plays Defense in Anthrax Scare For Now, U.S. Declines to Suspend Bayer's Patent and Authorize Generic Cipro*, WASH. POST, Oct. 20, 2001, at A4; Keith Bradsher, *Bayer Insists Cipro Supply Is Sufficient; Fights Generic*, NY TIMES, Oct. 21, 2001.

¹⁴² See Leslie Wayne and Melody Petersen, *A Muscular Lobby Tries to Shape Nation's Bioterror Plan*, NY TIMES, Nov. 4, 2001 (Lexis/Nexis database). Among other figures, the industry has 625 registered lobbyists,

B. Threat to the United States

Prior to the bioterrorism threat, this author had from time to time asked public audiences to engage in a thought-experiment. What if the President of the United States woke up one morning to find that 10% of the U.S. population was infected with a deadly virus, and was told by advisers that while a treatment existed, a patent on that treatment was held by a French company that refused to make the drug available at prices affordable in the United States? Do you think the President would say, “Well, I suppose we won’t have treatment because we must respect the French patent holder’s interest”? The results to this thought-experiment were self-evident prior to September 2001.

As has already been widely noted, the anthrax threat in the United States, while extremely serious from a public health standpoint, was nonetheless fairly speculative at the time the Secretary of Health and Human Services threatened to grant a compulsory license on the Bayer patent. The HIV/AIDS pandemic is a present reality, and literally thousands are dying from HIV/AIDS in Africa each day.

C. Foreign Sanctions

This author is not aware of any threats from the EU to impose trade sanctions on the United States if it granted a compulsory license on the Bayer patent.¹⁴³

Proposals for U.S. government funding of vaccines and other medicines highlight that there is a real risk that commercial industry may not pursue adequate research and development when potential returns are deemed insufficient, even if the target diseases are of particular relevance to potential public health crises.

VI. The Human Rights Dimension

From a legal perspective, the sources of human rights relating to TRIPS are in customary international law, the Universal Declaration of Human Rights, and in various other human rights instruments including the International Covenant on Civil and Political Rights and the International Covenant on Economic, Social and Cultural Rights. The report recently prepared by the Office of the High Commissioner for Human Rights, entitled “The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights”,

more than half are former members of Congress, their staff, or government employees. One hundred thirty four lobbying firms are retained. The industry spent a reported \$197 million on lobbying and campaign contributions in 1999-2000.

The major pharmaceutical firms have already proposed exemption from antitrust laws to permit greater cooperation. See *PhRMA Seeking Antitrust Waiver For Bioterrorism Vaccine Manufacturing*, HEALTH NEWS DAILY, Nov. 2, 2001.

¹⁴³ Reports on the price of ciprofloxacin indicate very substantial disparities both on an intra-country and an inter-country basis. In the United States, prices for ciprofloxacin are reported in the range of \$4.50-5.00 per tablet at the retail pharmacist level, \$1.80 per tablet to the U.S. government prior to recent negotiations, and \$.95 per tablet following negotiations under threat. Subsequent to the conclusion of the negotiations, it was reported that certain federal public health purchases are made at less than \$.50 per tablet. Shankar Vedantam, *HHS's Varying Costs for Cipro Criticized, U.S. to Pay 95 Cents a Pill Under One Program and 43 Cents Under Another*, WASH. POST, Oct. 26, 2001, at A16.

On the inter-country level, ciprofloxacin prices vary widely, appearing to largely depend on whether the drug is on patent or off patent in the country where sold. See James Love, posting to IP Health listserve, Oct. 21, 2001, including prices identified by Kirsten Myhr. Prices in Kenya, where the drug was under patent were dramatically higher than prices in Tanzania and Uganda, where the drug was not under patent.

insightfully surveys the relevant human rights instruments and their potential application to TRIPS issues.¹⁴⁴

Human rights instruments potentially represent a mechanism for establishing global constitutional balance between interests of public and private right holders in IPRs. Most human rights instruments are subject to wide adherence, and in many cases embody principles of customary international law. Incorporating the human rights dimension into analysis of the TRIPS Agreement and its impact on developing countries raises challenging legal issues that will be more fully elaborated in another report.¹⁴⁵

However, to illustrate the potential interaction of human rights and TRIPS Agreement rules, suppose that a developed country – perhaps the Netherlands -- grants a compulsory license within its territory solely for the manufacture and export of essential medicines that are urgently needed at low cost by developing country WTO Members.

In the analysis of the legal issues posed by this act, would the WTO Dispute Settlement Body (DSB) be required to stay within the strict terms of the TRIPS Agreement, or would it be able to consult the UN Declaration on Human Rights, or the International Covenant on Civil and Political Rights? Could the DSB look at the legislation adopted in the Netherlands and say that the WTO must take into account that its Members also affirmed the UN Declaration on Human Rights in deciding whether the Dutch are within their rights under that declaration to supply developing countries with needed medicines?¹⁴⁶

VII. Competition Law and Developing Countries

The supply side of the patented pharmaceuticals market is highly concentrated, and this raises substantial ongoing risk of anticompetitive conduct. Application of competition law is one mechanism that developing countries might use to achieve reduced prices for medicines and vaccines.

U.S. and EU competition authorities have addressed, and continue to address, pharmaceutical producers in respect to anticompetitive behavior.¹⁴⁷ The United States Department of Justice has required the compulsory licensing of patented technology as a remedy against patent abuse.¹⁴⁸ This is an approach that might be followed by the developing

¹⁴⁴ UN Economic and Social Council, E/CN.4/Sub.2/2001/13.

¹⁴⁵ The author of this report is Director of the American Society of International Law Research Project on Human Rights and International Trade. At the first formal conference organized in connection with this project, in Berne, Switzerland, August 2001, he presented an initial paper, *TRIPS and Human Rights: Preliminary Reflections*, which will be used as the basis for a more thorough examination of this subject matter.

¹⁴⁶ So far, the DSB in the *Shrimp-Turtles* case has acknowledged the relevance of international instruments outside the WTO texts for purposes of aiding in the interpretation of the Agreement. But how far does this flexibility extend? Could the UN Declaration be used to aid in the interpretation of Article 30 or 31? Could the Netherlands argue that its WTO legal obligations are conditioned on its respect for its international human rights obligations? Could, for example, the Netherlands invoke article 103 of the UN Charter and argue that the Declaration, elaborating on its obligations under the Charter, in fact takes precedence over its WTO commitments? What if the DSB rules against the Netherlands and that country brings a claim at the International Court of Justice arguing that suspension of its concessions under the WTO Agreement (in reaction to its exercise of rights under human rights instruments) constituted an international delict that should result in an award to it of damages? How would the ICJ treat a decision of the Appellate Body or DSB?

¹⁴⁷ Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements, Prepared Testimony of James M. Griffin Deputy Assistant Attorney General Antitrust Division, Before the Senate Judiciary Committee, FED. NEWS SERV., May 24, 2001. Recent enforcement actions in the United States include those involving the Vitamins price fixing conspiracy and ongoing inquiry into payments to generic producers to drop patent challenges.

¹⁴⁸ See Scherer 2000, observing:

countries when there is evidence that dominant position in a market is being used to sustain prices that are unreasonable in relation to local conditions.

Developing countries face administrative capacity barriers in pursuing competition law enforcement.¹⁴⁹ The legal resources available to Pharma are likely to exceed those available to most developing countries. However, in discrete cases of pharmaceutical pricing abuse, it may be possible to pursue anticompetitive behaviors with limited resources.

VIII. Outside the WTO

The WTO is by no means the only trade arena in which intellectual property rights relevant to public health are addressed. The European Commission makes explicit IP and data protection demands on countries in the process of applying for accession to the EU.¹⁵⁰ The United States uses its Special 301 legislation to demand compliance with U.S.-equivalent IP and data protection standards.¹⁵¹ Current proposals for the extension of U.S. trade promotion authority require pursuit of accelerated implementation of TRIPS commitments.¹⁵²

A Free Trade Area of the Americas (“FTAA”) is under negotiation, and it is anticipated the FTAA will include a chapter on IPRs.¹⁵³ A significant part of the official U.S. negotiating position on the IPRs component of the FTAA is directed toward enhanced data protection and term extension for pharmaceutical patents.¹⁵⁴

The World Intellectual Property Organization (WIPO) and its members are resuming work on substantive patent law harmonization.¹⁵⁵ Such work may well have an impact on the way in which patents, including those relating to medicines and vaccines, are granted and enforced.

The appropriate treatment of intellectual property in genetic resources, and the treatment of traditional medicines, among other subject matter, may have an impact on the interests of developing countries in access to medicines and vaccines. Issues in connection with this subject matter are being considered in a number of forums in addition to the WTO, such as within the framework of the Convention on Biodiversity and within the Food and Agriculture Organization forum.

“If abuse is found, and after consultation between governments of the nation in which the abuse occurs and the home nation of the intellectual property right holder, Article 31(k) of the TRIPS agreement permits compulsory licensing of the subject intellectual property, with the ‘need to correct anti-competitive practices’ being taken into account in setting compensation to the property right holder. This provision presumably reflects the experience of the United States, in which compulsory patent licensing has been used as a remedy in more than 100 antitrust case settlements, including cases involving Meprobamate, the antibiotics tetracycline and Griseofulvin, synthetic steroids, and most recently, several basic biotechnology patents owned by Ciba-Geigy and Sandoz, which merged to form Novartis.”

¹⁴⁹ A particular obstacle confronting developing country authorities is that data that may be useful in demonstrative anticompetitive behavior would often be held outside the country where the conduct is having its effects.

¹⁵⁰ Reports by Central and Eastern European delegations at WHO Warsaw meeting, Sept. 2001.

¹⁵¹ See, e.g., Dominican Republic and Thailand Timelines, *supra* note 28.

¹⁵² Bipartisan Trade Promotion Authority Act of 2001, H. R. 3005 (“A bill to extend trade authorities procedures with respect to reciprocal trade agreements”), introduced Oct. 3, 2001, at Sec. 2.

¹⁵³ See FTAA - Free Trade Area of the Americas, Draft Agreement, FTAA.TNC/w/133/Rev.1, July 3, 2001, Chapter on Intellectual Property Rights.

¹⁵⁴ Public Summary of U.S. Position, Negotiating Group on Intellectual Property, FTAA (<http://ustr.gov>), as of Nov. 11, 2001.

¹⁵⁵ See reports on activities of Standing Committee on the Law of Patents (<http://wipo.int>).

IX. The Supply of Medicines and Vaccines

Although there is a high level of awareness among politicians, public health, legal and economics experts that meeting the immediate public health needs of developing countries requires large-scale subsidization from developed countries,¹⁵⁶ to date there is little evidence that the political will necessary to create adequate funding mechanisms exists, or will evolve in the reasonably near future. That funding from external sources is not available means that developing countries may largely find it necessary to cope for themselves with disease threats and disease burdens. This is a major reason why attention to impediments imposed by the TRIPS Agreement are so important.

This part of the study examines the present situation regarding funding for the supply of medicines and vaccines, and R & D of particular relevance to developing countries. The intention is two-fold: first, to offer a few recommendations as to how funding might be better approached and, second, to highlight that on the best information available it is reasonable to conclude that developing countries should be prepared to “go it alone”. In responding to their own crisis situation regarding medicines and vaccines, developing countries must increasingly create capacity to provide medicines at low cost, and therefore be prepared to issue compulsory licenses, parallel import, and in general act in their own best interests.

A. Existing Medicines

1. Private donation programs

There is little expert support for substantial reliance on drug donation programs. There are several reasons for this. First, drug donation programs will not achieve the scale necessary to address the most pressing disease burdens, such as with respect to HIV/AIDS and malaria. Estimates regarding the costs of medicines to address the HIV/AIDS pandemic are in the range of several billions of dollars per year,¹⁵⁷ and potential private sector drug donors have not indicated a willingness to make contributions at that level. Second, from the standpoint of developing countries, drug donation programs threaten to create a situation of perpetual dependence on foreign governments and suppliers. This raises serious public security issues. If the public health in developing countries becomes highly dependent on continuing donative support from private sector enterprises, local control over health policy will be jeopardized. There is risk that the general economy of a country that becomes highly dependent on continuing donations would become more vulnerable to external policy demands.

2. Public funding

It will be extremely difficult for developing countries in general, and least developed countries especially, to purchase or manufacture medicines at the scale necessary to address the most pressing and immediate disease burdens. At the present time, there is no viable alternative to external public funding of efforts to meet such needs.

Several billion dollars per year are likely to be needed for the indeterminate future to purchase medicines to address the HIV/AIDS pandemic.¹⁵⁸ Obviously, the dollar amount

¹⁵⁶ *Accord* WHO Macroeconomics Commission 2001 and World Bank 2002.

¹⁵⁷ See discussion of funding levels, *infra*.

¹⁵⁸ There is as yet no generally agreed dollar amount of funding that will be required to purchase medicines to provide HIV/AIDS treatment. The Secretary General of the United Nations has indicated that \$7-10 billion per year will be required, but this figure incorporates all elements including prevention, training, infrastructure, and

necessary for drug purchases will depend on the price of drugs, and the price will depend on a variety of factors. On the open market, ARVs are available at substantially lower prices from generic producers than from patent holders.¹⁵⁹ Patent holders may elect to lower prices to supply a publicly funded program, though it would still not be certain that all such producers could match the prices of generic suppliers, some of which appear to have developed production techniques that are more efficient than the patent holders.¹⁶⁰

The present proposals for public funding to address the HIV/AIDS pandemic rely on contributions from individual governments to a Global Fund, and so far this has not proven an effective means of establishing adequate funding. While it is difficult to make predictions as to future political events, it is possible that this failure will be persistent, in particular as international security concerns have recently achieved a higher priority than public health concerns. Recognizing that the IMF and World Bank are already proposed to be involved in the organization of the Global Fund, it may be worthwhile to at least consider whether a shift in emphasis on the financial side might allow a more rapid and sustainable build-up of urgently needed funding.

Shifting the lead role for organizing funding of disease relief efforts to the IMF and World Bank may present advantages over current proposals. The IMF has substantial reserve funds that might in theory be drawn upon, although it is foreseeable that individual government contributions to the IMF and World Bank would still form the major component of a health-directed program. From a political standpoint, however, it may be easier for OECD governments to fund programs that are proposed and approved by the governing bodies of the principal multilateral financial institutions.¹⁶¹ The IMF and World Bank may certainly make the case that major epidemic disease threatens the world economy, and that programs designed to address such disease are within the scope of their financial objectives. A request from the World Bank for funding is likely to be perceived as more politically neutral than a request from the United Nations, and this might help to reduce internal political friction in respect to funding authorizations.

Funding by national and regional governments on an *ad hoc* basis is subject to myriad internal political pressures, ranging from groups advocating particular religious perspectives on the HIV/AIDS pandemic, to patent holder interest groups demanding that generic producers be excluded from the supply side, to competing internal budgetary demanders, including the military.¹⁶²

so forth. Others have suggested that \$1.1 billion per year would provide an adequate start. Jeffrey Sachs, *A Global Fund for the Fight Against AIDS*, WASH. POST, Apr. 7, 2001.

¹⁵⁹ See Pérez-Casas, et al. 2001.

¹⁶⁰ Reports from Indian generics producers at MSF meeting in New Delhi, June 2001.

¹⁶¹ The author also recognizes that IMF funding would involve legal and technical issues relating to the charter of the institution and to the generation of funding capabilities directed towards addressing the HIV/AIDS pandemic. However, without exploring those issues in depth here, the IMF has routinely provided large-scale financial support in situations of financial crises that threatened global public security, and when required, the institution has found the capacity to adapt its mission. The IMF has, for example, recently established trust funds directed toward poverty reduction.

There are always risks associated with drawing comparisons. In terms of aggregate numbers, we may recall that in the mid-1990s, the IMF and U.S. government offered loans and guarantees to the government of Mexico in the order of \$40 billion in the immediate aftermath of the peso crisis. The government of Argentina presently appears to be in default on some substantial part of \$140 billion in external debt. The IMF has lent a substantial amount to Argentina.

¹⁶² It is possible that potential funding by the IMF or World Bank will be met with the same kind of “moral hazard” argument that has been put forward in connection with efforts to support the capacity of developing country governments to repay bond obligations to private sector holders. The moral hazard argument is that “bailouts” encourage investors/lenders to undertake risks that they would not otherwise prudently undertake,

A program more directly overseen by the IMF/World Bank might well be designed to “jump start” more sustainable long-range programs. This might include:

- a. Funding the construction of manufacturing plants in developing and least developed countries;
- b. Funding training programs for persons involved in the manufacturing and distribution sectors of developing and least developed country economies;
- c. Assisting with technology transfer programs;
- d. Examining mechanisms to improve basic R & D capacities.

One might well envision that IMF/World Bank efforts to address the HIV/AIDS pandemic would provide a solid foundation for a sustainable long-term approach to public health and access to medicines in developing and least developed countries.¹⁶³

3. The role of generics

One of the principal ways to address the problem of access to medicines in developing countries is to increase the production and distribution of generics. A more limited approach to patent protection and an increase in the competitive structure of the global pharmaceuticals market should have the effect of reducing prices. It is abundantly clear that generic manufacturers in Brazil, India and elsewhere are able to supply drugs at prices far below those ordinarily charged by patent holders, and it is likewise apparent that increased reliance on generics would increase the number of persons who are able to afford medicines.

It is important that the quality of generic manufacturing be assured. To this end, the WHO and World Bank, along with organizations with experience in the area of pharmaceutical manufacturing, could play a useful role in providing assistance to entrepreneurs in developing countries so as to promote improvement in manufacturing practices where weaknesses are detected. This assistance would be within the TRIPS Agreement mandate of promoting transfers of technology.

B. New Medicines and Vaccines

1. Research and Development

The world pharmaceutical market is divided into two segments: commercially significant and non-commercially significant. In the commercially significant segment, pharmaceutical firms address the needs of OECD (largely through collectivized insurance

and ultimately act to encourage financially imprudent conduct by issuer/borrowers. By acting as guarantor of financially imprudent arrangements, the IMF, it is argued, encourages suspect behavior.

It is apparent that a moral hazard argument could be extended to the HIV/AIDS pandemic. HIV infection is often spread by sexual behavior characterized by high risk of infection, and substantial efforts in the public health sector are devoted to attempting to reduce preventable risk-taking conduct. Nonetheless, it seems doubtful that any person of conscience would seriously argue that the IMF and World Bank should refrain from funding programs to extend the life-span of HIV-infected individuals because this may promote future imprudent sexual behavior. Death from disease is clearly not the same warning message as potential financial loss from defaulted government bonds. Moreover, since many of those suffering from HIV/AIDS are children and persons infected without engaging in risk taking behavior, it would seem decidedly unfair to penalize them for the conduct of others.

¹⁶³ Accord World Bank 2002.

arrangements) and high-income developing country consumers with the ability to pay for expensive R & D, advertising budgets, executive compensation, returns to shareholders and so forth. Products that may fulfill the criteria of capturing a sufficiently large share of the potentially lucrative OECD market will attract investment. Pharma is tending to direct its research and development to cancer, cardiovascular disease and conditions generally affecting wealthy aging populations (*e.g.*, aging effects on skin).¹⁶⁴

In the non-commercially significant segment, pharmaceutical firms are willing to supply marginal cost products provided that the commercial market segment is not disrupted. Very limited investment is undertaken by the private firms in products that are primarily of interest in poor developing markets.¹⁶⁵ The non-commercially significant segment is dependent on public sources of funding for R & D, including funding from government budgets and from charitable contributions. Production of low-cost medicines and vaccines requires subsidization from some public source.

When cross-over products that are needed in both developed and developing markets are developed, a notable case being antiretrovirals (ARVs), Pharma first pursued a strategy of attempting to maximize profits by selling at high prices to the high income segments of developing country markets, ignoring the poorer segments of the population.

Neither the WTO as an institution nor the TRIPS Agreement as a legal instrument are designed or are capable of addressing this market failure. The TRIPS Agreement is designed to protect private rights in intellectual property and allows governments flexibility to take into account public health interests in regulating those private rights. The WTO is designed to liberalize markets and to promote generalized economic growth for the world economy. The WTO is not designed to promote or manage pharmaceutical development nor health care systems. The principal point regarding the TRIPS Agreement is that it is not designed to direct R & D expenditures to diseases of particular concern to public health officials in developing and least developed countries.

The question confronting policy-makers is how to increase the development and supply of medicines and vaccines to poor populations principally (though not exclusively) located in developing countries. There are two principal alternatives. First, ways might be sought to provide incentives to the private pharmaceutical sector to direct attention to non-commercial markets. Second, the public sector might take greater responsibility for R & D and production of pharmaceuticals.

The WHO Macroeconomics Commission majority largely supports the idea of public-private partnerships to address the underfunding of research on medicines and vaccines of specific interest to developing countries.¹⁶⁶ An international mechanism would be established to identify appropriate targets for publicly supported research, and this research would be conducted both by the private sector and public facilities. The majority proposal of the group would involve public purchases from private sector entities following publicly-supported R & D efforts. The minority proposal would enable developing country governments to purchase licenses from the R & D enterprises, and would allow them to contract with generic producers for supplies. A developing country government (either itself or through international support) would pay a royalty to the entity from which the license is obtained. According to this minority proposal:

¹⁶⁴ See Lanjouw 2001 regarding the direction of research.

¹⁶⁵ See Lanjouw 2001; Scherer and Watal 2001, and; World Bank 2002.

¹⁶⁶ Reported in Maskus, *Options* 2001.

“Guidelines for setting royalty rates for future medicines should be set, *inter alia*, in order to encourage market-based development of new indications for conditions in developing countries. They should also account for the proportion of R & D costs supported by public funds. Thus, royalty rates would be highest for conditions specific to the low-income countries.”¹⁶⁷

Lanjouw has advocated a patent rights system that would give R & D investors the option of patenting their inventions in the developed or developing country markets, but not both.¹⁶⁸ This would, she argues, lower the price in developing countries for medicines for “global diseases”, because investors will prefer to seek patent protection in wealthy developed markets, and not in poorer developing markets. She describes her proposal in the context of the underfunding of R & D on diseases of particular relevance to developing countries, and suggests that if a patent on an anti-malaria drug, for example, would be patented in the developing countries (but not the developed countries), this would provide an incentive for R & D on anti-malarial drugs. Yet it is difficult to see why this would be the case. If the market for anti-malaria drugs is in general too poor to attract investment by the major R & D based companies, why would limiting the range of patent protection to developing countries increase R & D incentives? Lanjouw’s proposal is a potential mechanism for lowering prices of medicines relevant to both developed and developing populations, but it is difficult to envision it as an incentive towards additional investments in medicines relevant to developing countries.

The Gilmore Report (III) recommending a U.S. response to bioterrorism, *inter alia*, concludes:

“We recommend the establishment of a government-owned, contractor-operated national facility for the research, development, and production of vaccines for specified infectious, especially contagious diseases.

The private sector is unlikely to be the answer to some of the more difficult vaccine issues. Direct government ownership or sponsorship is likely to be the only reasonable answer for producing vaccines for certain bio-organisms – anthrax and smallpox being at the top of the list. Limited production capabilities for small-market (i.e., military useful) vaccines are currently the largest hurdle facing DoD. The problem is significantly compounded for civilian bioterrorism preparedness.”¹⁶⁹

This author would recommend an approach to R & D for medicines and vaccines of particular relevance to developing countries that is more reliant on the public sector, and that places limited reliance on the private sector. Much of today’s basic research on medicines and vaccines takes place in public institutions funded by government grant.¹⁷⁰ Pharma asserts that one important value added it provides is to subject promising molecules, even if identified by publicly funded researchers, to the difficult and costly process of clinical trial and government marketing approval. Pharma indicates that only very heavily capitalized enterprises can afford the risks of myriad clinical experiments that may ultimately lead to successful marketing approval.

¹⁶⁷ *Id.*

¹⁶⁸ Lanjouw 2001.

¹⁶⁹ Advisory Panel to Assess Domestic Response Capabilities for Terrorism Involving Weapons of Mass Destruction 2001, at 8.

¹⁷⁰ See National Institutes of Health 2000.

It is difficult to understand why the major OECD governments would not be better candidates as highly capitalized investors capable of bearing the risks of clinical trial and error. Assuming that individual researchers may be encouraged to work harder or longer for the prospect of substantial economic reward, there is no reason why governments could not include a royalty stream or other “prize” in favor of successful research teams.¹⁷¹

The problem-set of finding cures or vaccines for targeted diseases is not the same as the problem-set facing an open economy that is generally attempting to promote innovation. As a global proposition, the U.S. economy, as example, takes the approach that a large amount of relatively unchanneled R & D will produce a substantial aggregate amount of innovation that the marketplace will sort through, rewarding the inventor “at the right place at the right time”. The search for a vaccine for malaria is rather different. The public health community knows “what” should be looked for, and R & D efforts must be channeled in that direction. A major potential source of government bureaucratic waste/inefficiency is taken out of the equation as the government is not attempting to identify marketplace winners and losers.

This author’s suggestion is that R & D on medicines and vaccines for diseases of particular relevance to developing countries should not be treated as the general open-economy patent case, but rather as calculated R & D directed toward a known goal. The public sector is capable of pursuing such R & D. Developing countries require partners that have their interests in the forefront in the development of new medicines and vaccines.

X. Executive Summary Redux

This study accepts the consensus of experts that developing countries should make use of policy options such as compulsory licensing and parallel importation to increase the supply of low-price medicines and vaccines. The interests of the OECD and its consumers will not be undermined by such action since, *inter alia*, Pharma is not significantly dependent on profits from developing countries to pursue its research mission.

The Doha Declaration on the TRIPS Agreement and Public Health mandates that the agreement be interpreted in a manner that supports public health interests and promotes access to medicines for all. This study analyzes the TRIPS Agreement in light of that mandate.

As of January 1, 2005, developing countries (excluding least developed) will be required to implement and enforce pharmaceutical product patent protection and operationalize patents based on mailbox applications that were submitted during the TRIPS transition period. At that time, the world supply of low-price off patent medicines will decrease. Not only will supplies of low-price medicines within developing countries decrease, but supplies available for export by these countries will gradually diminish.

The Doha Declaration provides to least developed countries (LDCs) an extension until January 1, 2016, to implement or enforce pharmaceutical product patent protection. That extension will have a limited effect on supplies since LDCs will remain dependent on low price imports from developing countries that may no longer be available. LDCs might best take advantage of the transition period by increasing their intra-LDC capacities to make and trade medicines and vaccines, but there are practical obstacles to accomplishing this.

¹⁷¹ Alternatives to the patent reward system of encouraging innovation are discussed in WILLIAM D. NORDHAUS, *INVENTION, GROWTH AND WELFARE* (1969).

When the developing country transition period ends, the restriction imposed by Article 31(f) of the TRIPS Agreement on exports under compulsory license is likely to have a significant effect on the world supply of low price medicines and vaccines. If a predominant part of compulsory licensed production must supply the local market, the quantity of available exports will be limited. To remedy this problem, the TRIPS Agreement should be amended to delete Article 31(f).

If Article 31(f) is not deleted, Article 30 of the TRIPS Agreement regarding exceptions to patent rights must be interpreted so as to permit making and export of pharmaceutical products and other public health related inventions to meet public health needs. The adoption of a formal interpretation by the WTO Ministerial Conference or General Council would provide legal security for countries following this approach. This study provides a detailed analysis of Article 30 indicating that such exception from the rights of patent holders is permitted, and suggests criteria on which implementation of this exception may be evaluated.

Article 8:1 of the TRIPS Agreement authorizes the adoption of necessary public health measures provided they are “consistent” with the terms of the TRIPS Agreement. There is no justification for the TRIPS safeguard to be more restrictive than the safeguards applicable to goods and services. Article 8:1 should be amended to permit the adoption of necessary public health measures inconsistent with the TRIPS Agreement.

Developing countries may consider revisiting the position many of them advocated during the GATT Uruguay Round, and propose amendment of Article 27:3(a) of the TRIPS Agreement to allow exception from patenting of public health related inventions, including medicines and vaccines.

Developing countries should implement the TRIPS Agreement recognizing that its provisions do not demand excessive levels of protection promoted by only a few OECD countries.

Knowledgeable observers agree that meeting the public health needs of developing countries requires substantial subsidization from OECD countries and international organizations such as the IMF and World Bank. The Global Fund does not to date evidence that it will be adequately funded so as to address urgent developing country needs for public health supplies. Developing countries must be prepared for self-reliance, and this self-reliance requires increased capacity to produce low price medicines and vaccines, whether or not such products are under patent by Pharma enterprises. This intensifies the importance of interpreting and amending the TRIPS Agreement to reinforce developing country capacity to act in their own best interests.

Increasing attention must be devoted to research and development on medicines and vaccines of particular relevance to developing countries. Neither the market nor the TRIPS Agreement provides a solution for the lack of attention to this R & D. An option to be further explored is increasing the level of funding for publicly undertaken R & D.

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ANNEX 1 to Commission Study 2a

Deriving Order of Magnitude Profit and R & D Estimates

Trade patterns

Sources on pharmaceutical trade patterns tend to reflect mainly intra-OECD data, with reference to the developing countries largely incorporated in “rest of world” figures.¹ Assuming, however, that all non-OECD countries are aggregated, it appears that about 20% of U.S. pharmaceutical products (on- and off-patent) are exported outside the OECD.² About 30% of EU (on- and off-patent) pharmaceutical exports appear to go to non-OECD countries.³

Only a portion of pharmaceutical exports consists of on-patent drugs, but data broken down on patent/non-patent lines does not appear to be available. A substantial part of pharmaceutical sales in developing countries are comprised of off-patent medicines such as pain relievers and established antibiotics. If it is assumed that half of OECD pharmaceutical exports by value to non-OECD countries are on-patent, then 10% of U.S. sales of pharmaceuticals are potentially dependent on patent protection in developing countries, and 15% of EU exports are likewise dependent. Assuming (using 1998) figures that 10% of US pharmaceutical exports (both preparations and bulk products) is about \$950 million (using OECD data cited by Gambardella, et al., at Table 3) and that the industry earns a 15% rate of return on sales, then the United States pharmaceutical industry would stand to lose \$142.5 million per year if all profits from sales of patented pharmaceuticals in non-OECD countries were to be eliminated. For Europe, the corresponding figures would be, with 15% of total EU exports, \$4.5 billion in exports and \$675 million in profits. (If the industry earns a 20% rate of return on sales, the corresponding profits figures would be \$190 million and \$900 million, respectively.)

The total of \$817.5 million (or, at the higher rate of return \$1.19 billion) represents all profits from sales of patented products. Obviously, not all profits would be eliminated by the loss of patent protection.

The foregoing figures represent only export-import trade, and do not therefore account for the substantial role that foreign direct investment, licensing, and so forth play in Pharma profitability. The sales and income numbers reported in SEC filings vary substantially in methodology, and are not readily broken down in ways that allow aggregation and comparison. The SEC-reported numbers incorporate import and export sales, and so are not additive to the trade figures discussed above. However, the trade aggregate figures, when viewed alongside the SEC-derived aggregate figures, are roughly comparable in an “order of magnitude” sense. As would be expected, the SEC-aggregate figures are substantially higher.

SEC filings

¹ The author recognizes that the estimates in this Annex are rough approximations, and stresses that they are only intended to suggest orders of magnitude.

² USITC at Table A-3.

³ See Gambardella, et al., at Table 1. Note, however, that since Australia and Canada are included in rest of world figures a non-OECD number is difficult to extract.

Bristol Myers Squibb (BMS) from 2000 fiscal year SEC From 10-K filing

Item 6: Selected Financial Data

Operating Results

(in millions, except per share amounts)

2000

Net sales	<u>\$18,216</u>
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Expenses:

Cost of products sold	4,759
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Marketing, selling and administrative	3,860
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Advertising and product promotion	1,672
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Research and development	1,939
--------------------------	-------

Other	508
-------	-----

12,738

Earnings from Continuing Operations Before Income Taxes	5,478
--	-------

Provision for Income Taxes	1,382
----------------------------	-------

Earnings from Continuing Operations	<u>\$4,096</u>
-------------------------------------	----------------

Note 14: Segment Information

Geographic Areas

United States	\$12,114
---------------	----------

Europe, Mideast and Africa	3,414
----------------------------	-------

Other Western Hemisphere	1,314
--------------------------	-------

Pacific	1,374
---------	-------

Net Sales	<u>\$18,216</u>
-----------	-----------------

Year-End Assets

United States	\$10,640
Europe, Mideast and Africa	4,453
Other Western Hemisphere	1,376
Pacific	1,109
Total Assets	<u>\$17,578</u>

Assumptions:

1. Pacific is preponderantly represented by Japanese market, at least 60%
2. Europe, Mideast and Africa is very preponderantly Europe, at least 80%
3. Canada is 10% of non-U.S. Western hemisphere

Pacific without Japan 443.6

Mideast and Africa, without Europe, 890.6

Non-Canada Western Hemisphere other, 1238.4

\$ 2,572.6 total possible in developing countries of total \$18,216 (or 14.1% of sales)

If half derived from patents, 7.05% of net sales at risk or \$1,286.3 million

Net income is 22.5% of sales, so \$289.4 million income is at risk

R & D expenses are 10.64% of net sales of \$1,286.3 million, or \$136.8 million. R & D expenses are 47% of income from continuing operations, or \$136 million.

Merck from 2000 fiscal year SEC From 10-K filing

Consolidated Statement of Income

(\$ in millions except per share amounts)

Sales	<u>\$40,363.2</u>
Costs, Expenses and Other	
Materials and production	22,443.5
Marketing and administration	6,167.7
Research and development	2,343.8
Acquired research	--
Equity income from affiliates	(764.9)
Gains on sales of businesses	--
Other (income) expense, net	349.0
	<u>30,539.1</u>
Income Before Taxes	9,824.1
Taxes on Income	3,002.4
Net Income	<u>\$6,821.7</u>

“Foreign Operations

The Company's operations outside the United States are conducted primarily through subsidiaries. Sales of Merck human health products by subsidiaries outside the United States were 36% of Merck human health sales in 2000, and 40% and 43% in 1999 and 1998, respectively.

Distribution of Foreign Human Health Sales

Western Europe	45%
Asia/Pacific	29%
Other Foreign	26%
Total	100%”

Analysis: It is difficult to work with Merck numbers because human health products are not broken down into a separate financial line item, and a significant portion of Merck income is derived from providing health benefits services through Merck-Medco. With these limitations in mind:

36% of total sales is \$14,530.7 million.

Exclude Western Europe 45% portion.

Assume Asia/Pacific is 60% Japan, so 11.6% is non-Japan Asia.

Other foreign includes Canada, assume 10% of Other, so remainder is 23.4%.

Therefore, 35% of 36%, or 12.6% of sales is potentially developing country.

Assuming half is patent dependent, 6.3% of sales may be at risk.

6.3% of \$40,363.2 (total sales) is \$2542.9

Income is 16.9% of sales, so \$429.75 million in income is at risk

R & D is 5.8% of net sales, or \$147.5 million at risk

R & D is 34% of net income, or \$146.1 million at risk

BMS and Merck:

Taking BMS and Merck together (289.4 + 429.75) \$719.15 million net income are at risk

Taking BMS and Merck together (136+147.5) \$283 million R & D is at risk

Available data suggests that the two largest U.S. Pharma companies may account for 17% of worldwide Pharma sales.⁴ Extrapolating BMS and Merck data suggests that \$4.227 billion in aggregate net income are derived by Pharma from sales of patent pharmaceutical products in developing countries, and if R & D is 39.36% of income (the aggregated BMS-Merck ratio), then \$1.664 billion R & D is at risk.

⁴ See Gambardella, et al., at Table 11a.

ANNEX 2 to Commission Study Paper 2a

Adequate Remuneration

Article 31(h) provides that “the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization”. The requirement of payment of adequate compensation was not part of the Paris Convention rules on compulsory licensing. The requirement applies to government use as well private party use of the patent.

The TRIPS Agreement rules on compensation embody substantial flexibility as a consequence of use of the terms “in the circumstances of each case”, indicating that factors relating to the underlying reasons for the grant of the license may be taken into account in establishing the level of compensation. Granting authorities are instructed to “take into account the economic value of the authorization”, but are not required to base the royalty payable to the patent holder on that value.

The term “adequate” generally is used to indicate something that is sufficient, or meets minimum standards, but not more than that.¹ In the context of payments to patent holders, adequate payment may be defined in a variety of ways.

Granting a compulsory license is not the same as ordering forfeiture or revocation of a patent. Compulsory licenses must be non-exclusive, and patent holders are not precluded from exploiting a national market by the grant of a compulsory license to a third party (including the government).

One way to approach adequacy of compensation is to ask what the licensee would have been required to pay as compensation to the patent holder for a commercial license under ordinary circumstances. Assuming that there is a market for licenses regarding the type of technology involved in the particular case, the market rate would provide an indication at least as to what patent holders might expect from licensing their technology.

However, the “market rate” may be difficult to determine or misleading for a number of reasons. First, in a market characterized by a limited number of patent-holder actors, there may be active or passive collusion among the patent holders that results in a market rate that is higher than would be the case if the market were functioning efficiently. Second, many, if not most, patent licenses are granted among members of the same enterprise group. It may well be in a group’s interest to charge high inter-enterprise patent royalties to reduce tax burdens, and it may be very difficult to disaggregate available data so as to establish what market rates would look like without reference to intra-group licenses. Even in regard to transactions involving nominal competitors, there may be factors such as joint venture interests that affect what might otherwise be presumed to be market-rate transactions.

Another possible approach involves requiring each patent holder to present a detailed justification for its royalty request. The patent holder could be asked to provide specific data on its research and development costs (including any offsetting tax or accounting benefits), whether it received or made use of any government-supported research in developing its

¹ A student who does “adequate” work is a student whose work meets the basic minimum standards, but whose work does not demonstrate qualities above that.

invention, its total global market for the patented invention, the percentage of the global market represented by the country granting the compulsory license, the average rate of return on its patented products, and so forth. The granting authority could on the basis of this data determine what level of royalty would adequately reflect the patent holder's interest in the country in question.

An international organization such as UNCTAD might be relied upon to establish royalty guidelines on an industry or product/process basis that might be used as a benchmark by authorities granting compulsory licenses.

The licensee's royalty obligation may be calculated as a percentage of its income from sales of the licensed product. That income may be represented, for example, by its wholesale sales, and may be net of tax liabilities.

The level of compensation depends on the circumstances of each case, and there are a number of factors that this potentially brings into play.

If a compulsory license is used to remedy an anticompetitive practice, the level of compensation may be adjusted to reflect the need to remedy past misconduct and to affirmatively promote the entry of new competitors in the market. Although Article 31 does not eliminate the requirement of compensation for compulsory licenses to remedy anticompetitive practices, neither does it in any way suggest that this compensation may not be strictly limited to reflect governmental objectives. Article 31(k) expressly recognizes that "The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases."

The authorities granting a compulsory license may also take into account the public interest in effective exploitation of the license as compared with the private interest in earning a particular level of return. For example, if a developing country government is granting a compulsory license to address a public health crisis that affects a large segment of its population, the government could justify the payment of a minimal royalty on grounds that the public interest in the circumstances of the case warrants a reduced royalty.

The economic value of the authorization is to be "taken into account" in establishing the level of compensation. In cases where a compulsory license is granted to achieve an industrial policy objective, the value of the license in the hands of the licensee may be a significant factor in determining the level of payment. Where the license is granted to address urgent public needs, the economic value of the license to the licensee may be a much less significant factor.

F. M. Abbott