Options for Revising the TRIPS Agreement as it Pertains to Essential Medicines

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Introduction

The purpose of this paper is to discuss some of the issues that arise as a consequence of the incorporation of the Trade Related Intellectual Property Rights (TRIPS) Agreement into the WTO, particularly with regard to access to essential medicines by developing countries. The signatories of the TRIPS Agreement were aware that extending intellectual property rights in all member countries would have the effect of increasing, and in some cases dramatically increasing, the price of life-extending pharmaceuticals in developing countries. For this reason, certain provisions were included in the TRIPS Agreement that were intended to lessen some of the most severe health consequences of intellectual property rights provisions.

A risk that was theoretical in 1994 had become a full-blow humanitarian crisis by the 2001 Doha Ministerial. In the intervening period, the spread of HIV-AIDS had reached pandemic proportions. Research into detection and treatment that began in earnest during the 1980's yielded a cocktail of drugs that could reduce the viral load nearly to zero. A disease that was a virtual death sentence two decades ago could now be treated, affording its victims a near normal life.

However, these new drugs are the subject of patent protection typically yielding a treatment cost of $12,000 dollars per year per person; a sum far out of reach of most AIDS victims throughout the developing world. Thus, a disease that has come to be seen as serious but treatable in the west, in the developing world more resembles the bubonic plague which ravaged Europe during the middle of the second millennium.

Tension between the TRIPS Agreement and the ongoing worldwide AIDS epidemic has prompted a discussion of possible amendments or reinterpretations that would

provide consumers in developing and least developed countries access to life-extending pharmaceuticals that are currently the subject of patent protection. During the fourth WTO Ministerial (Doha, November 2001), members of the World Trade Organization (WTO) endorsed the use of Article 31(b) which permits compulsory licensing in the event of a national health emergency. The weakness of the compulsory licensing approach is that pharmaceuticals produced under a compulsory license are constrained by Article 31(f) to be intended primarily for domestic use. As a consequence, countries with little or no pharmaceutical production capacity may still have difficulty procuring life-extending drugs once the TRIPS Agreement is completely implemented in 2005. Thus, the TRIPS Council of the WTO was directed to make recommendations concerning access for least developed countries by the end of 2002.

Proposed Remedies

The TRIPS council undertook the challenge of finding some strategy for providing access to AIDS drugs and other pharmaceuticals to developing countries without undermining the value of the TRIPS Agreement in stimulating and rewarding innovation. Several proposals have been put forward such as (1) suspending dispute resolution under the TRIPS Agreement as it pertains to essential medicines and other similar drugs for countries suffering with an AIDS epidemic; (2) postponing full implementation of the TRIPS Agreement for least developed countries until 2017; (3) extending the compulsory licensing provisions under Article 31 of the TRIPS Agreement to allow middle income countries to supply least developed countries at or close to marginal cost; (4) interpreting TRIPS Article 30 to include a limited exception to patent rights for export of essential

medicines to countries with insufficient pharmaceutical production capacity; (5) developing devices to separate markets (such as establishing a principle of national exhaustion or imposing a tariff against re-export) in order to facilitate deep price discounting in developing countries; (6) technical capacity building in the least developing countries to help them take advantage themselves of the compulsory licensing provisions of the TRIPS Agreement; and (7) increased incentives to price discriminate across markets by the patent-holder through the control of the property rights exhaustion or other mechanisms; and (8) humanitarian assistance in the form of subsidized purchases of pharmaceuticals for distribution in developing countries that lack their own capacity. Each one of the above proposals has weaknesses, as we discuss below.

Price Discounting. Some have argued that the current treatment of property rights exhaustion in the TRIPS Agreement already provides ample incentive for western pharmaceutical companies to provide essential medicines to developing countries at steeply discounted prices. Under the TRIPS Agreement, each country has the right to establish the terms under which property rights are exhausted in their own territory. The United States has adopted the principle of *national exhaustion*. Thus, patented pharmaceutical products initially marketed outside of the United States cannot be resold on the U.S. market without the expressed permission of the patent holder. Similarly, the European Union has adopted a principle of *regional exhaustion* that includes all EU members.

Market separation provided by national/regional exhaustion can facilitate price discrimination across national markets. Thus, the patent holder has a profit-incentive to

charge a profit-maximizing price in each market. In light of the very low ability to pay for essential medicines in sub-Saharan Africa, the profit-maximizing price may constitute only a tiny mark-up over marginal cost.

In spite of the market segmentation created by the exhaustion rights regimes adopted by the United States and the European Union, pharmaceutical companies have been reluctant to avail themselves of this profit-maximizing opportunity. Rather, pharmaceutical companies have, until recently, opted to not even attempt to serve least developed country markets.

There are several possible explanations for this behavior. First, even essential medicines priced at marginal cost may be prohibitively expensive for many developing-country consumers. A second possibility is the fear that deep price-discounting in developing countries will undermine the ability of pharmaceutical companies to charge a profit-maximizing price in industrialized country markets. HMO's and government agencies that purchase a large volume of essential medicines may press their suppliers to offer discounts similar to those offered to developing countries. Thus, domestic political complications created by price discrimination between industrialized and developing country markets may dominate the negligible profit opportunities available on sales to developing country markets.

The political complications may be mitigated somewhat during a severe health emergency. In such instances, pharmaceutical companies can readily represent price discounting more as a donation motivated by humanitarian concern for the very poor and very sick than profit-maximizing price-discrimination. However, it will be more difficult to make such a case with "life-style" drugs such as Viagra.

Compulsory Licensing under Article 31. As a consequence, there appears to be a preference on the part of the large industrialized countries for employing the compulsory licensing provisions under Article 31 as a mechanism for providing access to developing country markets. Under an extended Article 31 that provides for the export of essential medicines produced under a compulsory license, developing country consumers would receive generic rather than patented drugs.

While the use of compulsory licensing for export may finesse the political complications that arise from price-discrimination, opponents are concerned with the impact on the profits of pharmaceutical companies and unintended consequences for the incentive to innovate. This is a nontrivial concern in light of the possibility that some of these generic variants will find their way onto western markets.

For this reason, the United States has sought to limit the scope of diseases, medicines and beneficiaries that would be covered by an amended compulsory licensing provision. However, developing countries balked at the restrictions, arguing that each country should have the uncontested right to unilaterally invoke the safeguards provisions of Article 31. Further, there is no scope-of-diseases restrictions on compulsory licensing for domestic use in middle income countries. Thus, there appears to be little reason to introduce such limits on least developing countries. As a matter of principle, least developed countries should have at least the same level of access to safeguards *de facto* as middle income countries.

Compulsory licensing as a mechanism for providing access to essential medicines could potentially face two further challenges. In order for a middle income country to

supply a least developed country, both must face a health emergency and thus issue compulsory licenses, thereby allowing for the production and export by the middle income country and import by the least developed country. A patent-holder who regards this activity as illegitimate may choose one of two mechanisms to undermine the transaction. First, the patent-holder may choose to sell at a discounted price to the middle income country, thereby obviating the need to produce the drug under a compulsory license. Such a maneuver will effectively eliminate the source of supply to the least developed country. Second, the patent-holder may succeed in delaying the compulsory license by challenging its legality.

Suspending Enforcement. In light of the inability of the members of the TRIPS Council to reach a formal agreement on extending Article 31, the United States and the European Union have publicly declared their intention to suspend enforcement of TRIPS rules against the trade in some drugs produced under a compulsory license that are exported to a least developing country lacking manufacturing capacity. However, simply suspending enforcement in the case of AIDS drugs is *ad hoc* and does nothing to provide a permanent solution to a fundamental weakness in the current TRIPS Agreement.

Additionally, decisions concerning which pharmaceuticals and diseases are the subject of the suspension will, as a practical matter, be controlled by a small number of large industrialized countries. For example, according to U.S. government publications (United States Trade Representative, 2002), the suspension will cover drugs to control infectious epidemics such as HIV/AIDS, tuberculosis, malaria, ebola, African trypanosomiasis, cholera, dengue fever, typhoid and typhus. Current EU-US proposals

would exclude drugs used to treat HIV-AIDS related illnesses such as opportunistic infections and cancer as well as other pervasive disorders such as asthma, cancer and diabetes.

Further, the United States has placed limitations on the countries eligible to receive exports produced under a compulsory license. Countries classified as high income by the World Bank[1] are deemed to have sufficient production capacity or financial resources to acquire essential medicines in a manner consistent with the TRIPS Agreement. Developing countries in the grips of an epidemic will not have the ability to self-identify as is the norm with other safeguard provisions of the WTO Charter. As a consequence, the United States has achieved its desired limit on scope of diseases and pharmaceuticals without reaching a formal agreement in the TRIPS Council.

Perhaps more importantly, the uncertainty created by an *ad hoc* approach undermines the willingness of firms to make costly long-term investments in production capacity either in a potential middle income exporter or a least developed country manufacturing for domestic use. Investors will be unlikely to make the costly commitment to capacity if they fear that their future production will become the target of a WTO dispute.

Postponing Full Implementation. Although the TRIPS Council has so far been unable to agree on amending Article 31, the members did agree to postpone full implementation of the TRIPS Agreement for least developed countries until 2017. However, it is important to note that postponing full implementation provides virtually no relief. Least developed countries, by-in-large, do not have the pharmaceutical production capacity necessary to

[1] Barbados, Brunei, Cyprus, Hong Kong, Israel, Kuwait, Liechtenstein, Macao, Malta, Qatar, Singapore, Slovenia, Taiwan and the United Arab Emirates.

meet a full-blown epidemic and, thus, must purchase life-extending drugs from middle or high income countries. However, middle income countries are still required to implement the TRIPS Agreement on schedule and thus cannot legally produce patented pharmaceuticals for export to least developed countries after 2005. As a consequence, the TRIPS Agreement as it pertains to essential medicines in least developed countries is largely irrelevant.

Indeed, it is often noted that many developing countries had already adopted IPR regimes prior to the requirements imposed by the TRIPS Agreement. While this is the case, the key exceptions include precisely those middle income countries capable of producing and exporting essential medicines. It is the IPR regimes of this small number of middle income countries that were the particular focus of the TRIPS negotiations during the Uruguay Round. Restrictions on the patent violations of this limited number of middle income generic manufacturers will still be imposed on schedule in 2005, thereby effectively cutting off the legal supply of generics to least developing countries absent any other amendments to the TRIPS Agreement.

Article 30. Rather than rely on Article 31, some have argued that Article 30 already provides limited exceptions to patent rights for the purposes of research, prior-use rights, and pre-expiration testing and can be legitimately used by middle income countries to export essential medicines to less developed countries. However, it is the position of the U.S. government (U.S. Department of State, 2002) that such a construction of Article 30 would violate the requirement that exceptions not unreasonably prejudice the legitimate interest of the patent holder.

Subsidized purchases. Humanitarian aid in the form of subsidized purchases of AIDS drugs may seem at first blush to be an optimal solution. Indeed, subsidizing consumption of patented products is a first-best solution for stimulating efficient levels of R&D. However, it is important to realize that the cost of subsidizing purchases from the patent holder will likely be prohibitively expensive and, if undertaken, greatly increase the profits of pharmaceutical manufacturers. For these reasons, it is desirable to attempt to combine a consumption subsidy program with some other mechanism that separates developing and industrialized markets.

For example, the NGO Médecins sans Frontières acquires generic AIDS drugs used in its humanitarian operations from Brazil at a cost of $300 per patient per year. Export is tolerated by the United States and the European Union under its current commitment to suspend dispute resolution concerning the export of some generic drugs to least developed countries. The annual cost of funding such a humanitarian program is far smaller than would be the case if Médecins sans Frontières were required to purchase these drugs from the patent holder at a cost closer to $13,000 per patient per year.

Where Do We Go from Here?

Thus, as of this writing, the *status quo* consists of (1) a combination of a voluntary suspension of dispute resolution in the WTO concerning generics produced under an Article 31 compulsory license and exported to a least developed country and (2) limited additional humanitarian assistance for the purpose of purchasing and delivering pharmaceuticals used to treat an infectious epidemic. Thus, the potential exists to supply

at least some HIV/AIDS patients in the least developed countries with generics priced at or below the marginal cost of production. Yet to be determined are the range of drugs and diseases free from dispute resolution in the WTO and the duration of the suspension. Further, it is unclear whether *official* humanitarian assistance will be used to purchase pharmaceuticals from the patent-holder at the monopoly price or whether these funds will be used to purchase generics priced at or close to marginal cost. As a consequence, the investment environment for potential generic producers is highly uncertain.

From the point of view of the developing countries, it is necessary to determine whether they are satisfied with this *ad hoc* and uncertain approach or, alternatively, whether it is worth pressing for formal changes which regularize the treatment of health emergencies and address the fundamental inequities and inefficiencies in the current TRIPS Agreement.

A First Question

How should WTO rules be amended to address access to essential medicines? Three fundamental approaches present themselves.

The most ambitious is to attempt to reconfigure the TRIPS Agreement to more closely approximate the first-best management of the market for life-extending drugs. Such an approach is the most demanding in terms of the imagination, analytical ingenuity and, perhaps resources, necessary to design and implement such a system but will produce the most efficient outcome from an economic resource allocation perspective and will incidentally produce an outcome which is characterized by a compassionate concern for disease sufferers throughout the world.

A less ambitious approach would be to have a set of secondary IPR rules that are triggered during an international health emergency. Such an approach raises a number of questions upon implementation such as who decides when a health emergency exists, etc.

A third possibility is to accept the limitations of international law regulating property rights. Absent tax-payer funded optimal R&D and production subsidies, we are inherently in a second best world with analytically ambiguous solutions. There may be no practical method for regulating IPR that promotes research and development while satisfying basic humanitarian goals. In this view, each crisis must, at least in part, be managed in an *ad hoc* manner with a mixture of postponing the full implementation of the TRIPS Agreement, suspending enforcement and internationally marshaled charitable donations and humanitarian initiatives.

Efficient Product Development and Intellectual Property Rights

Analytically, the first best-approach to intellectual property is to subsidize its research and development and grant no patent rights or to grant patent rights and subsidize production up to the point where the patent-holder maximizes profits by setting price equal to marginal cost. In light of the fact that neither of these approaches is likely to be adopted for all pharmaceuticals, we must turn to second, third, etc., approaches to providing access to life-extending drugs.

Withdrawing form the TRIPS Agreement as if Pertains to Essential Medicines

Within the context of second-best solutions to financing innovation, one must reconsider the appropriateness of intellectual property rights within the WTO at all.

Panagariya (1999) argues that the TRIPS Agreement emerged as a "TRIPS for MFA" deal in which the developing countries agreed to extend intellectual property rights in exchange for liberalization of trade in textiles and wearing apparel. Panagariya makes the case convincingly that while the industrialized countries gained from both the extension of intellectual property rights and the removal of the MFA, developing countries gained only from the removal of the MFA and have been deeply harmed by the TRIPS Agreement.

The extension of intellectual property rights, particularly as it applies to pharmaceuticals, is clearly welfare reducing from a world point of view and particularly from a developing country point of view. This is the case since most developing countries have virtually no ability to contribute meaningfully to the cost of developing life-extending pharmaceuticals. Thus, there is little or no worldwide gain in terms of new product development funded by developing country purchases. By contrast, the cost to developing countries is enormous, foreclosing access to essential medicines and all that entails in the current health crisis. The monopoly distortion created by the extension of patent protection has served largely to cut many developing countries off from essential medicines. In other words, there has been no *innovation gain* as compensation for the *monopoly distortion loss* brought about by the extension of patent protection to the developing countries.

During the Uruguay Round, it was argued that developing countries would gain from TRIPS because the protection of intellectual property would provide a financial incentive to pharmaceutical firms to invest in drugs used for treating tropical diseases. However,

since the TRIPS Agreement, the opposite has occurred. R&D funds for developing country diseases has declined rather than increased.

The only global benefit of the TRIPS Agreement as it pertains to essential medicines has been to cut off trade in generic drugs that might undermine the monopoly control of patent-holders in the United States and Western Europe. Cutting off generic trade is economically valuable to the extent that the consequent monopoly profits are used to stimulate future product development.

However, the TRIPS Agreement is a blunt instrument, indeed, for this purpose. The United States and the European Union could have cut off the import of generics simply by mutually agreeing to use the domestic regulatory process to enforce property rights protection.

In light of this line of argumentation, the most straightforward method for dealing with the current health crisis is to remove medicines, essential or otherwise, from the TRIPS Agreement. However, countries would be permitted, indeed encouraged, to use their domestic regulatory process to enforce property rights according to the guidelines laid down in the World Property Rights Organization (WIPO). Such a reform, while not first-best, is weakly Pareto improving. The price paid by western consumers and the incentive to innovate would not be disturbed. This is the case since prices in industrialized countries have already been and will continue to be set at the profit-maximizing level. However, use of life-extending drugs in developing countries would rise from approximately zero to a point where price equals marginal cost.

Such an approach would simply formalize what has become the *de facto* response to the AIDS pandemic: suspending dispute resolution concerning property rights infringement for essential medicines.

Although such an outcome could be pursued coöperatively by amending the TRIPS Agreement, it is also the case that developing countries could unilaterally suspend enforcement of the TRIPS Agreement as it pertains to essential medicines. The United States and the European Union may choose to withdraw concessions of equal value under the Nullifaction and Impairment clause of the WTO Charter. However, the value of the withdrawn TRIPS concessions proposed here for western pharmaceutical companies is approximately zero, so the retaliatory consequences of withdrawing from parts of the TRIPS Agreement should not be severe, at least within the confines of the strict letter of WTO rules. Were the United States or the European Union to take such a complaint to dispute resolution in the WTO, the panel may well find in their favor on a point of law but find equally that no damage has occurred to US-EU interests.

Market-Based Solutions within the Current TRIPS Agreement

In the absence of a choice to abandon the TRIPS Agreement as it applies to essential medicines, we would like to argue that a second approach entails providing patent-holders themselves with an incentive to supply developing countries in a health emergency at a price at or below marginal cost.

Although large pharmaceutical companies have been reluctant to engage in price discrimination, Barton (2003) finds increasing evidence of differential pricing. Data gathered by Médecins sans Frontières' Campaign for Access to Essential Medicines

(Pérez-Casas, 2000), suggest that prices for HIV drugs outside the United States are typically 1/5th of the U.S. price and may be as little as 1/68 of the U.S. price. Not too surprisingly, the lowest prices are found in India and Brazil, two countries with healthy generic industries.

Pharmaceutical manufacturers may believe that property rights exhaustion provides inadequate protection against parallel imports, thereby limiting their willingness to engage in price discrimination. Thus, enlisting the power of customs officials in controlling re?xports of deeply discounted products from developing countries may increase the willingness of pharmaceutical firms to price-discriminate across markets. For example, Brown and Norman (2003) have demonstrated that if countries outside of a health emergency zone impose a tariff against re?xports of life-extending drugs equal to

$$t = \frac{c}{1-\frac{1}{\varepsilon_N}} - \frac{c}{1-\frac{1}{\varepsilon_E}}$$

where c is marginal cost and ε_N and ε_E are the elasticity of demand outside and inside a health emergency zone, then the patent-holder will sell at a profit-maximizing price in each market.

In addition to enlisting the power of customs agents to achieve market separation, pharmaceutical firms, themselves, can exercise some control over the supply chain with the use of batch numbers, bar coding, dating methods and differential packaging. Similarly, industrial country governments can support differential pricing through the regulatory process. For example, a product approval may pertain only to a particular production facility.

It should be noted at this point that there is significant scope for "civil society" to minimize the emergence of grey market activities in life-extended drugs. Reputable NGOs, such as Médecins sans Frontières, which purchase drugs for use in their own humanitarian operations, are in an excellent position to prevent at least the whole-sale diversion of drugs to industrialized country markets. Similarly, the Global Fund offers subsidized purchase of drugs for an initial two year period but requires demonstration of program effectiveness in order to continue supporting a program in subsequent years. Finally, it is possible to limit the number of units of a drug receiving a subsidy commensurate with the documented extent of the disease.

Efficiency would be further enhanced by providing some vehicle for subsidizing purchases of drugs. Even when life-extending drugs are offered at marginal cost, a complete regime is prohibitively expensive. For example, a generic package of ART for HIV-AIDS currently costs about $200 annually. While considerably below the $12,000 charged in industrial countries, such a sum still exceeds per capital GDP for some countries most severely impacted by the AIDS epidemic. Concerted efforts include private and national financial contributions to the Global Fund and discounted donations on a contract basis of pharmaceuticals to UNAIDS.

However, it should be noted that the problem with gray-market activities exists for subsidized drugs as well. In order to manage the challenge posed by gray market transactions, the tariff can be raised commensurate with the subsidy to prevent subsidized products from finding their way into industrialized country markets. .

The upshot of the Brown-Norman analysis is that a properly specified configuration of import tariff against re?xports from the emergency zone and subsidized purchases of

drugs in the emergency zone will lead the patent-holder to supply countries in a health emergency at a price they are able to afford, while increasing their own profits. Furthermore, in light of the fact that the opportunity to price-discriminate increases profits for the patent-holder, the duration of the patent can be reduced without undermining the incentive to innovate.

The proposed remedy that arises from the Brown-Norman analysis is strictly Pareto improving. Western consumers benefit from shortened patent duration, pharmaceutical firm profits increase with the opportunity to price-discriminate, developing country consumers have widened access to life-extending drugs and the external effect that arises when western citizens have a humanitarian concern for the well-being of patients in the developing world is internalized through the consumption subsidy. This approach has the added benefit of being a positive and constructive solution to the *impasse* in the TRIPS Council rather than being negative and confrontational, as would be the case if developing countries abridged some of their commitments under the TRIPS Agreement.

The Case for Expanded Compulsory Licensing Provisions

The patent-holder may find that with the added protection against parallel trade provided by a tariff against re?xport and the opportunity to share in the benefits of a consumption subsidy on sales to least developed countries, supplying least developed country markets at a steeply discounted price becomes attractive. However, it is entirely possible that the domestic political concerns remain paramount for pharmaceutical companies supplying industrialized country markets. Thus, generics would remain the only reasonable option for accessing essential medicines for least developed countries. A

formal amendment to the TRIPS Agreement providing for export of drugs produced under a compulsory license to the least developed countries would then be necessary to provide a modicum of security to investors seeking to build production capacity.

Nevertheless the question remains, "Who determines when a health emergency exists: The country in the health emergency, the national government of the patent-holding firm, the TRIPS Council …?" Under the current TRIPS Agreement, the right to declare a health emergency lies with the government in which the health emergency is occurring. In fact, it is generally the case with most safeguard provisions of the WTO Charter that each country is allowed to self-identify. Further, a compelling case can be made that if middle income countries can declare a health emergency and avail themselves of the safeguard provisions in the TRIPS Agreement, then the least developing countries should have the same privileges. An inequity is created when the IPR rules are written in a manner so as to foreclose unilateral access for the least developed countries to meaningful safeguards during a national health emergency that all other countries enjoy.

By the same token, it is clear that liberally resorting to compulsory licensing will undermine the patent system for rewarding innovation. For this reason, low and middle income countries may want to consider agreeing to a set of restrictions on the use of compulsory licensing for *domestic use* in exchange for the right to *export* generics to other countries suffering from a health emergency.

In addition and as discussed above, there are several mechanisms that can be used to protect the rights of the patent-holder in industrialized country markets, once a compulsory license has been issued and generic exports become a possibility. Perhaps, additional domestic regulations concerning the distribution of pharmaceuticals and a

properly specified tariff on generics would allow the patent-holders to tolerate generics supplied to least developed countries.[2]

The Concept of an International Health Emergency Zone

One way in which the TRIPS Agreement might be modified to acknowledge the legitimate concerns with liberal use of compulsory licensing is to introduce a set of mutually agreed-upon criteria for an international health crisis that would trigger a set of exceptions to the TRIPS Agreement. Current WTO law typically allows countries to self-identify when invoking special clauses of the GATT, such as during a balance of payments crisis. However, in the context of an international health crisis, there is much to be gained by identifying groups of countries in a crisis.

In the event of an international emergency, commercial transactions between countries inside and outside of an emergency zone could be regulated by one of three methods. (1) Regional exhaustion of property rights as they pertain to essential medicines could be imposed around countries within the zone. (2) Exports of essential medicines from the emergency zone could be subject to a tariff against re?xports of the sort discussed above. (3) Medicines produced under a compulsory license could be sold only within the zone. In each case, exports (or re?xports) of essential medicines from the emergency zone would be illegal and/or unprofitable.

If, for example, a principle of regional exhaustion or a trade tax were imposed to facilitate price-reductions for a country experiencing an epidemic, maximal price

[2] Sherman Robinson, however, notes considerable resistance to any form of patent infringement, as a general principle. As agricultural subsidies are replaced with patents as a method for rewarding innovation, protecting patent rights globally has become a priority that cuts across sectors of the economy. Thus, even if a compelling case can be made to limit IPR in the case of essential medicines, industrialized country governments may be resistant because of the precedent that such limitations establish for other sectors.

reductions will be available if crisis countries can be identified as a group distinct from those countries who can manage the crisis without special dispensation from international rules regulating property rights. Alternatively, if one or more countries with production capacity are included in the emergency zone and can export to other countries in the emergency zone, then the zone can be supplied under compulsory licensing provisions. Further, placing a group of countries in a zone potentially increases the number of suppliers operating under a compulsory license. A larger number of suppliers will increase the degree of competition, pushing the supply price closer to zero.

One of the weaknesses of the emergency zone concept is that it violates the principle of nondiscrimination. However, as noted by Barton (2003), if this is perceived as a serious weakness, then a principle of national exhaustion can be adopted for essential drugs.

Conclusions

In the preceding discussion we have explored some of the mechanisms that can be used to alter the TRIPS Agreement to create meaningful access to life-extending drugs in developing countries. Several possibilities exist, some more confrontational than others. Much of the attention in the TRIPS Council has focused on trying to amend the compulsory licensing provisions of Article 31. The negative response by the United States, in particular, was motivated by the reality that simply extending compulsory licensing provisions to allow for export does not adequately address the possibility that the market position of patent-holders will be undermined in industrialized country markets. In much of our discussion above, we have focused on the various devices for

separating markets. Introducing such devices will be essential to any TRIPS Council agreement to amend Article 31.

However, it is also the case that many of the strategies for creating market separation will themselves create access to life-extending drugs for developing countries and can be done with the cooperation of pharmaceutical firms. Thus, it is the case that while changes to the compulsory licensing provisions of Article 31 may seem an expeditious solution, deeper reforms may have greater success by in terms of gaining support in the entire TRIPS Council and in expanding access to essential medicines.

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