Article

The Doha Declaration on the TRIPS Agreement and Public Health, Access to Pharmaceuticals, and Options Under WTO Law

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ABSTRACT

The WTO Ministerial recently agreed the Doha Declaration on Public Health, whose political goal is "to promote access to [patented] medicines" in developing countries. This mandate is given to TRIPS Council, who must report by the end of 2002 on solutions to this problem.

I argue in this paper that the pharmaceuticals access problem is, at best, imperfectly remediable by TRIPS Council; and of the options it can choose, the best is to decide that actions to improve access to patented pharmaceuticals are conditionally non-justiciable for the purposes of WTO dispute settlement. This can be done quickly without needing to amend or re-interpret TRIPS itself; and favorable precedents of conditional non-justiciability exist elsewhere in WTO law.

Leaving TRIPS aside, however, the more immediate benefit of the Doha Declaration for pharmaceuticals access results by applying it to GATT. Steps to promote differential pricing of pharmaceuticals for poor countries, or to reduce import tariffs and prices, are both consistent with the Declaration and fall within the jurisdiction of GATT. I propose that a single decision of the WTO Ministerial,

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taken by consensus, is sufficient to simultaneously address a number of pharmaceutical access issues arising under TRIPS and GATT, yielding the maximum benefit for public health.

INTRODUCTION

The World Trade Organization (hereinafter "WTO") is an international organization whose primary purpose is to make and implement the rules of trade between world's nations, most of whom are members of the WTO system. Traditionally, this has meant the trade in goods as controlled by the General Agreement on Tariffs and Trade (hereinafter "GATT"); but in addition, the WTO is also striving to become the lead organization in overseeing the rules of "trade" in intellectual property, which are embodied in the Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter "TRIPS").

For an organization having such a vast reach, it is only a matter of time before the WTO gets into serious trouble. That trouble is now here, in the form of a heated debate over the effect of patent protection on access to pharmaceuticals in poor countries. For the first time in its history, international health and development are being discussed at the highest levels of the WTO.[2] These discussions have now culminated in the November 2001 declaration of the Fourth Ministerial Conference in Doha, and in particular, the Declaration on the TRIPS Agreement and Public Health (hereinafter "Doha Declaration").[3]

The Doha Declaration is a success for the highly visible, international activist movement that over the last three years has illuminated the problem of access to pharmaceuticals in poor countries. International Non-Governmental Organizations (hereinafter "NGOs") such as Action Aid, Doctors Without Borders

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[2] The highest forum in WTO governance is the Ministerial meeting, which is essentially a convocation of the trade ministers of all the WTO member states. Since the inception of the WTO, Ministerial Conferences have been held in Singapore (Dec. 1996), Geneva (May 1998), Seattle (Nov.-Dec. 1999), and most recently Doha, Qatar (Nov. 2001).

[3] Doha Declaration on the *TRIPS* Agreement and Public Health. WTO Doc. WT/MIN(01)/DEC/2, 20 November 2001 [hereinafter *Doha Declaration*].

(alternately referred to in the French, Médecins Sans Frontières) and Oxfam have campaigned strongly in support of the thesis that TRIPS, which requires developing countries to offer patent protection for pharmaceutical products, has had and will continue to have a chilling effect on access to live-saving pharmaceuticals in poor countries. The activists conclude, inter alia, that to improve access, TRIPS needs to be re-interpreted, or possibly amended, to permit more liberal exceptions to patent rights. Such exceptions could include "compulsory licensing," which is the government-ordered divestment of a patentee's exclusive rights in a patent, in favor of a third party who obtains a license to manufacture, import, or sell the patented pharmaceutical.[4] That, combined with more generous transition periods for the "least developed countries" (and possibly other developing countries),[5] is among the strategies activists favor to end what some call a "one-size-fits-all TRIPS," in which rich and poor countries are for the most part treated similarly.

Not surprisingly, the activist thesis is resisted by the international pharmaceutical industry, which is extremely reliant on patent protection for its survival. The disagreement begins at the initial premises: the industry argues that patents have little to do with impairing pharmaceutical access in the poorest countries, while factors such as an absence of international aid finance, weak political

[4] "Compulsory licensing" is therefore a government-ordered sharing or expropriation of patent rights, without the consent of the patentee. This extraordinary remedy is in contrast to "voluntary licensing," which is a consensual transaction.

[5] At this writing, the most significant preferential treatment in *TRIPS* for developing countries is to give a subset of these (the so-called "least developed countries," which the United Nations defines as those having a per capita gross national income of less than $755 annually, plus other serious problems in achieving development) until the end of 2005 to come into compliance with the *TRIPS* intellectual property regime. *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization [hereinafter *WTO Agreement*], Annex 1C, Legal Instruments—Results of the Uruguay Round vol. 31, 33 I.L.M. 81 (1994), Article 66.1 [hereinafter *TRIPS*], *available at* http://www.wto.org/english/docs_e/ legal_e/final_e.htm (last visited March 7, 2002). However, the *Doha Declaration* now extends this and gives least developed countries until 2016 to comply for pharmaceutical products. *See* Paragraph 7. In addition, developing countries which are not "least developed" (e.g., India) may delay the application of product patent protection for some areas of technology (often including pharmaceuticals) until 2005, although their patent laws must have been amended by 2000 to lay the legal framework for product patents in the future. *See TRIPS*, Articles 65.4 and 65.2.

will, and poor medical infrastructure are demonstrably more significant barriers. While the pharmaceutical industry is not totally insistent on a "one-size-fits-all TRIPS," it is also chary of amending TRIPS, because of the danger that greater flexibility for poor countries could "creep" to middle-income or rich countries, which might abuse that flexibility. That would destroy the lucrative markets where the industry generates its nearly all its profits, and importantly for public health, would destroy the revenue base that pays for the research and development of new pharmaceuticals.

This is, of course, a very large debate, and it is not possible for this paper to fully examine the differences—or the common ground—in the activist and industry beliefs. Rather, this paper is concerned with how to best solve a challenge now posed by the WTO Ministerial in Paragraph 6 of the Doha Declaration, which requires a timely policy response. Broadly speaking, the Declaration is concerned with a problem whose legitimacy is acknowledged by activists and industry both: What to do about ensuring that, in poor countries with urgent public health needs and a lack of pharmaceutical manufacturing capacity, patents and patent laws (such as those for compulsory licensing) do not harm access to top quality pharmaceuticals at the best prices? Since Paragraph 6 charges WTO Members, and, specifically, the TRIPS Council, with the mandate of finding "an expeditious solution to this problem . . . before the end of 2002," this paper analyzes and discusses some possible solutions.

This paper is organized in the following parts. We first analyze Paragraph 6 and the Doha Declaration in detail, to appreciate accurately the mandate created by the WTO Ministerial. We then consider two current proposals from the NGO community and the European Communities, and discuss these in relation to that mandate. We then offer a proposal of our own, which we believe excels in resolving the mandate and the problem of pharmaceuticals access more generally. Finally, we discuss some legal issues not in the TRIPS, but in the GATT, which affect the subject matter of the Doha Declaration no less significantly.

II. WHAT IS THE PARAGRAPH 6 MANDATE?

Before attempting to assess or raise any proposals in response to the Paragraph 6 mandate, it is important to understand exactly what that mandate says. That is, what task did the WTO Ministerial intend to set? This requires a close reading of Paragraph 6, not in and of itself, but in relation to the surrounding context of the Doha Declaration. As will be seen, Paragraph 6 itself is textually flawed, and must be read in that broader context to yield a logical and coherent meaning. Paragraph 6 states:

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

Thus it is clear that Paragraph 6 expressly confers a political mandate in respect of countries with the concurrent problems of: (1) "insufficient or no manufacturing capacities in the pharmaceutical sector," and; (2) "difficulties in making effective use of compulsory licensing." There is, curiously, *no requirement* that a country face a genuine public health need, and this leads to perverse results. For instance, in speaking of countries with "insufficient or no manufacturing capacities" for pharmaceuticals, Paragraph 6 apparently includes the (non-existent) pharmaceutical access "problems" of highly affluent, healthy, but small countries without a pharmaceutical sector: Liechtenstein and Luxembourg come to mind. Also, in speaking only of countries that have "difficulties in making effective use of compulsory licensing," Paragraph 6 necessarily excludes countries that are very poor, utterly diseased, but which have no patents on important pharmaceuticals, simply because it is meaningless to speak of compulsorily licensing patents where none exist.

Thus, taken literally, Paragraph 6 is so badly worded that it might be read to "solve" the fictitious problems of rich and healthy

countries, while ignoring the real problems of poor and sick countries! This is, of course, an absurd and unacceptable result; and it is an artifact of the reality that WTO agreements are drafted by "diplomats, not lawyers."[6] TRIPS Council must therefore reject a strictly legalistic interpretation of the Paragraph 6 mandate, and be prepared to supplement that interpretation with the wider political context of the Doha Declaration as a whole, in order to divine and give effect to the purpose of that document. Failure to do this will, almost certainly, lead to policy recommendations that are only poorly effective at solving the health problems of developing countries, while perhaps creating other collateral problems.

Contextually, the key principles of the Doha Declaration are found in Paragraphs 1 and 4, and these clarify the ambiguities of Paragraph 6.

Paragraph 1 states that the WTO Ministerial "recognize[s] the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics." This reflects the historical origin of the Doha Declaration in proposals initiated by developing and diseased countries themselves. *Accordingly, any proposed solution to the Paragraph 6 mandate must be predicated on a country's weak economic and health status, or else that proposal is overbroad*. If this advice is followed, it neatly dispenses with the "Liechtenstein and Luxembourg" problem.

Further, Paragraph 4 affirms the WTO Ministerial's belief "that 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." This is a truly remarkable statement, because once the WTO Ministerial acknowledges and declares that WTO members possess a "*right* to protect public health," it follows that the WTO must contemplate *all steps* within its jurisdiction to advance that right, wherever these "promote access to medicines for all." Once that right is declared, a line is crossed, and it becomes

[6] DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING ANALYSIS AND NEGOTIATING HISTORY 27 (1998).

unprincipled and untenable that the WTO's duty is exhausted by taking measures within the scope of TRIPS, while turning a blind eye to the other agreements in its jurisdiction—legal rights cannot be so artificially dissected.[7] It is a fact that all the WTO agreements which embody that organization's wide-ranging jurisdiction (TRIPS, GATT, etc.) exist on an equal footing, without a hierarchy among them, and so the right declared by Paragraph 4 must pervade them all equally.[8] The alternative interpretation—that WTO member countries enjoy a right to protect public health so far as TRIPS goes, but that other agreements (GATT, say) are untouched by that right—is surely nonsense.[9]

This conclusion has a general and a specific outcome. The specific outcome is that the Paragraph 6 mandate cannot be limited to assisting only those poor countries with "difficulties in making effective use of compulsory licensing . . . under . . . TRIPS," but must extend to other poor WTO Members—including those without patents—whose problems in achieving pharmaceutical access are in any way remediable through the WTO's jurisdiction. The general outcome is that the WTO must exercise that jurisdiction *fully* and take measures beyond just TRIPS, particularly where the barriers to promoting pharmaceutical access lie outside the patent system, as is often the case. Pharmaceutical taxes and tariffs, for example, are non-TRIPS barriers to pharmaceutical access in poor countries,

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[7] Although the *Doha Declaration* is a political and not a legal text, there is an argument that Paragraph 4 is "soft law," because it lends interpretive precision to an existing agreement which is itself legally binding. Nearly all WTO Members are also signatories to the *International Covenant of Economic, Social and Cultural Rights*, which provides at Article 12 for "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health." By making it clear that WTO Members may "promote access to medicines for all" to advance the right to health, Paragraph 4 gives precision to Article 12 of the *Covenant*. *See generally* Gunther Handl et al. (panel discussion), *A Hard Look at Soft Law*, 82 AM J. INT'L L. 371 (1988).

[8] *WTO Agreement*, *supra* note 5, provides that all the substantive agreements listed in Annexes 1, 2 and 3 thereunder "are integral parts of [the WTO] Agreement, binding on all members."

[9] A constitutional law analogy is useful here. It would be nonsense if a constitutional right—say, the Fifth Amendment right that private property not "be taken for public use, without just compensation"—were held to be paramount in one jurisdiction, but meaningless in another. Such a holding would vitiate the purpose and meaning of the Fifth Amendment. *See* U.S. CONST. amend. V.

which the WTO can appropriately work to roll back under GATT and the rules for trade in goods. Thus the Doha Declaration, read in proper context, is not limited to TRIPS, but must provide an avenue to remedy these other problems too.

It does not escape our attention that this contextual interpretation of the Paragraph 6 mandate may be uncomfortable to the TRIPS Council, which has expertise in intellectual property, and not the WTO Agreements as a whole. However, it would be intellectually dishonest of the TRIPS Council to treat the pharmaceutical access problem as limited to a patent-and-TRIPS problem, where the evidence is that in the poorest countries, patenting is almost never the rate-limiting barrier to pharmaceutical access (the situation can be different in middle-income countries).[10] This is important, because if patents infrequently harm pharmaceutical access for the poorest, it stands to reason that reinterpreting or amending TRIPS will infrequently produce a satisfactory solution to that problem. As the European Communities very eloquently submitted:

> Any solution that may result from the current process in the TRIPS Council will not provide the universal panacea of solutions for the problem of access to medicines. [I]mproving access to medicines requires a mix of complementary measures in different areas. . . . The discussion within the TRIPS Council should not over-

[10] Current evidence from a study of patents on antiretroviral medicines for HIV/AIDS in Africa suggests that the poorest WTO members (those that are low-income and least developed) often have few or zero patents on these medicines, while somewhat richer WTO members (those that are middle-income) tend to have more, or even many, patents. Also, in interpreting these data, it is wrong to categorically equate the mere *existence* of patents with a *barrier* to accessing AIDS treatment, because the relationship between patents and access is a complex and nuanced one, which depends on non-market factors such as the medically accepted guidelines for antiretroviral drug treatment; offers by pharmaceutical firms to discount or donate medicines, notwithstanding patent status; and, above all, the availability of international aid finance to purchase drugs. *See generally* Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?*, 286 JAMA 1886-92 (2001). This qualitative distinction in the extent of patenting between low-income and middle-income countries holds for many other medicines and diseases, and not just the antiretrovirals used for AIDS (Amir Attaran, unpublished data) (on file with author).

> shadow these [other] aspects and efforts to make medicines available at affordable prices in a number of international fora. . . .[11]

We would add that among the relevant "international fora" are the WTO Ministerial and General Council, which exercise plenary jurisdiction over all the WTO Agreements.[12] As will be argued below, these bodies, and not TRIPS Council, hold the most effective keys to solving the pharmaceuticals access problem—keys that would help to more equitably discount or donate pharmaceuticals, or to reduce tariffs and the price of imported pharmaceuticals, among others. The Ministerial seemed to anticipate its broader responsibility when it acknowledged in the Doha Declaration that TRIPS is only "part of the wider national and international action [needed] to address [the] problems" of public health and pharmaceuticals access.[13]

Thus it is important that TRIPS Council keep its own limitations in mind. We suggest the best course for TRIPS Council is: (1) to formulate recommendations to address Paragraph 6 within the scope of TRIPS, as it was directed, and; (2) to remit back to the Ministerial such other recommendations that are outside the narrow jurisdiction of TRIPS Council, but which the WTO could implement to advance "WTO members' right to protect public health, and . . . . to promote access to medicines for all." We repeat: this means pushing the Ministerial to take steps under GATT, including rolling back pharmaceutical access barriers such as taxes and tariffs. This two-track action plan meaningfully confronts the pharmaceuticals access problem *throughout* the WTO's jurisdiction, not just in TRIPS, and as such is the most intellectually honest, helpful thing that TRIPS Council might do for poor and diseased countries.

We accordingly propose policy interventions, for both TRIPS and GATT, in the sections below.

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[11] *Draft Communication from the European Communities and their Member States to the TRIPS Council. Concept Paper for Approaches Relating to Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, at Paragraph 4 [hereinafter *EC Proposal*].
[12] Article IV, *WTO Agreement*, *supra* note 5.
[13] Paragraph 2, *Doha Declaration*, *supra* note 3.

III. PROPOSALS UNDER TRIPS

At this writing (mid-February, 2002) two proposals have been widely circulated in response to the Paragraph 6 mandate: one from the European Communities, and another from a coalition of NGOs.[14] [15] Both suggest creating a new exception under Article 30 of TRIPS (which is entitled "Exceptions to [Patent] Rights Conferred") to authorize the manufacture and export of generic pharmaceuticals from producer to poor importing countries, notwithstanding that the pharmaceutical is patented in the producer country.[16] [17] Alternatively, the European Communities, but not the NGO coalition, suggests amending Article 31(f) of TRIPS, to create a new exception to the rule that forbids producer countries from exporting more than a small amount of any generic pharmaceutical they make under compulsory license.[18]

Both these proposals deserve serious consideration. The table below summarizes how each would work, in various scenarios of patenting:

[14] *EC Proposal*, *supra* note 11.
[15] Joint Letter to *TRIPS* Council (Jan. 2002). Signed by Médecins Sans Frontières, Oxfam, Consumer Project on Technology, Third World Network, Essential Action, and Health Gap [hereinafter *NGO Proposal*].
[16] It should be noted that the NGO coalition's proposal does not explicitly limit the Article 30 exception to *developing* countries with pharmaceutical access needs, though this is probably implied from the context. Other NGOs that disagree with limiting the Article 30 exception to developing countries go to lengths to make that disagreement explicit. *See* the statement of the Trans Atlantic Consumer Dialogue, "Consumer Groups Call for the Implementation of WTO Clause Enabling Countries to Import Cheap Medicines", (Feb. 15, 2002).
[17] The *EC Proposal* is, probably through oversight, quasi-explicit about limiting the Article 30 exception to developing countries. This criterion is missing from Paragraph 28 of that Proposal, though it probably is implied via Paragraph 31, which refers back to preceding paragraphs where the challenges of developing countries are discussed.
[18] As it now reads, Article 31(f) requires that a compulsory license must be "*predominantly* [for] the supply of the domestic," and not the export, market.

<table>
<tr><td></td><td></td><td colspan="2">ARTICLE 30 EXCEPTION</td><td></td><td></td><td colspan="2">ARTICLE 31(f) AMENDMENT</td></tr>
<tr><td></td><td></td><td colspan="2">Patent in PRODUCER country?</td><td></td><td></td><td colspan="2">Patent in PRODUCER country?</td></tr>
<tr><td></td><td></td><td>YES</td><td>NO</td><td></td><td></td><td>YES</td><td>NO</td></tr>
<tr><td rowspan="2">Patent in IMPORTING country?</td><td>YES[19]</td><td>Producer country relies on Article 30; <u>and</u> importing country must issue compulsory license.</td><td>Importing country must issue compulsory license.</td><td rowspan="2">Patent in IMPORTING country?</td><td>YES</td><td><u>Both</u> producer and importing countries must issue compulsory licenses (2 licenses total).</td><td>Importing country must issue compulsory license.</td></tr>
<tr><td>NO</td><td>Producer country relies on Article 30.</td><td>No problem.</td><td>NO</td><td>Producer country must issue compulsory license.</td><td>No problem.</td></tr>
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This table points out a relevant, but easily overlooked, difference between the Article 30 and 31(f) proposals: both may be *theoretically* workable, but where there is a patent in the producer country, the Article 30 exception is more *politically* workable than the Article 31(f) amendment. Why? Unlike the Article 31(f) amendment, an Article 30 exception allows the producer country to manufacture and export *without* issuing a compulsory license. This is significant, because compulsory licensing is such an extraordinary remedy that a producer country's government is unlikely to make that effort just to help a poor country wanting to import pharmaceuticals—indeed, governments can be slow to act on the

[19] It is theoretically possible that an Article 30 exception could be created also for *importing* countries, to circumvent the requirement of issuing a compulsory license for importation of patented pharmaceuticals. However, this is found in neither the *EC* nor the *NGO Proposals*, and so it is not further considered.

health needs of their own citizens, much less rush to invoke compulsory licensing every time foreigners want to import a medicine.[20] It should be remembered that compulsory licenses for pharmaceuticals are so rare and exceptional that no WTO member has issued one for the manufacture of a generic product since TRIPS entered force six years ago (though threats have occurred).[21]

Considering these factors, it is likely that even after amendments to Article 31(f), compulsory licensing for export to poor countries would rarely if ever occur. It therefore seems much more operationally feasible that exporting countries would make the one-off amendments to their domestic patent laws that would be necessary to implement an Article 30 exception.

As between the Article 31(f) amendment and the Article 30 exception, then, the latter is politically more workable. From the activist perspective, it is certainly more straightforward to put into use. From the industry perspective, it avoids broaching amendments to TRIPS, which could lead to the undoing of TRIPS in more dangerous ways (e.g., tampering with Article 27.1 and WTO members' obligation to offer patent protection for pharmaceuticals). From all perspectives, it is likely to be more expeditious, which means less time and energy spent on conflict, and more rapid progress toward solving what could be a future barrier to pharmaceutical access.[22]

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[20] Compulsory licensing must be invoked on a case-by-case basis owing to Article 31(a), which stipulates, "authorization of [compulsory licensing] shall be considered on its individual merits".

[21] For something that has never been used, compulsory licensing excites a surprising amount of confrontation, pitting activists who tirelessly advocate it, against the pharmaceutical industry that lives in fear of it. It has acquired a mythical power rather like the nuclear bomb: a device whose significance is found in the threat, and not the eventuality, of its use. To date, in every case that a country has threatened to compulsorily license a pharmaceutical, it has backed down from that threat after negotiating a mutually satisfactory agreement. Examples include Brazil's threats for less expensive antiretroviral drugs, and the United States and Canada's threats for less expensive ciprofloxacin (manufactured by Bayer and sold under the brand name Cipro) in the event of an anthrax bioterrorist attack.

[22] It should be remembered that any amendment to *TRIPS*, respecting Article 31(f) or otherwise, would probably be delayed until after the current Round of WTO negotiations is concluded, and this can take a very long time. Although amendments can theoretically occur at any Ministerial on a 2/3 vote, this has never happened, and even if it did countries

Having said this, there is a third proposal we believe is preferable to the Article 30 approach. We propose that the Paragraph 6 mandate is better satisfied by a *rule of non-justiciability,* narrowly tailored to deal with the manufacture and export of generic versions of patented pharmaceuticals, when these are intended for poor and diseased countries that lack pharmaceutical manufacturing capacity. The rule of non-justiciability would exempt this conduct from WTO dispute settlement, but would do so conditionally; if the conditions were broken, the rule would be set aside, and dispute settlement could proceed against the offending country. *That is, the rule of non-justiciability does not give blanket immunity from dispute settlement, but a rebuttable immunity, which lets dispute settlement proceed when abuse is involved.* An example of abuse would be, for example, if generic pharmaceuticals manufactured under protection of the rule for a poor and diseased country were instead wrongfully exported, to a rich and developed country.

In other words, the rule of non-justiciability makes careful and tailored use of the dispute settlement system to solve the Paragraph 6 mandate. This has at least three advantages over the Article 30 approach.

First, it skirts some of the potential conflicts between the Article 30 approach and other Articles of TRIPS. For example, it is not self-evident how the Article 30 exception, consistently invoked with respect to pharmaceuticals, could be reconciled with the requirement in Article 27.1 that "patents shall be available and patent rights enjoyable without discrimination as to. . .the field of technology" of the invention. Similarly, it is not self-evident how an exception created in the domestic patent law of a producer country, which operationalizes the Article 30 approach by authorizing the manufacture and export of generic versions of patented pharmaceuticals for nationals of poor countries, but not for nationals of developed countries, could be reconciled with the Article 4

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objecting to the amendment could refuse to be bound by it. *See* Article X:3, *WTO Agreement*, *supra* note 5. As for waiting for a new Round, it is relevant that the Uruguay Round took nearly eight years to complete, plus a further two years to achieve ratifications. The Doha Round could easily take just as long.

requirement of Most-Favored-Nation Treatment. Neither the EC nor the NGO proposals explain how these conflicts are to be addressed.[23]

Second, it has none of the difficulties that Article 30 encounters with unfavorable case law. The only WTO Panel decision to date to have seriously considered Article 30 interpreted it very narrowly, and ruled that it is illegal to manufacture and stockpile a patented product, even if that stockpiled product is *never sold* while the patent remains in force.[24] If that conduct cannot be authorized under Article 30, a fortiori it seems impossible to authorize the manufacture for export and sale of a product all the time that the patent remains in force. This means that any proposal to operationalize the Article 30 approach must create an exception for the latter situation, while maintaining the illegality of the former situation, or it will in effect "repeal" existing case law, causing legal uncertainty.

Finally, unlike the Article 30 approach, which for the reason just explained must break new legal ground, there are already precedents for a rule of non-justiciability in WTO law. One is found within TRIPS itself, at Article 6, which makes disputes with respect to exhaustion of intellectual property rights totally non-justiciable. A more nuanced, better example is found at Article 8 of the Agreement on Subsidies and Countervailing Measures, which designates a number of subsidies that are not justiciable for purposes of

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[23] Neither the *EC* nor the *NGO Proposals* mention the most-favored-nation conflict at all. The *EC Proposal* mentions the Article 27.1 issue, but does not offer any solution. *See* Paragraph 33, *EC Proposal*, *supra* note 11. The *NGO Proposal* recommends language for the Article 30 exemption that is facially neutral and "that is broader than medicines, and does not raise concerns regarding Article 27.1 restrictions on discrimination by field of technology." However, this is unlikely to work, because even a facially neutral exception can discriminate in violation of Article 27.1, if in practice it is invoked repeatedly in respect of a single technology, such as pharmaceuticals. This is because in WTO law, it is not just the *substance* of a rule that is reviewable for discrimination (de jure discrimination), but also the *manner* in which that rule is applied (de facto discrimination). *See* the Appellate Body report in *United States—Import Prohibition of Certain Shrimp and Shrimp Products*, WTO Doc. WT/DS58/AB/R (Oct. 12, 1998); and the Panel report in *Canada—Patent Protection of Pharmaceutical Products—Complaint by the European Communities and their Member States*, WTO Doc. WT/DS114/R (Mar. 17, 2000), at Paragraph 7.94.

[24] The Panel held that this conduct is not a "limited exception" which can be exempted under Article 30. *See Canada—Patent Protection of Pharmaceutical Products—Complaint by the European Communities and their Member States*, *supra* note 23.

countervailing duties, including certain subsidies that are oriented to regional economic development.[25] This is not so different in principle from declaring that certain, limited exceptions to patent rights are non-justiciable to promote health and human development. Importantly, the Article 8 immunity for development-oriented subsidies can be lifted in cases of abuse, following an investigation by the WTO Committee on Subsidies and Countervailing Measures. If the Committee confirms abuse, then dispute settlement can go ahead.[26] Some similar mechanism to this one for an independent investigating committee, led by trade and health experts together, could be used to set aside the rule of non-justiciability where an illicit pharmaceutical trade occurs under the guise of an exception to patent rights.[27] We stress this proposal is to mutual advantage: poor countries gain from the inclusion of health experts in what would otherwise be a dispute process led only by trade officials; and industry gains from having an independent investigation of alleged violations, which helps to "de-politicize" the entry into dispute resolution.

We emphasize that these considerations are not meant to dismiss the Article 30 approach outright—with careful thought, probably it can be made workable. Our only points are that the rule of non-justiciability: (i) is more consistent with the overall legal scheme of TRIPS, and; (ii) can draw on useful precedents already found in WTO law, which the Article 30 approach cannot. In other respects, the two options can be made comparable, including in making provision for compensation to the patent holder.[28]

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[25] Article 8.2(b).

[26] Articles 8.4 and 8.5.

[27] For an example where WTO law calls on dispute panels to seek "advice from experts" on "scientific and technical issues," *see* Article 11(2) of the *Agreement on the Application of Sanitary and Phytosanitary Measures*.

[28] Unlike Article 31, which entitles the patentee to "adequate remuneration . . . taking into account the economic value of the authorization" to the compulsory licensee, neither the Article 30 nor the non-justiciability approach have an intrinsic rule for compensation. Certainly *TRIPS* Council will need to supply some such rule for compensation, and preferably, it should be one which is expeditious and avoids the bureaucracy of "double compensation" when a pharmaceutical is patented in both the producing and importing countries. *See NGO Proposal*, *supra* note 15.

The question then arises of how to actually operationalize the Article 30 or non-justiciability approach within the framework of WTO law. Neither the EC nor the NGO Proposals offer much by way of explanation, but both assert that the WTO could propound a new "interpretation" of Article 30. It is debatable whether this would work. The procedure for adopting official interpretations is found in Article IX:2 of the Agreement Establishing the World Trade Organization (hereinafter "WTO Agreement"), which states that an interpretation "shall not be used in a manner that would undermine the amendment provisions" that also exist.[29] That is, an interpretation cannot achieve by the back door what would otherwise require an amendment. It is here that the potential conflict of an Article 30 interpretation with Article 27.1 (non-discrimination) and Article 4 (most-favored-nation) appears problematic: is the WTO allowed to adopt an official "interpretation" of Article 30 that, while not de jure violating Articles 27.1 and 4, will de facto violate these Articles once it is relied on and used? That is arguably the case if the Article 30 interpretation, put into practice, only affects pharmaceuticals, or only benefits nationals of poor countries. Might the Article 30 interpretation in this case be impliedly overruling Articles 27.1 and 4, making it a covert (and prohibited) amendment?[30] There being no precedent in WTO law for an "interpretation"—Article IX:2 seems to have never been used—no clear answers to these questions exist.

An alternative might be to use the waiver of some kind, but this raises some important uncertainties because the word "waiver" has a specific legal meaning in the WTO Agreement, and comes with specified legal procedures that must be obeyed. One advantage is

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[29] See *WTO Agreement*, *supra* note 5. The different amendment procedures are contained in Article X.

[30] It has been said that the interpretation power "may not . . . do violence to the text of the [*TRIPS*] Agreement. It cannot change 'yes' to 'no' or 'no' to 'yes.'" *See generally* Frederick M. Abbott, *The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference*, Friends World Committee for Consultation, Quaker United Nations Office—Geneva, Occasional Paper 7 (Sept. 8, 2001), *available at* http://hostings.diplomacy.edu/quaker/new/doc/ OP7%20Abbott1.pdf (last visited May 6, 2002). It is beyond the scope of this paper to consider Professor Abbott's "no-to-yes" test in detail, but assuming its correctness for argument's sake, an interpretation of Article 30 that authorizes actions that would otherwise violate Articles 27.1 and 4 seems problematic.

that the waiver procedure has some very recent (2001) precedent behind it.[31] But a disadvantage is that the waiver procedure appears slow and cumbersome: any WTO Member may apply for a waiver, but it takes an act of the Ministerial to grant these,[32] and it meets only every two years.[33] Also, any waiver lasting over one year must be reviewed *each year thereafter* by the Ministerial[34] (or, between its meetings, by the General Council[35]). In practice, much of this burden is likely to be shouldered by TRIPS Council, but that still leaves the problem that year-to-year decision-making could complicate governments' ability to make long-term public health plans. Also, if seeking waivers ever became popular, managing applications and annual reviews for each pharmaceutical exporting country (or perhaps, for each pharmaceutical product they export?) could eat up no small amount of the Ministerial or TRIPS Council's time. At this writing there appears to be no precedent for annual reviews at TRIPS Council, and so how onerous or time consuming this would be must be treated as an unknown.

Compared to these options, operationalizing the rule of non-justiciability is easier. A single, one-time "decision" of the Ministerial by consensus suffices both to determine when and for whom the rule of non-justiciability applies,[36] what compensation is

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[31] The two waivers now in force are *European Communities—The ACP-EC Partnership* Agreement, WTO Doc. WT/MIN(01)/15 (Nov. 14, 2001), and European *Communities—Transitional Regime for the EC Autonomous Tariff Rate Quotas on Imports of Bananas,* WTO Doc. WT/MIN(01)/16 (Nov. 14, 2001).

[32] The Ministerial grants waivers on the advice of *TRIPS* Council. *See* Article IX:3, *WTO Agreement*, *supra* note 5. Note also that the General Council probably can grant waivers when the Ministerial is not in session. *See infra* note 35.

[33] Article IX:1, *WTO Agreement*, *supra* note 5, states that the "Ministerial Conference . . . shall meet at least once every two years." In practice, Ministerials have met every two years, and not more often. *Supra* note 2.

[34] Article IX:4, *WTO Agreement*, *supra* note 5.

[35] Article IV:2, *WTO Agreement*, *supra* note 5, reads that "in the intervals between meetings of the Ministerial Conference, its functions shall be conducted by the General Council."

[36] Article IV:1, *WTO Agreement*, *supra* note 5, reads that "the Ministerial Conference shall have the authority to take decisions on all matters under any of the Multilateral Trade Agreements." There are no explicit constraints on this power of decision, so it can be used imaginatively. Article IX:1 further states that decision-making shall normally be by consensus.

due to the patentee,[37] and to amend Appendix 2 of the Dispute Settlement Understanding (hereinafter "DSU"),[38] where all the "special [and] additional rules" of WTO dispute settlement are located.[39] That is, the rule of non-justiciability can be made into law using an established mechanism in the DSU, needing only that the WTO Ministerial take a "decision" by consensus; and this avoids all the difficulties associated with "interpretations" or "waivers."[40] The advantages of the "decision" procedure are further underscored by two precedents, including one where a decision was used to prescribe special dispute settlement procedures for the General Agreement on Trade in Services,[41] and another where a decision was used to create new rules "notwithstanding the provisions" already found in the WTO agreements.[42] It is therefore absolutely clear that a decision can hone the dispute resolution procedures to introduce a new rule of non-justiciability for TRIPS, and apparently can do so notwithstanding inconsistency with other WTO law.

[37] Article 31(h) of *TRIPS* is a good starting point in deciding what constitutes a reasonable standard of compensation; *but see supra* note 28.

[38] Note that the procedure for amending Appendix 2 of the DSU is less involved and problematic than the amending procedure for *TRIPS* discussed earlier. A consensus decision of the Ministerial is required to amend the DSU, and that amendment automatically binds all WTO members. *See* Article X:8, *WTO Agreement*, *supra* note 5. Also note that the full (and never used) name of the DSU is the *Understanding on Rules and Procedures Governing the Settlement of Disputes*.

[39] The DSU lays down the ordinary dispute settlement rules, but makes these "subject to such special or additional rules and procedures on dispute settlement . . . as are identified in Appendix 2 [of the DSU]." *See id.* at Article 1:2. At this writing Appendix 2 lists or has listed eight sets of special rules and procedures for dispute settlement. It is a well-used mechanism.

[40] *Compare* Article IX, Paragraph 1 (decisions), *with* Paragraph 2 (interpretations) and Paragraphs 3 and 4 (waivers).

[41] The *Decision on Certain Dispute Settlement Procedures for the General Agreement on Trade in Services* [hereinafter *GATS*] lays down special qualifications for dispute settlement panelists in *GATS* cases, which differ from the ordinary qualifications required by Article 8 of the DSU. Because the *Decision* is listed Appendix 2 of the DSU, it takes precedence. If the dispute settlement procedures in *GATS* have been changed using a decision, arguably it should be possible to do the same for *TRIPS*.

[42] The *Decision on Financial Services* lays down a specific timeline for WTO Members to finalize their positions on trade in the services sector "notwithstanding the provisions of Article XXI of the [*GATS*]." It is beyond the scope of this paper to consider whether decisions ought to covertly amend the WTO agreements, as this seems to, and the author's only point is that the WTO has done it before.

We conclude that a carefully tailored rule of non-justiciability, rebuttable in cases of abuse, is the most practical way to meet the Paragraph 6 mandate. One decision of the Ministerial by consensus can enact it, while avoiding the fraught issue of amending TRIPS, and the difficulties of an "interpretation" or a "waiver." It also has the weight of some precedent behind it, which these other options do not.[43]

Finally, we reiterate one point of tremendous importance: no matter what the legal specifics of the chosen solution, the success or failure of the Doha Declaration depends on having appropriate eligibility conditions. It would be devastating if a legitimate exception to benefit poor countries were hijacked and turned into loophole for rich countries. The incentive for future pharmaceutical research and innovation lies almost totally in rich country sales, and if concessions were to "creep" into this market, that incentive would be spoiled, with dire results for the future of public health. This fact is recognized and agreed by many others.[44] [45] [46] Eligibility conditions therefore must define, with meaningful precision, which countries: (i) are poor, and; (ii) have disease burdens disproportionate to the local pharmaceutical manufacturing capacity. This sounds straightforward enough, but in practice selecting which countries are "in" and which are "out" is an inexact science, and has enormous potential to become politically contentious. Conflict can be minimized by basing eligibility not on ambiguous guesswork or bare prejudice, but instead on *objective, recognized statistical criteria*—for example, United Nations data sources of wealth, health and industrial status. Statistical methods promote transparency and consistency as no other set of rules can. The alternative—ambiguity—is both unfair and dangerous for everyone: deserving

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[43] These same considerations apply to the Article 30 approach, if for some reason that is preferred over the rule of non-justiciability: within WTO law, a "decision" is simpler than a "waiver," more legally appropriate than an "interpretation," and has the weight of precedent that these other two lack.

[44] *See* the WHO Commission's report, *Macroeconomics and Health: Investing in Health for Economic Development* (2001).

[45] Report of the Workshop on Differential Pricing and Financing of Essential Drugs, convened by the WHO and WTO secretariats (Apr. 8-11 2001, Høsbjør, Norway).

[46] *EC Proposal*, *supra* note 11.

countries will be unsure of their eligibility and will hesitate before using the Paragraph 6 exception, while undeserving countries will seize on any ambiguity to abuse the rules, leading to "creep." We therefore very strongly recommend that the Ministerial's decision incorporate guidance for statistically-based eligibility criteria, along with a rapid procedure to investigate and lift the immunity from dispute settlement when countries engage in wrongful practices (discussed above).[47]

III. PROPOSALS UNDER GATT

We have argued that when the WTO Ministerial declared that its Members have a "right to protect public health," it set a fundamental norm that it cannot (except dishonestly) be confined to the TRIPS agreement, but that this norm affects all of the WTO's jurisdiction, and all the WTO agreements. We discuss in this section several issues arising within the subject matter of GATT, and which if given the necessary attention could have a tremendous impact on improving pharmaceutical access. Briefly, these are: whether it is allowed under GATT to deeply discount pharmaceuticals for poor countries; whether those countries can reap the benefit of those discounted pharmaceuticals, without losing out to arbitrageurs; and whether prices can be further lowered by removing import tariffs for pharmaceuticals.

To begin with, it is important to have a factual and pragmatic understanding of what has succeeded in the recent past to improve access to newer pharmaceuticals (i.e., those that are new enough to maybe be patented). Most of the progress that has been made revolves around negotiating *deep discounts* or *donations* to supply the public health system of poor countries.[48] The leading example is

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[47] We are currently researching various methods to aggregate different world development indicators (e.g., those published by the WHO, United Nations Development Programme, World Bank, etc.), to create a manageable, principled and transparent statistical method to determine eligibility. We will report the findings of this research elsewhere at the earliest possible date, at or around the publication date of this paper.

[48] In this paper "discounts" and "donations" are discussed at times together, and at times separately. It should be remembered, though, that they are conceptually related: a donation is simply a 100% discount.

the Accelerating Access Initiative, which is a partnership of UNAIDS with six pharmaceutical companies, all of whom are discounting (usually by about 90%) or donating their antiretroviral drugs for AIDS. Other important schemes include the Lymphatic Filariasis Program (donating albendazole), the Mectizan Donation Program, the Zithromax Donation Program, and so on. Expanding on these generous discount and donation programs is often economically feasible for the pharmaceutical industry, and has the endorsement of many health experts, including the authoritative WHO Commission on Macroeconomics and Health.[44] [45] In short, there is widespread agreement, among industry and activists alike, that facilitating more discount or donation programs would benefit public health.[49]

Against this background of agreement, the difficulty is that pharmaceutical industry's ability to engage in discount and donation programs is seriously complicated by unfavorable GATT rules, and these should be changed. This is because any program of discounts or donations for poor countries runs into: (1) GATT's antidumping prohibitions, at least in theory, and; (2) vulnerability to arbitrage, where GATT's prohibition against quantitative restrictions appears to rule out barriers that could halt discounted products from being re-imported back to rich countries.

Consider first arbitrage, which is by far the most serious problem. Companies that agree to supply discounted pharmaceuticals to poor countries, at or near the not-for-profit price, run the risk that unauthorized wholesalers (arbitrageurs) in those countries will hoard the supply intended for poor people, only to re-export it back to rich countries, undercutting profit-making sales there—medicines intended for Luanda end up diverted to Lisbon, robbing poor people

[49] It should be noted that activists, while not opposed to pharmaceutical donations, are sometimes ambivalent about them. Médecins Sans Frontières, for example, "does not believe that drug donations are a long-term solution to the access crisis," but agrees "drug donation programmes can be a short-term solution in some situations." MSF is much more optimistic about pharmaceutical discounts, or in its terminology, "equity pricing," which it defines as "pricing policies that ensure that . . . the price of a drug is fair, equitable and affordable, even for a poor population and/or the health system that serves them." *See* Médecins Sans Frontières, Campaign for Access to Essential Medicines, Frequently Asked Questions, *at* http://www.accessmed-msf.org/campaign/faq.shtm (last visited May 6, 2002).

of their benefit, and costing the pharmaceutical company revenue. The capacity of the customs service or health ministry is often insufficient to interdict this unauthorized trade, especially in the least developed countries where the need for discounted pharmaceuticals is the most acute. While arbitrage has not been too problematic to discount and donation programs so far, it could become so, and securing guarantees against arbitrage is *absolutely* important if companies are to be persuaded to discount or donate "blockbuster" (i.e., very profitable) products for poor countries.[50] As the EC Proposal notes:

> [Without] such conditions [against arbitrage], there could be a risk that any abuse . . . would undermine confidence in . . . initiatives taken to supply medicines at affordable prices to poor countries and weaken industry support for any subsequent initiative on access to medicines.[51]

This is exactly correct. Although the EC raises this point in the context of TRIPS, the problem and its solution actually belong to the domain of trade in goods—or GATT.

We propose that the most appropriate way to introduce anti-arbitrage measures is by a limited exception to Article XI of the GATT. Legally, the problem to be solved is that discounted pharmaceuticals sold to poor countries are "like products" to those sold at full price to the rich countries; and therefore, to interdict arbitrage from poor to rich countries, quantitative restrictions have to

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[50] Pharmaceutical companies have stressed the importance of this precondition on many occasions when speaking with this author. It is probably because there are no secure guarantees against arbitrage now that only pharmaceuticals with modest or no market in rich countries are discounted or donated. For example, a malaria drug sold cheaply or donated in poor African countries is unlikely to be arbitraged back to Europe or North America, because the demand for malaria drugs is small there. But a discounted or donated asthma drug, which has sales measured in the billions of dollars in Europe or North America, might very well be arbitraged, with the company losing significant revenue for its humanitarian gesture. Stopping the conditions for arbitrage is important to making discounts and donations viable in the latter case, and this can be of great public health significance. Asthma and other chronic obstructive lung diseases rank seventh in causes of death in developing countries, ahead even of malaria. *See* WHO Global Burden of Disease Study.

[51] *EC Proposal*, *supra* note 11, Paragraphs 24-25.

be imposed at exportation and/or importation—in this case, a prohibition or (effectively) a quota of zero. As the law now stands, that prohibition would violate Article XI:1;[52] and it cannot be assumed that violation would be justified under GATT's human health exception in Article XX(b).[53] As already explained, this could be remedied by a one-time "decision" of the Ministerial by consensus, GATT itself does not need to be amended.[54] The required decision would deem permissible anti-arbitrage prohibitions as between poor and rich countries for discounted pharmaceuticals, notwithstanding Article XI:1.[55] Further, it could call on rich WTO Members both to amend their domestic laws to put these anti-arbitrage rules in place, and also, to refrain from using the deeply discounted prices offered to the poorest countries as a "benchmark" in the setting pharmaceutical prices at home.[56]

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[52] *GATT* Article XI is entitled "General Elimination of Quantitative Restrictions." Subparagraph 1 reads:

> No prohibitions or restrictions other than duties, taxes or other charges, whether made effective through quotas, import or export licences or other measures, shall be instituted or maintained by any contracting party on the importation of any product of the territory of any other contracting party or on the exportation or sale for export of any product destined for the territory of any other contracting party.

Note that where an import prohibition is concerned, that perhaps is legal on this wording, if one takes the narrow view that the arbitraged pharmaceuticals are not the "product of the territory" of the poor country from which they are re-exported. No such creative interpretation works for export prohibitions, however, which are undoubtedly prohibited. *Id.*

[53] Article XX(b) allows non-discriminatory derogations from *GATT* where "necessary to protect human, animal or plant life or health." However, it has often been interpreted very narrowly by Panels, and it cannot be assumed that Article XX(b) would save this sort of Article XI:1 violation.

[54] *See Decision on Financial Services*, *supra* note 42.

[55] Note that in the *GATT*, it is allowed to discriminate on the basis of field of technology; there is no equivalent to Article 21:1 of *TRIPS*. It is therefore no problem to limit this remedy to pharmaceuticals only.

[56] At this writing, Canada and several European countries practice statutory benchmarking or "reference pricing," which draws on the prices of a pharmaceutical in other developed countries to set the price in the home market, often by taking the average of those prices or applying some other mathematical formula. However, it would be obviously damaging if benchmarking grew to include *developing* countries, such that a government with the economic strength of (say) Germany set reference prices based on the deeply discounted, non-profit prices offered to Afghanistan, Burkina Faso, Congo, or the like. This sort of aggressive benchmarking would destroy the pharmaceutical industry's support for differential pricing between rich and poor, and would be devastating to public health, which

At the same time, it is also worth addressing the issue of antidumping, although this is perhaps only a theoretical problem, and is not now hindering access to discounted or donated pharmaceuticals. Article VI of the GATT defines dumping as, inter alia, the practice "by which products of one country are introduced into the commerce of another country at less than the normal value of the products . . . when destined for consumption in the exporting country".[57] Dumping can lead to dispute settlement if its "effect . . . is such as to retard materially the establishment of a domestic industry."[58] Both conditions appear to be met where a deeply discounted or donated pharmaceutical is exported to a developing country lacking a pharmaceutical manufacturing industry of its own. Nevertheless, it almost inconceivable that such a practice would lead to a dispute: a country whose health ministry is importing discounted or donated pharmaceuticals is unlikely to launch a dumping complaint from its trade ministry. Thus, the only way that Article VI might become problematic is if some unrelated antidumping litigation were to set a precedent that had a chilling effect on discounts or donations. Nothing is lost by tidying up the law preemptively; and again, a Ministerial "decision" is sufficient to deem that pharmaceutical discounts and donations for poor countries do not trigger concerns about dumping.

Last of all, there is a pragmatic point about pharmaceutical tariffs. It is woefully counterproductive that companies might deeply discount a pharmaceutical, only to have that price driven up by an import tariff, yet this is the case in many poor countries now. In Africa, tariffs can add 20% to the import price, of *both* brand-name and generic products.[59] The case against pharmaceutical tariffs is acknowledged by activists, the pharmaceutical industry, and the

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is why a Ministerial decision to deal with anti-arbitrage should, politically at least, commit rich countries to eschew it. For an example of a benchmarking law, *see* Canada's Patent Act, R.S.C. 1984, c. P-4, §§ 79-103; and Schedule 1 of the Patented Medicine Regulations 1994, SOR/94-688.

[57] Articles VI:1 and VI:1(a).

[58] Article VI:6(a).

[59] Harvey E. Bale, Jr., *Consumption and Trade in Off-Patented Medicines*, Commission on Macroeconomics and Health Working Paper No. WG 4: 3 (May 2001), *available at* http://www3.who.int/whosis/cmh/cmh_papers/e/pdf/wg4_paper03.pdf (last visited May 6, 2002).

WHO Commission on Macroeconomics and Health alike—it is not controversial. Because the long-run economic benefits to poor countries of improved health certainly outweighs the one-off revenues that tariffs generate, it is reasonable that poor countries agree to abolish these tariffs as their reciprocal contribution to the objects of the Doha Declaration. The WTO's authority to facilitate a multilateral agreement doing so is found in Articles II and XXVIII*bis* of GATT, which aim at tariff reductions generally.

In closing, we stress that these GATT issues must not be treated as ancillary to the TRIPS issues, but are of equal, if not greater, importance to the Doha Declaration's goal of pharmaceutical access. At this writing, the risk of arbitrage hinders the expansion of pharmaceutical discount and donation programs, and tariffs make medicines costlier than necessary. These problems exist *already*, and are costing lives *today*. By comparison, TRIPS will not be problematic before 2005, when developing countries must start to patent pharmaceutical products, threatening the supply of generics.[60] It would therefore be utterly mistaken to believe that the TRIPS issues are pressing while the GATT issues can wait—the timeline is just the opposite, and anyway, both can be dealt with together, in a single decision of the Ministerial.

We therefore suggest that TRIPS Council immediately remit these GATT issues to the Ministerial or General Council (or, better still, directly to the Council for Trade in Goods), explaining that the Doha Declaration mandate cannot be solved by TRIPS Council alone. The WTO's other jurisdictions must be engaged too. To repeat, this is the most intellectually honest, helpful thing that TRIPS Council might do for poor and diseased countries.

[60] This is acknowledged in the *EC Proposal*, *supra* note 11, Paragraphs 12 and 17. Médecins Sans Frontières notes the problem that "sources of affordable medicines may dry up when producer countries such as India reach their 2005 deadline for TRIPS implementation." *See* Ellen 't Hoen, *Doha: a Breakthrough for Public Health?*, Médecins Sans Frontières, ACCESS NEWS (Feb. 2002).

CONCLUSION

As the above has hopefully illustrated, there are concrete steps that the WTO can take within its total jurisdiction to deliver on the Doha Declaration's promise of health for poor people. We will not reiterate the reasons for doing so, except to say that they are pressing, and offer a valuable opportunity for the WTO to demonstrate that globalization can be equitable, for rich and poor alike. For an institution desperately in need of establishing a positive reputation, this is an opportunity not to be missed.

But it is also important to recall how the Doha Declaration was reached—through an episode of heated confrontation between activists and the pharmaceutical industry. This is unfortunate, and it should not be repeated now. *It should never be forgotten that improving pharmaceuticals access is not a zero-sum game: one side's loss need not be the other side's gain, meaning that confrontation can—and must—be avoided.*

Instead, now that both sides have the attention of the world's most powerful rules-making institution, a good, cooperative start would be to emphasize mutually acceptable solutions. These do exist. For example, there can be no disagreement that creating a legally conducive environment in GATT for pharmaceutical discounts and donations would be outstanding for public health. There can also be no disagreement that invoking the power of GATT to seek tariff reductions on important pharmaceuticals would advance both the health, and ultimately the wealth, of poor people and poor governments. The flexibility and power of a consensus Ministerial "decision" under the WTO Agreement means that all these issues, and more, can be tackled in one fell swoop, putting an uncontroversial end to much that now frustrates pharmaceuticals access for the poor.

But this optimism has to be tempered by a word of caution. It would be a dire tragedy if these "easy" agreements were lost in a fevered confrontation over the most contentious ground, which is TRIPS itself. Ironically, reckoning with the GATT issues at the

same time can help. By embracing some of the less contentious issues, common ground might be created and confrontation pacified—and that certainly is worth doing. Imagine the happy surprise if activists refrained from treating the Doha Declaration as a springboard for virulent anti-corporate demagoguery; or the pharmaceutical industry instead of fighting the Doha Declaration inch by inch, welcomed the opportunity to address tariffs and other long-standing barriers to pharmaceutical access. To repeat, this is not a zero-sum game; both sides can win. We strongly urge that timely recognition.