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Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Options for TRIPS Council

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For the first time in its history, international health and development are being discussed with interest at the World Trade Organization. The November 2001 declaration of the Fourth Ministerial Conference in Doha, Qatar, and its cousin, the *Declaration on the TRIPS Agreement and Public Health* (the “Doha Declaration”),¹ address trade topics of economic importance to developing countries, and in particular, the controversial issue of how the WTO’s rules on patents may harm public health in poor countries.

The *Doha Declaration* is a success for the highly visible, international activist movement that over the last three years has illuminated the problem of pharmaceutical access in poor countries. International NGOs such as Action Aid, Doctors Without Borders (Médecins Sans Frontières) and Oxfam have campaigned strongly in support of the thesis that the TRIPS agreement of the WTO, which binds developing countries to offer patent protection for pharmaceuticals, has had and will have a chilling effect on access to life-saving pharmaceuticals in poor countries. The activists conclude, *inter alia*, that to improve pharmaceutical 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 pharmaceutical patent, in favor of a third party who obtains a license to manufacture, import, or sell the patented pharmaceutical.² This, combined with more generous transition periods for the least developed countries (and possibly other developing countries), is among the strategies activists favor to end what some call a “one-size-fits-all TRIPS”, in which rich and poor countries are treated similarly.

Not surprisingly, the activist thesis is resisted by the international pharmaceutical industry, which stands to benefit from TRIPS-based patent protection. The disagreement begins at the initial premises: the industry argues that patents actually have little to do with impairing pharmaceutical access in the poorest countries; and that factors such as a lack of political will, absence of international aid finance, and weak medical infrastructure actually are demonstrably more significant barriers. While 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 in the agreement for poor countries could

¹ Doha Declaration on the TRIPS Agreement and Public Health. WTO Doc. WT/MIN(01)/DEC/2, 20 November 2001 (hereinafter “Doha Declaration”).

² “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.

“creep” to rich countries which might abuse that flexibility to destroy the industry’s profit centers, with research and development investment following in the wake.

This is, of course, a very large debate, and it is not possible for this Working Paper to fully examine the differences—or the common ground. Rather, this Working 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. Paragraph 6 is concerned with a special and narrow 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 do not harmfully impair the availability of pharmaceuticals at the best prevailing prices? Since paragraph 6 invests WTO Members (and specifically, the TRIPS Council) with the job of finding “an expeditious solution to this problem and to report to the General Council before the end of 2002”, this Working Paper analyses and discusses some possible solutions.

This Working 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 Commission, and discuss these in relation to the Paragraph 6 mandate. We then offer a proposal of our own, which we believe excels in resolving the Paragraph 6 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*.

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 task was set by the WTO Ministerial. This requires a close reading of Paragraph 6, as well as the surrounding context of the *Doha Declaration*. As will be seen, Paragraph 6 itself is textually flawed, and must be read in the context of the whole *Doha Declaration* to have any useful meaning. Paragraph 6 states:

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

Thus it is clear that Paragraph 6 expressly confers a 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, leaving the possibility that the Paragraph 6 mandate includes the non-existent pharmaceutical access problems of very affluent, healthy countries that lack

pharmaceutical manufacturing capacity (e.g. Liechtenstein, Luxembourg). Also, in speaking only of countries that have “difficulties in making effective use of compulsory licensing”, the Paragraph 6 mandate by implication excludes attention to countries that are very poor, utterly diseased, and which have no patents on important pharmaceuticals, simply because it is meaningless to speak of compulsorily licensing patents that don’t exist.

Thus, taken literally, the Paragraph 6 mandate is so badly worded that it might “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 result; and it is an artifact of the reality that WTO agreements are drafted by “diplomats, not lawyers”, with sometimes unclear results.³ Thus TRIPS Council must reject a simply technical interpretation of the Paragraph 6 mandate, and be prepared to supplement that interpretation with the wider context of the *Doha Declaration* as a whole, in order to divine a truer sense of the mandate that document sets out to create. *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, which illuminate the ambiguities of Paragraph 6. Paragraph 1 reads 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 countries themselves. Accordingly, any proposed solution to the Paragraph 6 mandate must meaningfully predicate its remedies on a country’s weak economic and health status, or else that proposal is overbroad. If this advice is followed, it dispenses with the “Liechtenstein and Luxembourg” problem.

Paragraph 4 further 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 remarkable, because once the Ministerial declares and acknowledges as customary law of the WTO that members possess a “right to protect public health”, it follows that the WTO Ministerial itself must contemplate *all steps* within its jurisdiction to advance that right, wherever these effectively “promote access to medicines for all”. Once that line is crossed, there is no principled (or even tenable) argument that the WTO’s duty to respect that right is exhausted by taking measures within the scope of TRIPS (e.g. compulsory licensing), while turning a blind eye to the other WTO agreements—the duty to respect an avowed legal right is not so artificially compartmentalized. Thus the Paragraph 6 mandate cannot be limited to assisting only those poor countries having patented pharmaceuticals and “difficulties in making effective use of compulsory licensing” under TRIPS, but must extend to other poor countries, with or without patents, which are thwarted in achieving pharmaceutical access, if assistance for their problem can be found elsewhere in the WTO’s jurisdiction.

³ Quote from Daniel Gervais, *The TRIPS Agreement: Drafting Analysis and Negotiating History*, (London: Sweet & Maxwell, 1998), at page 27.

Accordingly, any proposed solution to the Paragraph 6 mandate must contemplate measures *beyond* merely tweaking TRIPS, particularly where the barriers to promoting pharmaceutical access are demonstrably outside the patent system, but remediable elsewhere in the WTO’s jurisdiction.

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, if not the WTO Agreements as a whole, and certainly not public health. However, it would be intellectually dishonest of the TRIPS Council to treat the pharmaceutical access problem as tautologous with a patent and TRIPS problem, where current 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).⁴ This is significant, because if patents infrequently constrain pharmaceutical access, it stands to reason that steps to reinterpret or amend TRIPS will infrequently solve that problem. As the European Commission 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. As the EC have already emphasised, improving access to medicines requires a mix of complementary measures in different areas... The discussion within the TRIPs Council should not overshadow these [other] aspects and efforts to make medicines available at affordable prices in a number of international fora...”⁵

We would add that among the other relevant international fora is the WTO Ministerial itself, which exercises plenary jurisdiction over all the WTO Agreements, not just TRIPS. Indeed, the Ministerial itself stated in the *Doha Declaration* that TRIPS is only “part of the wider national and international action [needed] to address [the] problems” of public health afflicting developing country WTO members.⁶ Thus there is nothing unexpected or inappropriate in TRIPS Council offering its Paragraph 6 recommendations for TRIPS, while also remitting back to the Ministerial its recommendations on other steps that are

⁴ 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 or least developed) have few, or even zero, patents on these medicines, while somewhat richer WTO members (those that are middle-income) 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 AIDS treatment, because the relationship between patents and access is a complex and nuanced one, which depends on factors such as the current, medically accepted guidelines for antiretroviral drug treatment; discount agreements with pharmaceutical companies; and, above all, the availability of international aid finance to purchase drugs, whether patented or not: see A. Attaran and L. Gillespie-White (2001). Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa? *Journal of the American Medical Association* 286:1886-1892. The qualitative distinction in patterns of patenting between low-income and middle-income countries holds for many other medicines and diseases, and not just the antiretrovirals used for AIDS (unpublished data).

⁵ 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 para. 4.

⁶ Paragraph 2, *Doha Declaration*

outside its own jurisdiction, but within the jurisdiction of the Ministerial, to give effect to “WTO members’ right to protect public health, and, in particular, to promote access to medicines for all”. That is the most intellectually honest, helpful thing that TRIPS Council might do for developing countries.

We accordingly discuss proposed policy interventions, for both TRIPS and the other WTO Agreements, in the sections below.

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 Commission, and another from a coalition of Non-Governmental Organizations (NGOs).^{6 7} Both suggest creating a new exception under Article 30 of TRIPS (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.^{8 9} Alternatively, the European Commission, 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.¹⁰

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

⁷ Joint Letter to TRIPS Council (January 2002). Signed by Médecins Sans Frontières, Oxfam, CPT, Third World Network, Essential Action, and Health Gap.

⁸ 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” (15 February 2002).

⁹ The EC proposal is, probably through oversight, quasi-explicit about limiting the Article 30 exception to developing countries. As articulated in paragraph 28 this criterion is missing, though it probably is incorporated via paragraph 31, which refers back to preceding paragraphs where the challenges of developing countries are discussed.

¹⁰ 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.

		ARTICLE 30 EXCEPTION		ARTICLE 31(f) AMENDMENT			
		Patent in PRODUCER country?		Patent in PRODUCER country?			
		YES	NO	YES	NO		
Patent in IMPORTING country?	YES ¹¹	Producer country relies on Article 30; <u>and</u> importing country must issue compulsory license	Importing country must issue compulsory license	Patent in IMPORTING country?	YES	<u>Both</u> producer and importing countries must issue compulsory licenses (2 licences total)	Importing country must issue compulsory license
	NO	Producer country relies on Article 30	No problem		NO	Producer country must issue compulsory license	No problem

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 a such an extraordinary and rare remedy that a producer country’s government is unlikely to take that route just to help a developing country desirous of importing—indeed, governments can be slow to act on the health needs of their own citizens, much less invoke compulsory licensing on a case-by-case basis to meet the health needs of foreigners.¹² It should be remembered that compulsory licenses are so rare and exceptional that not one has been issued by any WTO member for the manufacture of a generic pharmaceutical since TRIPS entered force six years ago (though threats have occurred).

Considering these factors, it is not only possible, but likely, that notwithstanding amendments to Article 31(f), compulsory licensing for export to developing countries would rarely if ever occur.¹³ It therefore seems much more operationally feasible that

¹¹ 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 has not been proposed by any stakeholders to date. It is accordingly not further considered.

¹² Compulsory licensing must be invoked on a case-by-case basis owing to Article 31(a), which stipulates that “authorization of [compulsory licensing] shall be considered on its individual merits”.

¹³ But compulsory licensing for export to *developed* countries is probably a different matter. In the (extremely improbable) scenario that a rich country with a large market (say, the United States) issued a compulsory license to import a patented medicine, the very size of that lucrative market would act as a temptation to other countries to issue compulsory licenses and make export sales—and this scenario underlies the fear in the pharmaceutical industry that some countries (say, India) could use a loosened Article 31(f) liberally to supply export markets. We believe this is very unlikely: even before TRIPS, no large, rich country had seriously undertaken compulsory licensing for many years; and without those lucrative export markets, India’s export sales will remain a small proportion of global market share, just as now.

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 better. From the activist perspective, it is certainly more straightforward to use. From the industry perspective, it avoids the need to amend TRIPS, which is a politically uncertain and risky process that could lead to the undoing of TRIPS in much more substantial ways (e.g. a repeal of Article 27(1) and 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.¹⁴

Having said this, there is a third proposal which we believe is preferable to the Article 30 exception. We propose that the Paragraph 6 mandate is more expeditiously satisfied by an agreement creating a *rule of non-justiciability* for the manufacture and export of generic versions of patented pharmaceuticals to developing countries lacking sufficient manufacturing capacity to meet their health needs. The rule of non-justiciability would ordinarily bar the bringing of a legal action (i.e. dispute resolution, in the WTO context), except where that rule could be set aside because there were evidence of it being abused—for instance, if pharmaceuticals were wrongly being exported to a developed country, or a country with extensive pharmaceutical manufacturing capacity. In other words, the rule of non-justiciability would not confer an absolute immunity, but a *rebuttable immunity*, that would give way to the dispute resolution process (or some other enforcement mechanism) if the agreed conditions underlying the rule were broken.

A rule of non-justiciability probably enjoys some advantages over the Article 30 exception. These include:

1. 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 in respect of pharmaceuticals, would 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.¹⁵ Similarly, it

¹⁴ It should be remembered that any amendment to TRIPS, respecting Article 31(f) or otherwise, would only come into force after the current Round of WTO negotiations is concluded, and this can take a very long time. The Uruguay Round took nearly 8 years to complete. Assuming that the current Round takes as long (some say it will take longer) and that another 1-2 years is needed thereafter to obtain ratifications, it could be 10 years before any proposed amendment comes into being.

¹⁵ The NGO coalition’s proposal attempts to deal with Article 27.1 by advancing language for the Article 30 exemption that is facially neutral as regards field of technology. However, this is unlikely to work, for two reasons. First, a facially neutral exception affecting all technologies exceeds the Paragraph 6 mandate, which is limited to technologies for public health, and may not survive scrutiny of the WTO Ministerial. Second, a facially neutral exception can still produce discrimination that violates Article 27.1, if in practice it is invoked repeatedly in respect of a single technology (e.g. 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

is not self-evident how an exception created in the domestic patent law of a producer country, which seeks to operationalize the Article 30 approach by authorizing the manufacture of generic versions of patented pharmaceuticals for export to nationals of developing countries, but not for export to nationals of developed countries, would be reconciled with the Article 4 requirement of Most-Favored-Nation Treatment. Of course, we concede that both legal conflicts could have political overrides, but neither the EC nor the NGO proposals for Article 30 states what those would be.

2. Unlike the Article 30 exception, which breaks new ground, there are already precedents for a rule of non-justiciability already in WTO law, and these could serve as useful models. The nearest is found within TRIPS itself, at Article 6, which makes disputes in respect of exhaustion of intellectual property rights totally non-justiciable. A more nuanced, and perhaps better example is found at Article 8 of the *Agreement on Subsidies and Countervailing Measures*, which designates a number of subsidies that are not actionable for purposes of countervailing duties, including certain subsidies intended to promote regional economic development.¹⁶ This is not so different in principle to designating certain, limited exceptions to patent rights as non-justiciable to promote health and human development (i.e. to help a developing country with insufficient manufacturing capacity). Importantly, the Article 8 rule that certain subsidies are not actionable is rebuttable in cases of abuse, where a WTO member complains and the matter is investigated by the WTO Secretariat and Committee on Subsidies and Countervailing Measures (the complaint then goes to binding arbitration).¹⁷ Some similar mechanism for investigations, very loosely modeled on this one, and perhaps involving the mandatory input of health experts, could be used to lift the presumption of non-justiciability where the exceptions to patent rights were being abused by an exporting country.¹⁸

We emphasize that these considerations are not meant to dismiss the Article 30 approach, while declaring a rule of non-justiciability superior—with careful thought, probably either approach can be made to work. Our only points are that the rule of non-justiciability: (i) is easier to integrate into the overall scheme of TRIPS, and; (ii) can draw on precedents already found in WTO law. And like the Article 30 approach, it does not require an amendment to TRIPS to effect.¹⁹

(12 October 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 (17 March 2000), at para. 7.94.

¹⁶ Article 8.2(b).

¹⁷ Article 8.4 and 8.5.

¹⁸ For an example in WTO law where “advice from experts” on “scientific and technical issues” is a mandatory part of dispute resolution, see Article 11(2) of the *Agreement on the Application of Sanitary and Phytosanitary Measures*.

¹⁹ There is latitude in how a rule of non-justiciability could be effected. Certainly an amendment to TRIPS could be used to introduce a non-justiciability provision, such as already exists at Article 6. But it would be very much faster (see footnote 14) to declare a rule of non-justiciability politically. Political agreements are already used to defuse some of the WTO’s thorniest problems: e.g. the *détente* of Cuba and the United States, which are both parties to the WTO agreements.

Finally, we emphasize one point of tremendous importance. Whatever the legal approach taken, the success or failure of the Paragraph 6 exceptions depends on having appropriate eligibility conditions. These must define, with meaningful precision: (i) which countries are developing, and; (ii) which countries lack sufficient manufacturing capacity to meet their health needs. The immediate requirements of public health are that these parameters be humane and inclusive; but the requirements of future research and innovation are that these parameters resist “creep” into developed countries or the more advanced middle-income countries. *There is no precise point at which this trade-off is met, and it is futile to imagine there is.* Nevertheless, there is a broad-based international consensus that the poor and diseased countries, and not the rich and healthy, require help in improving pharmaceutical access, and that product diversion from the former to the latter group is undesirable (discussed further below).^{20 21} Distinguishing between these groups should be done by reference to objective, recognized statistical criteria, which lends welcome transparency: ambiguity about which countries are (or are not) eligible for the Paragraph 6 exceptions both frustrates the public health benefit of those exceptions, and makes it harder to identify and condemn “creep”. We propose that a *statistical aggregation of world development indicators* (e.g. those published by the WHO, UNDP, World Bank, etc.) is the most principled and transparent way to determine eligibility. We are researching possible statistical methods now, and will share the results with the international community at the earliest possible date.

Proposals for the Other WTO Agreements (i.e. not TRIPS):

For reasons described above, the WTO Ministerial’s declaration of members’ “right to protect public health” means that the Ministerial cannot (except artificially) disavow the duty to examine the pharmaceutical access problem in *all* aspects of its jurisdiction, include WTO Agreements other than TRIPS. We now consider some of those other relevant aspects of its jurisdiction.

To begin with, it is important to have a factual and pragmatic understanding of what steps have been taken in the recent past to improve access to newer (*i.e.* possibly patented) pharmaceuticals for the poor. Most of the WHO- or UNAIDS-sponsored initiatives now underway revolve around negotiated *price discounts* or *product donations* (which are just 100% discounts) to supply the public sector market in poor countries. A leading example is the *Accelerating Access Initiative*, which is a partnership of UNAIDS with six pharmaceutical companies for the provision of discounted antiretroviral drugs for AIDS. Smaller initiatives include the *Viramune Donation Program* (for pediatric AIDS prevention), the *International Trachoma Initiative*, *Diflucan Donation Program* (for complications of HIV), and so on. Further development of discount and donation

²⁰ See the report of the WHO Commission on Macroeconomics and Health (2001). *Macroeconomics and Health: Investing in Health for Economic Development* (Geneva, WHO).

²¹ Report of the Workshop on Differential Pricing and Financing of Essential Drugs. Convened by the WHO and WTO secretariats (8–11 April 2001, Høsbjør, Norway).

programs is widely endorsed by the WHO, the WTO, and most recently, by the WHO Commission on Macroeconomics and Health.^{20 21}

Discount or donation programs, however, are complicated by unfavorable GATT law. Central to all these programs are: (1) deep discounts in poor countries, which technically fall within the scope of dumping prohibitions, and; (2) a vulnerability to arbitrage and the re-importation of deeply discounted products back into rich countries, which technically cannot be interdicted because of the prohibition against quantitative restrictions.

Consider first arbitrage. Companies that agree to heavily discount or donate their products in poor countries, on a non-profit or even loss-making basis, run the risk that arbitrageurs will re-import and sell these products in rich countries, undercutting profit-making sales there. The capacity of the customs service or health ministry is often insufficient to interdict this unauthorized trade, particularly in the least developed countries where the need for these discounts is acutest. While arbitrage has not been fatal to discount and donation programs to date, it could become so, and guarantees against arbitrage are probably important to persuading companies to discount or donate “blockbuster” (*i.e.* very profitable) products in poor countries.²² As the EC proposal correctly notes, there are “two important conditions” that underlie progress on pharmaceutical access:²³

- the need to provide safeguards against exports to countries which do not face serious public health problems;
- the need to provide safeguards against re-exportation from the country of destination, especially to rich country markets, in view of avoiding "black markets" for the products concerned.

These two conditions essentially amount to anti-arbitrage measures. The EC further notes:

[Without] such conditions, 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.

This is exactly correct. But while the EU raises these considerations in the *Doha Declaration* and TRIPS context, they actually belong to the domain of trade in goods and the GATT.

²² The risk of arbitrage varies with the product in question. For example, a malaria drug sold cheaply or donated in least developed African countries is unlikely to be arbitrated back to Europe or North America, because the demand for malaria drugs is small there. But a discounted or donated asthma drug, with annual European or American sales in the billions of dollars, might very well be arbitrated, with the company suffering significant losses for its gesture. It is probably not coincidence that all of the discount and donation offers now concern products with small markets in rich countries, while other very significant diseases (*e.g.* asthma and other chronic obstructive lung diseases, which rank 7th in cause of death in developing countries, ahead of malaria) do not benefit from the same deep discounts or donations as for AIDS or other drugs.

²³ EC Proposal, paras. 24-25.

We propose that the most natural place to accommodate anti-arbitrage measures is within a limited exception to Article XI of the GATT.²⁴ Arbitrated pharmaceuticals are “like products” to those approved by regulators and sold in the rich countries; and therefore, to keep them from entering commerce, these must be interdicted at exportation and/or importation by imposing a quantitative restriction, and in this case a prohibition, or quota of zero. However, as the law now stands, such a prohibition or zero quota appears to violate the Article XI:1; and it is not a straightforward question whether that violation could be justified or saved under the exception for human health in Article XX(b).²⁵ The legal situation under GATT is therefore ambiguous.

Ambiguities also arise with anti-dumping. 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”.²⁶ Further, dumping is actionable in WTO dispute settlement where “the effect of the dumping...is such as to retard materially the establishment of a domestic industry”.²⁷ Both conditions appear to be met where a heavily discounted or donated pharmaceutical is made available in a developing country that lacks a pharmaceutical manufacturing industry of its own. The practical significance of this is unclear: while it is absurd to imagine that a developing country WTO member would request dispute settlement to stop the “dumping” of discounted or donated pharmaceuticals made available to its own health ministry, it is possible that future developments in GATT anti-dumping litigation could have a chilling effect on discounts or donations. It is better that this ambiguity not exist in GATT.

It is beyond the scope of this paper, and indeed the function of TRIPS Council, to recommend how exceptions in GATT might put these legal issues to rest. But the fact that they arise in the context of pharmaceutical discounts and donations, which are today the most frequent policy response to important goal of pharmaceutical access in the *Doha Declaration*, means that reifying the *Declaration* may require analysis beyond TRIPS. We therefore suggest that the TRIPS Council remit this matter back to the WTO Ministerial, explaining that rules in GATT could adversely affect some of the most practiced public health options for improving pharmaceutical access in poor countries. It would then be up to the WTO Ministerial to proceed, possibly with a wide-ranging agreement both to specify certain exemptions to GATT, and to recommend that WTO members take other steps to facilitate pharmaceutical access (*e.g.* an undertaking by rich, developed countries to not “benchmark” their domestic pharmaceutical prices by reference to discounts or donations for the poor).

²⁴ Article XI is entitled “General Elimination of Quantitative Restrictions”. Its details and surrounding case law are beyond the scope of this paper.

²⁵ 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.

²⁶ Articles VI:1 and VI:1(a).

²⁷ Article VI:6(a).

Conclusion:

The *Doha Declaration* is correctly viewed as a remarkable document in the WTO’s canon, in making health and development cognizable to the world trading system. A full answer to that problem requires the WTO to undertake all steps within its jurisdiction, not just those within TRIPS, particularly where the evidence suggests that affecting TRIPS and international patent rules alone will have uncertain, and probably small, benefits for pharmaceuticals access in poor countries. An equal, or possibly greater, impact could be realized by facilitating current practices to make medicines available cheaply for poor countries, and in particular, discounts and donations, which are complicated by legal uncertainty in GATT. Accordingly the Doha Declaration requires comprehensive attention to the WTO agreements, and at a minimum TRIPS and GATT together.