

5. Access to Medicines: After Doha

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Introduction

1. TRIPS and the Doha Declaration

At the WTO Ministerial Conference in Doha, Qatar of November 2001, trade ministers had to consider how international standards of intellectual property should be adapted to help deal with public health crises and problems. The global HIV/AIDS epidemic had made it clear that a statement of principle was needed.

At Doha, the ministers adopted a declaration dealing with the relationship between public health issues and the intellectual property standards contained in TRIPS in the form of the Declaration on the TRIPS Agreement and Public Health (Doha Declaration). The Doha Declaration serves as a constitutionalizing statement by WTO members as to the proper relationship between intellectual property rights and the rights of members to regulate public health.

The Doha Declaration affirmed what TRIPS already permitted, namely the right of states to issue compulsory licences. However, ministers were unable to finally settle the relationship between the compulsory licensing provision of TRIPS (Article 31) and access to medicines by developing countries that lacked manufacturing capacity. To this end, the Doha Declaration instructed the Council for TRIPS “to find an expeditious solution to this problem and to report to the General Council before the end of 2002” (see paragraph 6 of the Doha Declaration). The search for this solution relates to a structural feature of international pharmaceutical markets, a structural feature that TRIPS further entrenches.

2. TRIPS and the Structure of International Pharmaceutical Markets.

Access to medicines that have been patented by pharmaceutical multinationals has, in part, been dependent upon generic manufacturers in developing countries producing those drugs at a lower price. Generic manufacturers were able to manufacture pharmaceuticals under patent because, firstly, they had the capability to reverse engineer such products and secondly, their respective national patent regimes enabled such capability to be exercised because pharmaceuticals were not patentable or patentability was confined to processes rather than products.

Only a small number of developing countries possess reverse engineering capabilities on an industrial scale. A study in 1992 by UNIDO pointed out that only five developing countries had innovative capabilities in the pharmaceutical sector (defined as the capability of producing new drugs by a process of reverse engineering). These countries were Argentina, China, India, Korea and Mexico. Since the UNIDO study a number of developing countries have, as a result of the HIV/AIDS crisis, placed resources into the pharmaceutical sector and as a result have a much stronger sector. Brazil and Thailand are leaders in the manufacture of cheap anti-retroviral drugs. *However, no developing country is self-sufficient in the pharmaceutical sector. All developing countries have interests in importing in this sector and some have interests in exporting.* The same study went on to point out that no developing country possessed a sophisticated pharmaceutical industry with a significant research base that 87 developing countries could only assemble finished products and that 59 developing countries had no pharmaceutical industry.

TRIPS essentially closes off the development of a pharmaceutical industry based on reverse engineering and export to achieve economies of scale. Under TRIPS all developing countries will have to recognize patents on pharmaceutical products. Assuming that multinational pharmaceutical companies patent pharmaceutical products in developing countries, generic manufacturers in those countries will not be able to reverse engineer and bring those products to market without the permission of the patent owner. Patents held by pharmaceutical multinationals in the relatively small number of developing countries that have the necessary or potential export capacity in their pharmaceutical sector will have a major effect on supply in the many developing countries that will be looking to import pharmaceuticals.

Under TRIPS developing countries have the benefit of transitional arrangements:

1. Developing countries that did not have product protection for pharmaceutical products have the option of delaying such protection until 1 January 2005.
2. Least-developed countries have been given until 1 January 2006 to apply the provisions of TRIPS. The Doha Declaration has, in the case of the provisions with respect to pharmaceutical products, extended this date to 1 January 2016.

The benefits of these transitional arrangements, however, are qualified by Article 70 of TRIPS. Essentially these provisions require developing countries not granting patent protection for pharmaceutical or agricultural products to provide a means for the filing of those patents and to assess them for patentability when those countries assume full TRIPS obligations on patentability (referred to as 'mailbox' provisions). In the interim period,

developing countries are obliged to offer protection in the form of exclusive marketing rights for five years or until the product has been assessed for patentability (pipeline protection). Under a waiver approved by the TRIPS Council least-developed countries are exempted from having to provide exclusive marketing rights until 1 January 2016. There is evidence that pharmaceutical multinationals are patenting in many developing countries. For example, India has reported that between 1 January 1995 and 15 October 1997, 531 applications on pharmaceutical and agricultural products were received from US companies that wanted to take advantage of India's obligation under the mailbox provisions of TRIPS.

Not all developing countries have taken the benefit of the transitional arrangements available to them under TRIPS. Argentina, Brazil and Turkey, for example, have moved down the path of recognizing product patents on pharmaceuticals. The move by some developing countries to adopt TRIPS sooner than required has occurred largely as a result of bilateral trade negotiations with the US.

One other provision of TRIPS has an important bearing on access to medicines. Article 31 of TRIPS provides that if a Member allows for the use of a patent without the authorization of the patent owner (compulsory licensing) then certain principles have to be respected. Importantly, Article 31(f) of TRIPS states that any such use has to be "predominantly for the supply of the domestic market". This provision places a significant restriction on access to medicines in the case of the HIV/AIDS treatments. Even if a potentially large exporter of cheap drugs like India issues a compulsory licence on a patented treatment for AIDS, it is very likely that it will be unable to meet the total demand of developing countries for that treatment, because the demand in its own country would have to exceed the total demand in the rest of the world. Article 31(f) poses a much greater problem for generic manufacturers in small domestic markets.

Paragraph 6 of the Doha Declaration recognizes that states with little or no pharmaceutical capability will not be able to make "effective use of compulsory licensing" under TRIPS. Developing countries with little or no manufacturing capacity would be faced with one of two situations. In some cases there would be no patent in the developing country in respect of which to issue a compulsory licence. Where there was such a patent the issue of the compulsory licence could only be satisfied by importation. In both cases of insufficient manufacturing capacity developing countries could rely on parallel importation, but their ability to source sufficient supplies at an affordable price would be dependent upon the price discriminatory practices of the relevant patent owner in other-country markets. Whether or not a developing country exporter could take the benefit of a compulsory licence issued by another developing country has been the subject of differing legal views.

3. The Basic Options and their Supporters - Stage 1.

At the March 2002 meeting of the TRIPS Council, four basic solutions were put forward to deal with the problem in paragraph 6 of the Doha Declaration:

1. The issue of an authoritative interpretation of Article 30 of TRIPS. (Article 30 recognizes the sovereign right of states to regulate the rights of the patent owner in the interests of social welfare subject to the qualifications that such regulation does not “unreasonably conflict” with the “normal exploitation of the patent” and that such regulation does not “unreasonably prejudice the legitimate interests of the patent owner”).
2. An amendment to Article 31 to overcome the export problem created by Article 31(f).
3. A waiver of the obligation imposed by Article 31(f).
4. A moratorium on dispute settlement in the WTO for the breach of Article 31(f).

The US basically favoured Option 4.

The EU favoured Option 2.

The Africa Group favoured a broad package of strategies combining some of the elements above, including other elements such as the ability of an export country to rely on a compulsory licence issued by another country.

Other developing countries also favoured approaches based on an Article 30. (This group of countries included Brazil, India, China, Indonesia, the Philippines and Thailand).

Basically all developing countries were more favourably disposed to an Article 30 approach than either the US or the EU.

4. The Discussion Broadens - Stage 2.

As the discussions in the Council for TRIPS wore on they extended beyond the issue of exports of medicines to developing countries with insufficient manufacturing capacities. By June 2002 they included issues of market structure in such countries as well as issues of technology transfer.

The African Group continued to advocate a mix of options based on an amendment of Article 31, the use of Article 30 and the use of compulsory licences. On the issue of product coverage, the African Group took an inclusive reading so that technical processes and technical equipment were covered. The African Group took the view that any country needing support for public health problems should get the benefit of the new arrangements and similarly any country ought to be able to supply. The Group also suggested that right holders be given remedies to prevent the diversion of cheaper medicines into developed country markets. The principle of adequate remuneration was to

apply where licences had to be issued, but there was no obligation to go beyond this principle.

The European Union argued for a new paragraph to be inserted into Article 31 to overcome the difficulties of export. On the issue of product coverage, it wanted a more specific provision that mentioned public health crises in developing countries such as HIV/AIDS, tuberculosis, malaria and other epidemics. The beneficiaries would be developing countries and both importing and exporting members would have the obligation to prevent trade diversion. The principle of adequate remuneration was to apply.

The Group of Developing Countries, suggested that an authoritative interpretation of Article 30 was the most effective solution. These countries, especially Brazil, took an expanded view of product coverage, rejecting the suggestion that product coverage should be defined by reference to the diseases mentioned in the Doha Declaration. The category of beneficiary and exporting countries should remain open. The principle of adequate remuneration was to apply.

The US advocated either the use of waiver or a moratorium on dispute settlement. Product coverage was to be restricted by reference to diseases afflicting developing countries (in particular, HIV/AIDS, malaria and tuberculosis). Beneficiary countries were to be developing countries with insufficient manufacturing capacity and exporters were to come from developing countries. Ultimately all WTO members had obligations to take steps to prevent trade diversion. Compensation was to be decided by reference to the principle in Article 31 and the burden of compensation was to fall on the exporting country.

5. *Emergence of a Draft Text - Stage 3*

On 16 December 2002, the Chairman of the TRIPS Council circulated a draft text of a decision on implementation of paragraph 6 of the Doha Declaration. The chief features of the draft text are:

1. the use of a waiver of obligations in Article 31 (f) and (h), pending an amendment to TRIPS based on the draft decision
2. a definition of pharmaceutical product that refers to patented products needed to address public health problems as “recognized in paragraph 1” of the Doha Declaration.
3. a definition of “eligible importing Member” that includes by definition any least-developed country Member and any other member that has notified the TRIPS Council of its intention to use the system as an importer. A number of developed countries including Japan, Germany, the UK and the USA have indicated they will not use the system *as importing members*.

5. a definition of exporting Member that allows any member to use the system
6. a system that allows a waiver of obligation for an exporting country if an importing country has notified the TRIPS Council of the names and quantities of drugs that it needs, confirms that it has no or insufficient manufacturing capacities in relation to that drug and that it has or will issue a compulsory licence that meets other TRIPS conditions.
7. under this system notification is mandatory, but it does not have to be approved by the WTO.
8. least-developed country Members are deemed to have insufficient capacities in the pharmaceutical sector. Other potential importing Members have to show that they have no manufacturing capacity in the pharmaceutical sector or where they have some capacity that that capacity is currently insufficient for their needs.
9. eligible importing Members are obliged to prevent re-exportation of imported products and eligible exporting Members in issuing compulsory licences must stipulate conditions requiring the manufacture and export of only the needed amount, the clear labelling of the special nature of the products and the posting of shipment information to a website. Exporting members have to notify the WTO of the issue of the compulsory licence and the conditions in it.
10. adequate remuneration to be paid by an exporting Member when it has issued a compulsory licence in relation to a patented product and no such obligation to pay in the importing country in respect of that same product where remuneration is paid in the exporting Member.

6. *Breakdown of Talks - Stage 4*

On 21 December 2002, the talks over the draft decision broke down. The cause of the problem related to the definition of pharmaceutical product. According to a press release of 20 December 2002 from the Office of the United States Trade Representative, some WTO members and advocacy organizations were seeking to expand the scope of products beyond “the ‘poor country epidemic’ focus of Doha to allow much wealthier countries to override a wide range of drug patents, for example, Viagra”. Unable to agree to the draft decision the US announced that it would continue to work in the WTO to obtain a solution and in the meantime it would apply an interim measure.

7. *Interim Measure by the US*

According to the US its interim measure will allow least-developed countries to import drugs from other WTO Members to help deal with “HIV/AIDS,

malaria, tuberculosis, and other infectious epidemics of comparable gravity and scale". The importation would have to comply with the WTO rules on compulsory licences.

Developed countries and developing countries that are high income countries according to the World Bank will not get the benefit of the measure. The interim measure is essentially based on the US agreeing not to bring a dispute resolution procedure against an exporting state that supplies a least-developing importing state with patented drugs in a way that breaches either the importing or exporting state's obligations under TRIPS.

8. *Reactions to Breakdown - Stage 5*

EU

In a letter of 7 January 2003 addressed to trade ministers Pascal Lamy, the EU Trade Commissioner, has stated that the current draft text remains acceptable. By way of a compromise solution he suggests that the definition of pharmaceutical product contains a footnote listing those infectious epidemics that have the most damaging impact on developing countries. In addition, Members could request the World Health Organization to give advice as to other potential public health problems. Presumably this would be a way of adding other diseases to the list. The EU also announced that it would not challenge any member exporting medicines under the terms of the draft decision. At a recent EU-Commonwealth Roundtable at the London School of Economics on 20 January 2003 he stated that "we cannot rely for very long on individual unilateral waivers".

African Group Reaction

In a statement issued after the breakdown of the talks the African Group expressed support for the text on the basis that it represented the most likely consensus point. It opposed the inclusion of a footnote in the draft text listing only a handful of diseases under the system on the grounds that it would re-define and limit the effect of the Doha Declaration.

9. *Next Stage?*

The current draft decision is supported by the EU and by many developing countries. Even though developing country groups like the African Group are not particularly happy with the draft text they see it as a likely consensus document. Technically the agreement of the US to a waiver is not needed. But the WTO is a consensus organization and it is unlikely that WTO members will want anything other than a consensus on this matter that includes the US. The draft decision is actually quite close to the outcome that the US has sought in any case. Any final decision on paragraph 6 is not likely to deviate

too much from the present draft. In order for that to happen developing countries would have to unite multilaterally and co-ordinate bilaterally to push for a solution based on Article 30. They would also encounter the united opposition of the US and EU since both have indicated that an Article 30 solution is not an option.

How soon an agreement will eventuate will depend on the urgency that the US assigns to the matter. In the past on intellectual property matters the US has used rounds of bilateral negotiations to obtain agreement on standards that act as a springboard for a multilateral deal. President Bush's announcement in his State of Union address of an Emergency Plan for AIDS relief, a \$15 billion initiative that is aimed at African and Caribbean countries, may also affect perceptions and the sense of urgency about the need for a final agreement. Under the plan there is a proposal to provide antiretroviral drugs for 2 million HIV-infected people.

10. Evaluation

Interim Measure by the US

The aim of the interim measure according to the US is to benefit least-developed countries by allowing them to import drugs from other WTO members under the compulsory licensing rules of TRIPS.

The interim measure changes very little. Least-developed countries get the benefit of TRIPS transitional provisions. Under those transitional provisions they do not have to apply the patent provisions of TRIPS. Even if a least-developed country has implemented TRIPS there may be no patent registered in its patent system on the drug it wants to import. Even if there is such a patent, TRIPS permits a country to issue a compulsory licence for the use of the patent. Developing country exporters also get the benefit of TRIPS transitional arrangements.

If a least-developed country has no or insufficient manufacturing capacity and a public health crisis, it will have to find an exporter of the drugs it needs at a quantity and price it can afford. The crucial question is whether the US interim measure offers generic manufacturers an incentive to manufacture medicines needed by least-developed countries. Generic manufacturers, like multinational manufacturers, need a certain legal environment before investing in the production of drugs. The US interim measure is by definition temporary. The scope of the products it covers is uncertain and some developing economy markets have been ruled out making it harder for generic manufacturers to achieve economies of scale in production.

The incentive effect of this measure is minimal. It appears to offer little beyond what the TRIPS transitional arrangements already offer to developing countries. The TRIPS arrangements at least offer the certainty of dates and

the prospect of extension. Moreover they are binding on all parties. The interim measure is a piece of discretionary unilateralism that offers neither clarity to developing countries, nor commercial certainty to generic manufacturers.

11. The draft decision paragraph 6

The draft decision as it stands largely fails to achieve the primary goal of the Doha Declaration of promoting “access to medicines for all”.

The emergence of competitive pharmaceutical markets of relevance to poor people depends upon sufficient numbers of generic manufacturers entering the market. Generic manufacturers in developing countries will only enter the market if the intellectual property rights regime is clearly defined, it allows them to import the ingredients and technologies they need for manufacture and it allows them to export in order to achieve economies of scale. Pharmaceutical multinationals and generic companies in the US, EU and Japan have large domestic markets that allow them to produce at an economic scale. They also deal with issues of having to source ingredients and technologies from other companies by means of complex cross-licensing arrangements. Their bargaining power based on extensive patent portfolios allows them to reach satisfactory commercial licensing arrangements.

An approach based on Article 30 would have allowed states to devise a solution that allowed generic manufacturers to have certainty over the importation of the ingredients/technologies they need on the input side. On the export side it would have allowed for the possibility of economies of scale.

The current draft decision fails to achieve these things for the reasons that follow:

- The definition of pharmaceutical product is drafted in exhaustive form (‘means’ rather than ‘includes’) and carries the possible implication that paragraph 1 of the Doha Declaration sets up a limited category of reference for products and diseases. The attempt to confine the definition of product by limiting the category of disease is unsatisfactory for a number of reasons, including the fact that a single disease can cause a cluster of health problems in an individual that then creates the need for a range of treatment products that are not directly related to the treatment products for the initial disease.
- The definition of ‘eligible importing member’ relies on countries that are not least-developed countries to establish that they have no manufacturing capacity in the pharmaceutical sector. The UNIDO study referred to earlier pointed out that in 1992, 87 developing countries had some manufacturing capacity. Under the draft proposal these states would have to carry out an assessment of their capacity

and establish that they had insufficient capacity to meet their needs. They could only use the system for importation while they had insufficient capacity. It is hard to see how this approach offers an importing or exporting generic manufacturer long term certainty.

- The draft is also ambiguous on the issue of importing eligibility. The Annex requires a developing country to link insufficient manufacturing capacity to “its needs”. However, under its notification obligation in the main text an importing member has to confirm that it has insufficient manufacturing capacities “for the product(s) in question”. Needs and the shortage of specific products are not the same. The former may exist even if the latter is temporarily met. The present draft is bound to give rise to arguments over eligibility.
- The system set up by the draft means that a generic manufacturer in an exporting country is dependent upon *both* the exporting and importing country each complying with the mandatory system of notification and conditions. The consequences of failure to comply are not spelt out, except that the waiver would not operate. Generic manufacturers would in practical terms have to monitor the bureaucracies of two countries in relation to every act of export in relation to a single product (potentially many bureaucracies). The failure of a country to comply with a condition might conceivably turn a shipment of drugs into an infringing importation allowing the intellectual property owner to seek legal remedies.
- The draft decision imposes policing obligations on both importing states and exporting states. These obligations are in addition to the rights and remedies that TRIPS requires in respect of intellectual property rights as well as the regulatory hurdles that states normally apply to the export and import of medicines. It is hard to see how making developing states bear these extra costs is consistent with the goal of promoting access to medicines for all.

12. Entrenching dependency

It is interesting to note from the present draft that the main pharmaceutical exporting nations (France, Germany, Japan, Switzerland, UK and the USA) have indicated that they will not use the system *as importers*. This suggests that the pharmaceutical companies (including the generic affiliates of multinationals) in these countries may use the system *as exporters*. Generic manufacturers in developing countries may well face strong price competition in the export markets left to them under the system from these companies. This price competition is likely to be subsidized by the lucrative domestic markets of these companies, markets that would remain protected under the

proposed system. In the long run this will simply increase the dependency of least-developed countries upon individual acts of charity or politicized development aid programmes.

13. An unilateral approach based on Article 30

The breakdown of the talks does present an opportunity for developing countries to re-think their options. It is open to a developing country or more preferably a group of developing countries to draft and enact an exception based on Article 30 to deal with the export and import issues. Developing countries need not wait for approval from the WTO to use Article 30 in this way. The Article recognizes the sovereign right of members to create exceptions to the exclusive rights of patent owners. Both the US and the EU have used Article 30 to create such exceptions (for example, research exemptions and testing of patented products prior to expiry of the patent).

If other WTO members took the view that an exception drafted by a group of developing countries went beyond the bounds of what was permitted by Article 30, the matter could be the subject of a WTO dispute resolution procedure. Of course, the costs, both economic and reputational, would, in the first instance, fall on the member bringing the action.

A drafting model for an Article 30 exception on the exporting side is to be found in Amendment 196 to the European Medicine Directive:

Manufacturing shall be allowed if the medicinal product is intended for export to a third country that has issued a compulsory licence for that product, or where a patent is not in force and if there is a request to that effect of the competent public health authorities of that third country.