

Center for Global Development

*Trade for Development: Delivering  
On Doha's Promise*

Monday, September 8, 2003

*Panel Two*

*Essential Medicines and Beyond: The Future of Trips*

*Remarks of Jen Brant*

Trade Policy Advisor, OXFAM America

At Oxfam, we have a lot to say about the appropriateness of intellectual property in developing countries and the TRIPS agreement, but I think I'm going to limit my comments to specifically the Paragraph Six issue that was under discussion in the past two years, and for which a week ago Saturday there was finally a deal.

Before discussing Paragraph Six, however, I'd just like to say a word on generics and our position on generic competition. I've seen a couple of very interesting op-eds recently in the newspapers saying we're the Trojan horse for the generics industry, and I'd just like to clarify why we endorse generics competition. By definition, patents grant a limited monopoly to an innovator on the manufacture, copying and commercialization of his product, including a new medicine. In this absence of competition, the innovator can basically charge whatever he wants for the drug. We've seen in the US and developing countries alike that generic competition brings down prices even lower than discount and other unilateral initiatives by drug companies. So given the fact that one third of the world's population lacks access to medicines and that we work in a number of very, very poor countries, we're definitely behind anything that will bring down prices to affordable levels and essentially save lives. This said, patents do matter and prices do matter. They

are part of the problem, and we recognize that this is only . . . pricing is only one issue among many, including additional funding, better infrastructure, training, as Tom was saying, if we're going to improve health care in the developing world. But that said, lower prices mean more people can be treated. So, again, I just want to emphasize that's why we endorse the introduction of competition. I think that Tom and I have different interpretations of what was at the center of the Doha declaration, predictably. In the declaration, WTO members unanimously agreed that patents can have an adverse impact on access to medicines by virtue of the price impact by raising the price of medicines and pricing them essentially out of the hands of many poor people.

Members in the declaration agreed that their goal was to promote access to medicines for all. That's a quote from the declaration. And they recognize the problem that Tom was discussing of the two-tiered system of rights, basically by which developing countries were unable to take advantage of the safeguard of compulsory licensing to obtain affordable medicines. And how to operationalize that right for these countries was basically at the heart of the discussions over the last two years.

The deal that was reached on Saturday we feel is a flawed deal. It was a big disappointment for advocates. And I think for developing country members, and I'd just like to discuss a little bit about that deal and why we feel, or fear rather, it won't work in reality to provide access to medicines. This said, we really hope to be proven wrong and we'll definitely be working with countries to try and use that solution and make it work somehow.

In terms of the specifics of the deal reached on Saturday, there are some problems regarding political realities and the procedural hoops that the deal sets up for countries to

actually use the solution to obtain medicines. One big problem, in our view, is that there is a dual compulsory licensing requirement. This means that the importing country needs to issue the compulsory license, then request that the producing and exporting country do the same.

Clearly, first of all, this makes the importing country dependent on the political will of that second country to actually undergo the administrative procedure to override the patent, authorize the production export of drugs, and then supply the drugs. In addition, this introduces a point of pressure potentially, whereby, for example, a rich country with a strong branded drug lobby could pressure that country to not export the drugs and not respond favorably to that license request.

This is a big worry given the past behavior of some WTO members that we've observed. In addition, this adds an extra layer of administrative action unnecessarily in our view. Typically, the compulsory license should be issued in the country where the drugs will be consumed. That's the market that's impacted by these generics. Not in two places. I mean I can get into this maybe during the question and answer session, but the procedures set forth for obtaining the drugs under this involves about nine steps.

It's very complex, it's burdensome, it's difficult to use, and we think that's going to deter countries from trying to use it. In addition, I mentioned the possible pressure on the exporting country to not respond. There are other pressure points and areas where countries could be challenged in their use of this solution.

For example, there's a new notification requirement that was alluded to by Tom. This is a new thing. This is not part of any WTO provisions that were existing before the Paragraph Six question. We feel this constitutes improper WTO monitoring of a

country's sovereign decision as to how to respond to public health problems. And we also fear that when a country notifies its intention to use the system, that will create another possible pressure point where a country could then pressurize the exporting country to not respond because they have the heads-up that they're going to use the system through that notification. In addition, the deal sets up a new role for the TRIPS council as a mediator of disputes.

Again, the WTO rules say that countries can identify their own health problems and make their own decisions as to how to deal with them, including using compulsory licensing. So we fear that that's going to be a forum for countries to bring challenges or generally clog up the procedure of getting the medicines by throwing up obstacles in the way of countries trying to use the solution.

I'd just like to emphasize also a couple of issues regarding the supply of the generics and economic incentives for the generics producers to supply under the initiative. These are not interesting commercial markets that we're talking about. Basically, these are poor countries. They cannot afford branded drugs. They can't domestically manufacture their own generics. So any obstacles that we're throwing up which render supplying them more costly, legally uncertain, which could invite retaliation from countries such as the US, are going to definitely diminish the willingness of generic producers to supply the generic drugs. And this is a real problem, considering that the whole point of the Doha declaration and of Paragraph Six was to promote access to affordable medicines.

I mentioned the procedural hoops to jump through. I'd just like to go back to that. The compulsory licenses need to be negotiated on a country-by-country, drug-by-drug

basis. And this is something that not only is kind of a pain for countries to go through, but also it segments markets and makes it hard for the generic producers to achieve the economies of scale to produce in a cost efficient manner. In addition to that, the US has gotten a number of countries to opt out of using this solution.

So basically, about eighty-five percent of the world's drug market, commercial drug market, is not part of this solution and cannot be supplied under this solution. So what's left is about fifteen percent of the world's drug market, no middle-income developing countries. The countries in transition have opted out. So again, we're rendering the market to be supplied a little bit less interesting for these producers.

The producers need to negotiate compensation with the rights holder before exporting. This again is typically something that should be done in the market that's importing the drugs because that's where the generics are going to cut into the earnings of the patented drug. There is reference made to the anti-diversion measures, the different size and shape and color of pills. This is a requirement that, initially in discussions, was set forth as something that should be done as long as it didn't impact the price of the medicines supplied too much, as long as it didn't raise the cost of production too much.

Unfortunately, in the most recent deal, it appears that this is a requirement, and we've spoken with a number of people in the generics industries and they say that it's very costly to change the size and shape and color of the pills and that typically what they do is they just differentiate the packaging, the name of the drug, other things that are less costly.

And I'd just like to take this moment to point out also there has never been diversion of generic drugs for a developing country to rich country markets. This is a red

herring that's constantly thrown up and we've never seen an instance of this. So finally, just to reiterate, we're very concerned about the possibility of certain countries pressuring countries not to use this solution.

We're concerned about the legal uncertainty of the solution. And we're concerned that generic producers won't invest in the production export of these drugs if the compulsory license under which they're supplying is open to challenge. So we'll be watching carefully to see how that plays out. I don't want to be entirely negative. There were some positives about the negotiations, notably that the profile of the issue was really raised and I think a lot more people are aware of the potentially negative impact of intellectual property on some countries. And the developing countries also saw that they could get the US to cave in, as you said, which was positive.

Next steps are definitely going to be to urge countries to operationalize the system and to figure out how to make it work, flawed though it is. And we'll be urging rich countries to issue compulsory licenses so their producers can supply under the system because it's important that developing countries in need of the medicines be able to choose from a wide array of companies producing the medicines to get the best, cheapest, most secure supply.

And I'll just stop there. We can discuss other issues, as you mentioned, later.