TACD

TRANS ATLANTIC CONSUMER DIALOGUE
DIALOGUE TRANSATLANTIQUE DES CONSOMMATEURS

Ambassador Robert Zoellick
United States Trade Representative
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Washington, DC 20508
United States of America

Pascal Lamy
European Commissioner for Trade
European Commission
Rue de la Loi 200
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Belgium

Cc:
Joseph S. Papovich, Assistant United States Trade Representative for Services, investment, and Intellectual Property

Paul Vandoren, Head of Unit for New technologies, intellectual property, public procurement, DG TRADE

February 15, 2002

Dear Ambassador Zoellick and Commissioner Lamy,

Re: TACD-Doha-Declaration on TRIPS

We are writing to express the views of the TransAtlantic Consumer Dialogue (TACD) on the WTO implementation of paragraph 6 of the Doha Declaration on TRIPS and public health. As you know, the TACD is a US/EU trade consultation body, which presents the consensus views of 65 consumer groups located in the United States and the European Union. The issue of access to medicines has been one of the top priorities of the TACD since its inception, and has been the focus of a number of resolutions and the topic of TACD discussions with government officials.

The TACD applauds the WTO for adopting the Doha Declaration on TRIPS, which asks countries to implement the TRIPS accord in a manner that will "protect public health and, in particular, promote access to medicines for all." However, for this statement of intention to be realized, the WTO will have to resolve the issues raised in paragraph 6 of the declaration, which address important concerns regarding the ability of countries to import medicines when domestic production is not feasible or efficient. Paragraph 6 of the Doha declaration frames the issue as follows:

> 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.

The problem discussed in paragraph 6 of the Doha Declaration on TRIPS is related to Article 31.f of the TRIPS, which says that normally the use under such a license "shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use." While noting the exception to this restriction set out in Article 31.k, when the license is issued as a remedy for anti-competitive practices, it is clearly an important limitation on the free movement of goods, and would in important cases require a country to obtain medicines domestically, since exports from a foreign source would be limited by Article 31.f.

Here we would note (as have others) that the Doha Declaration frames this issue too narrowly, because (a) there are important medical technologies that are not considered medicines (such as HIV diagnostic technologies), and (b) there will be cases where the importing country will not have a patent, but will need to find a foreign source for the product. In both cases the issue will be the same: will countries that need health care technologies be able to obtain them from countries that are the most efficient producers?

The debate over this issue has rightfully focused on the most difficult cases, such as where a country in Africa needs to import a life-saving HIV drug from generic manufacturers in India, Thailand, Brazil or elsewhere. However, it is important to note that the problem is not only one that concerns developing countries. Any country may find it lacks the ability to manufacture a needed health care technology. The most recent reminder of this concerned the anthrax attacks where the US government considered purchasing CIPRO from foreign producers, to address a pressing public health problem and a concern over Bayer pricing of CIPRO. The US case was instructive, because it involved the largest pharmaceutical market in the world. The problems facing countries such as New Zealand, Portugal, Norway, or Finland would be the same, and indeed, there is no country in Europe or North America that can be expected to be self sufficient in all-important medical technologies. This of course is an extremely important issue because we are entering a new era in high technology medicine where we may observe new and difficult problems of abuses of patent holder privileges.

Here is its helpful to note sections from some of the past TACD resolutions that deal with these issues.

> Health-01-99, Pharmaceuticals, April 1999
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> *Regarding Patents and Exemptions for Exports:*
> Agree that a country may provide exemptions to patent rights to companies who are exporting the product to another country where patent rights have expired or where patent rights have been licensed under compulsory licensing and the legitimate interests of the patent owner have been protected under Article 31 of

the WTO Agreement on Trade Related Aspects of Intellectual Property (TRIPS Agreement).

Regarding Compulsory Licensing:
Agree that governments, the World Health Organisation (WHO) and the World Intellectual Property Organisation (WIPO) should consult with the academic community, consumer groups and a wide range of industry groups to determine where compulsory licensing of medical technologies is needed to overcome market failures, such as those that are related to complex inventions, follow on inventions, or for providing access to inventions on reasonable terms.

Health-02-00, Access to Medicines in Developing Countries, February 2000

5. TACD asks the US and the EU to support patent exceptions for the export of medicines.

The EU and the US should send communications to the WTO supporting interpretations of WTO Agreement on Trade Related Aspects of Intellectual Property (TRIPS) provisions that would permit patent exceptions for production of medicines for export, when the legitimate rights of patent owners are protected in the export market. For example, patent exceptions should permit the production and export of a medicine to a country that had issued a TRIPS compliant compulsory license for medicine. A failure to address this issue will substantially undermine the usefulness of compulsory licensing of medicines in countries with small domestic markets.

Health-05-00, Patents on Genetic Diagnosis, February 2000

TACD asks the European governments to immediately apply for compulsory licenses or to use patent exceptions, permitted under the WTO Agreement on Trade Related Aspects of Intellectual Property (the TRIPS agreement), to address technologies used for the screening of genetic diseases. Consumers and patients are harmed by unreasonable uses of patents that monopolize the screening for genetically determined diseases such as the BRCA1 and BRCA2 patents associated with breast cancer. Public health authorities and laboratories in Britain and Sweden say that unreasonable use of such patents presents a threat to the public health, and reduced access to screening procedures.

TACD asks DG SANCO to report on the public health and ethical consequences of patenting of genes and technologies for screening of genetic diseases.

Trade-10-01, TACD resolution on global access to health care, May 2001

3. The US and the EU should communicate to the WTO TRIPS council that they will support policies to ensure that compulsory licensing of medicines will also benefit small market countries. Specifically, that mechanisms to enable production of medicines for export markets will be supported where such exports benefit public health and where the legitimate rights of patent owners are protected in the markets where the products are used.

We urge you and your staff to review the complete text of these and other TACD resolutions on health care and trade, which are on the TACD web site at http://www.tacd.org. A reading of these resolutions will confirm that the TACD is both strongly supportive to policies that address the concerns of developing countries and also concerned about access to health care technologies in North America and Europe. In this regard we note that the concerns in TACD resolution Health-05-00 concerning patents on the BRAC1 and BRAC2 breast cancer gene are a very large concern today in many European countries, and as we enter the future, we must have the flexibility to effectively address abuses of patent holder privileges that would impede the ability to obtain efficient sources of new technologies from foreign suppliers.

The Doha Declaration itself was the product of advocacy from developing countries in Africa, Asia and Latin America that were concerned about their ability to protect the public's health. The US and the EU made a bargain with these countries in order to obtain new trade negotiations. It is thus essential that we make good on this bargain, and ensure that the WTO addresses these issues in ways that reflect public health concerns.

TACD has long supported the concept of the implementation of exceptions to patent rights to address the export issue, and we endorse the positions advanced by MSF, Oxfam, CPTech, the Third World Network, Health Gap and Essential Action in their 28 January 2002 letter, which asks the WTO to endorse the use of Article 30 of the TRIPS to allow exports of health care technologies, when the legitimate interests of the patent owners are protected in the country where products are consumed. The only reason to oppose such an exception to patent rights is to frustrate the ability of countries that lack technology or economies of scale to obtain medicines and other important health care technologies from the most efficient suppliers. One of the touted benefits of globalization is the ability to take advantage of efficient and superior technologies, and it is morally offensive that the trading system would deny these benefits to those who suffer from illnesses of any kind in any country.

Sincerely,

Ben Wallis

Ben Wallis, TACD Coordinator
On behalf of the TACD Steering Committee

Anna Bartolini, CNCU (Italian National Council of Consumers and Users)
Benedicte Federspiel, Forbrugerraadet (Danish Consumer Council)
Jean Ann Fox, Consumer Federation of America
Rhoda Karpatkin, Consumers' Union
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Ed Mierzwinski, Public Interest Research Group
Jim Murray, BEUC (European Consumers Organisation)
Lori Wallach, Public Citizen