TACD

TRANS ATLANTIC CONSUMER DIALOGUE
DIALOGUE TRANSATLANTIQUE DES CONSOMMATEURS

Ambassador Robert Zoellick
United States Trade Representative
600 17th Street, N.W.
Washington, DC 20508
United States of America

Pascal Lamy
European Commissioner for Trade
European Commission
Rue de la Loi 200
B-1049 Brussels
Belgium

13 November 2002

Dear Commissioner Lamy and Ambassador Zoellick,

The Trans Atlantic Consumer Dialogue wishes to express our support for the position taken by the European Parliament on the issue of exports of medicines under WTO rules for patents, a topic that is a matter of considerable controversy in the current WTO negotiations over the "solution" to paragraph 6 of the Doha Declaration on TRIPS and Public Health.

In brief, paragraph 6 of the Doha Declaration addresses the problems that arise when domestic production is inefficient or impossible, due to economies of scale or scarce know-how, and countries will have to import generics when seeking to address abuses of patent rights.

TACD addressed this issue on many occasions, beginning with TACD's April 1999 Resolution Health-01-99, which called upon the EU and the US to support exceptions to patent rights for exports of medicines in cases where the legitimate interests of the patent owners (if any) were protected in the market where the product is used by patients. Since 1999, TACD has addressed this issue in a series of resolutions and letters, including most recently our February 15, 2002 letter to Ambassador Zoellick and Commissioner Lamy[1], as well as in numerous meeting with EU and US trade negotiators.

[1] http://www.tacd.org/docs/?id=122

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We completely support the approach taken by the European Parliament on October 23, 2002, when it adopted Amendment 196, in an effort to update the EU Directive 2001/83/EC relating to medicinal products for human use. This Amendment states that:

> *Manufacturing shall be allowed if the medicinal product is intended for export to a third country that has issued a compulsory license 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 country.*

The approach taken by the European Parliament is consistent with the position recently endorsed by the World Health Organization in its recent communication to the TRIPS council[2] and also by a large number of public health and development groups, as well as by generic suppliers in Europe, the United States and in developing countries.

News reports suggest the EU and US trade negotiators are seeking to limit the solution to paragraph 6 of the Doha Declaration to only certain drugs to some countries. There is no basis for either restriction.

- Patients suffer as much from cancer as they do from AIDS, and it is completely offensive to suggest that national governments should not be able to protect the public health in cases involving diseases like diabetes, asthma or heart disease.
- There are countless scenarios where both developed and developing countries will need to benefit from solutions to paragraph 6 of the Doha Declaration as the WTO's global rules on patents are implemented, and countries seek to balance the need for universal access to medicines with limited budgets.

When one looks at a wide range of cases that countries might face, from patent thickets on stem cell research, to extremely aggressive prices on innovative drugs for cancer (such as Glivec), to bioterrorism (the recent Anthrax case), it is clear that the trading system should have sufficient flexibility to ensure that every country can protect the public health.

Therefore, no agreement on paragraph 6 of the Doha Declaration should be inconsistent with the public policy set out in European Parliament's Amendment 196 to EU Medicines Directive.

Sincerely,

James Love, US co-chair, TACD Special Group on Intellectual Property
Machiel van der Velde, EU co-chair, TACD Special Group on Intellectual Property

[2] (see also WHO publication: Implications of the Doha Declaration on the TRIPS Agreement and Public Health, WHO/EDM/PAR/2002.3),