TACD

TRANS ATLANTIC CONSUMER DIALOGUE
DIALOGUE TRANSATLANTIQUE DES CONSOMMATEURS

DOC No. IP 07-09 DATE ISSUED: May 2009

Resolution on Intellectual Property Aspects of Pandemics

Introduction

In recent years there have been several cases of possible new pandemics of infectious diseases. This includes recently concerns about SARS, and both avian and A(H1N1) influenza. In cases involving a possible pandemic, health authorities must address many different issues, including those relating to the availability of relevant medicines and vaccines, and the policies and practices that ensure adequate and equitable access to such medicines.

The TACD is concerned that there is insufficient transparency of and focus on several important issues that concern the availability of medicines and vaccines in cases of pandemics. On April 29, 2009, the WHO raised its pandemic alert phase for A(H1N1) to level 5 which means that a pandemic is considered imminent.

Bearing in mind the gravity of the situation arising from the spread of A(H1N1) across 5 continents, TACD calls upon health authorities to create policies that realistically address concerns over the management of intellectual property and the supply of and access to generic medicines and vaccines.

TACD agrees to the following recommendations:

1. Patent Landscape. The EU and the US should ask the WHO to develop and make available to the public information on the patent landscape for products relevant for the treatment of actual and potential pandemics, including but not limited to influenza, SARS and HIV/AIDS. Priority should be given to the patent landscape for the A(H1N1) strain of Influenza.

2. Patent Pool. The EU and the US should ask the WHO to establish immediately an influenza patent pool (IPP). The pool should include sufficient rights to use patents to manufacture any necessary medicine or vaccine needed to address an influenza pandemic, including to address the needs for stockpiles of products. The WHO may consider collaborating with UNITAID on this activity, assuming the UNITAID mandate can be sufficiently expanded to deal with pandemic responses, and high-income countries.

3. Pre-qualification. The EU and the US should ask the WHO to immediately expand the current WHO pre-qualification program to cover all medicines and vaccines relevant to influenza or other potential public health emergencies. This should include any qualified generic supplier, without regarding to intellectual property rights.

4. Restrictive Contracts. The EU, the US and the WHO should request copies of licenses by Roche, GSK, or other companies with suppliers of activity pharmaceutical

ingredients (APIs), to determine if the contracts include restrictions on the sale of API to legitimate generic suppliers, and if they do, to immediately ask that such contracts be revised.

5. Transparency of Expected Demand and Adequacy of Stockpiles. The EU and the US should ask the WHO should determine the global demand for medicines and vaccines that would occur if a pandemic takes place, and provide transparent and accurate assessments of the current state of stockpiles of products by country, and the strategy and plan to address the demands, in the event a pandemic takes place.

6. Capacity building for generic producers. In November 8, 2005 testimony to the US Congress, former Secretary of DHHS, Michael Leavett said that in an emergency pandemic, countries will block exports of medicines, so they can be used for local populations. If this is true, it would seem important to build developing country capacity to manufacturer medicines that would be used in a pandemic. The WHO needs to have a realistic action plan for increasing the capacity of developing countries to manufacturer medicines in cases of pandemics.

7. Intellectual Property Barriers. The EU and the US should ask the WHO, WTO and WIPO to collaborate on comprehensive global assessment of all intellectual property right (IPR) barriers to the manufacturing, distribution and sale of medicines to both public and private sector markets. This would include issues such as the legal mechanisms for granting compulsory licenses, including to allow the import and export of such products when compulsory licenses are involved. This assessment should include an analysis of the restrictions of the use of the 30 August 2003 decisions of the WTO regarding the exports and imports of medicines manufactured under a compulsory license, the rules regarding the exclusive rights to use pharmaceutical test data to register products, and the potential flexibilities under TRIPS Article 44 to manufacturer, export and import medicines without the permission of intellectual property right owners.

8. The EU and the US should amend rules on exclusive rights in pharmaceutical test data to allow the registration of generic products in cases relating to pandemics.

9. The EU Member States and the US should notify that WTO that they are an “eligible importing Member” of medicines or vaccines, in cases relating to Pandemics and other National Emergencies.

10. ACTA. The EU and the US should undertake an immediate assessment of the legal provisions that have been tabled in the current ACTA negotiations regarding the enforcement of patents to ensure there are no inappropriate barriers to the transit of legitimate medicines.

11. Patent Rights for Medicines in Stockpiles. The EU and the US should evaluate the proposal to allow governments to build stockpiles of medicines for pandemics from generic suppliers with the understanding that patent owners will receive royalties in the event the stockpiles are actually used.

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- TACD letter sent to the WHA Executive Board and to the WHO Commission on Intellectual Property, Innovation and Health Re: Request to Evaluate Proposal for New Global Medical R&D Treaty; letter sent on 25 February 2005: http://tacd.org/index.php?option=com_docman&task=doc_download&gid=17&Itemid=40
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