



October 30, 2003

The Honorable J. W. Lee, M.D.
Director-General
World Health Organization
Avenue Appia 20
1211 Geneva 27
Switzerland

Dear Mr. Director-General:

As passed by the 56th World Health Assembly (WHA), Resolution WHA 56.27 on intellectual property rights, innovation and public health requested the Director-General of the World Health Organization to establish the terms of reference for an appropriate time-limited body to collect data and proposals from various stakeholders and produce an analysis of intellectual property rights, innovation and public health. The United States is pleased to take the opportunity to provide ideas for the terms of reference for this working body.

The issues the working body will address are extremely important to the United States and other Member States. The United States believes strongly that intellectual property rights are essential to foster the necessary innovation to keep the pharmaceutical research and development pipeline filled with new technologies and medicines to better handle current and emerging diseases. Please find enclosed our specific ideas. Also please find enclosed biographical information on a number of experts we present for your consideration as candidates to serve as members of the working body.

We appreciate the opportunity to participate and provide ideas to you, and we would be pleased to answer any questions or provide additional clarification. You may reach me at (202) 690-6174. Lou Valdez, Deputy Director for Policy in the Office of Global Health Affairs, can also be an additional resource for you (telephone 301-443-1774 or e-mail mvaldez@osophs.dhhs.gov).

Sincerely,

William R. Steiger, Ph.D.
Special Assistant to the Secretary
for International Affairs

Enclosure

Proposed Terms of Reference and Areas for Substantive Consideration of an Intellectual Property Body

The 56th World Health Assembly (WHA), in WHA Resolution 56.27 requested the Director-General of the World Health Organization (WHO) to:

establish the terms of reference for an appropriate time-limited body to collect data and proposals from the different actors involved and produce an analysis of intellectual property rights, innovation and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries, and to submit a progress report to the Fifty-seventh World Health Assembly and a final report with concrete proposals to the Executive Board at its 115th session (January 2005).¹

The process by which this body will be created and the content of its work are critically important to U.S. Government (USG) agencies and other U.S. public and private stakeholders. In support, the United States advocates for the following general provisions in the body's terms of reference:

Terms of Reference

1. **Technical Mandate.** The mandate of the body should focus on technical solutions relating to the innovation process. The mandate is to focus in particular on "mechanisms for the creation of new medicines and other products," and this should include the role of assuring intellectual property (IP) protection to generate investment to develop new products, funding mechanisms for the development of new products, structures for research projects and other partnerships, and incentive mechanisms. A top-down, general analysis of broad international issues would duplicate the already extensive efforts of the United Kingdom Commission Report, the WHO/World Trade Organization (WTO) joint study on trade and public health and the findings of the WHO Commission on Macroeconomics and Health. These and other documents should form the background for initial discussions. Additional work along these lines would waste a valuable opportunity for international consideration of the issues to be informed by a detailed, empirically based study of the innovation process directly relevant to development of new products in the health sector.

2. **Fostering Innovation.** Given the specific mandate and vital role of this body, its focus should be on surveying existing mechanisms through case studies and identifying and documenting potential new ways to foster innovation at the national level. This could include specific topics such as national orphan drug legislation, research and partnership policies of key public funding agencies, mechanisms to create incentives for the development of publicly funded research, mechanisms to fund purchase of IP-protected products, and the negative impact of price controls. The body should not be engaged in considering amendment to existing international legal or trade instruments or new instruments such as an international research and development (R&D) treaty.

¹ WHA 56.27

