



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

3. **The Role of the World Intellectual Property Organization (WIPO).** The body convened should tap into the considerable expertise of the patent experts at the International Bureau of WIPO, which is the international organization *most specialized* in the field of IP rights. The WHO must consult these experts when considering those issues within the terms of reference of the body that relate directly to IP rights.
4. **Membership.** In addition to the customary considerations of geographical distribution, membership of the body should be limited to individuals with *demonstrated* expertise in administering a patent system, managing a public-private innovation process linked to R&D for public health outcomes, private investment in research and development and academics with disciplines most relevant to this topic. The ideal candidate would be someone who has worked in a number of stages of the innovation process, from patenting a discovery made by researchers to licensing technologies to the commercial sector. Government experts might also be appropriate, as long as they play a substantive policy role in the reviewing and granting of patents and/or the regulatory approval process for pharmaceuticals, biologics and medical devices. Members should serve in their individual capacity, rather than as representatives of a bloc or interest group. Among non-government experts, there should be no distinction between those experts from for-profit or not-for-profit entities.

With regard to expertise, economists and lawyers *must* be included to provide appropriate input to the group, in particular with regard to financing and intellectual property issues.

5. **Sunset Provision.** In accordance with Resolution WHA 56.27, which mandates that this body be time-limited, the Director-General should establish a sunset provision that would conclude the work of this body with the submission of a report to the 115th WHO Executive Board on January 2005.
6. **Consensus Adoption.** The final report of the body should be issued only on the basis of a consensus among members who served on the body, as well as endorsement by the WHO and WIPO governing bodies.
7. **Budget and Cost.** The Director-General should submit a detailed budget for this item to the Executive Board in January 2004 so the Board may evaluate the appropriateness of allocating funds and WHO staff time to this project rather than other priority areas.

Possible Substantive Areas

1. **Disease Mapping.** A key fact-finding exercise for this body is the identification of key diseases in developing countries in terms of mortality and morbidity and a survey of existing R&D in these areas. This should include public and private research as well as research conducted as part of a public private partnership (e.g. the Medicines for Malaria Venture). This mapping will help the body identify the challenges it needs to address and point the way toward possible case studies.
2. **Transplanting the “Stanford Model” (also know as the “Wisconsin Model”).** The Stanford Model is based on the notion that public and university research best

serves the public interest through a robust patent and licensing policy. The patenting of basic technologies developed with government and/or university funding and the licensing of these technologies to for-profit enterprises ensures the necessary additional research to bring new products to market will take place.

In contrast, the current thinking of many non-governmental organizations (NGOs) is that there needs to be an expansion of “open source” research. Non-proprietary research, however, generally does not stimulate the intensive investment necessary to transform basic technologies into innovative products because there is no prospect of exclusivity to reward the risk of devoting scarce capital to product development. Explaining how the Stanford Model works and how it might be used to leverage government- and university-sponsored biomedical innovation in such countries as India, Brazil, and South Africa can create a stronger argument for IP in developing countries. It also establishes the private sector as a valued partner in the process of transforming basic research into life-saving medicines. The Stanford Model is a principal public-private partnership for innovation in the United States. Other models of public private partnership that could be examined include the Global Alliance for Vaccine Initiative (GAVI), the Global Alliance for Improved Nutrition (GAIN), and the Medicines for Malaria Venture.

3. **Approval/Licensing of New Medicines for the Developing World, Including Medicines Approved in Developing Countries but for Uses Other Than Those Needed in Developing Countries.** The role of developed country regulatory agencies in facilitating the development and licensure of medicines for developing country markets should be investigated. Evaluating mechanisms for expanding the role of regulatory agencies is a critical step in facilitating the introduction of new medicines into countries disproportionately affected by infectious diseases. Regulatory agencies in the developed world have the knowledge and processes to significantly accelerate the uptake of new medicines and diagnostics for the developing world without compromising safety and effectiveness of the products. However, mechanisms for evaluating and approving new vaccines, drugs, and diagnostics for use in the developing world by regulatory agencies, such as the Food and Drug Administration (FDA) within the U.S. Department of Health and Human Services (HHS), are complex, and may not be accessible in these situations. The group should also study of the role of these types of agencies in reviewing clinical trials of new products in countries with different risk/benefit assessments and the sharing of information with Drug Regulatory Authorities (DRAs) in developing countries. The body should examine barriers in developing countries to approving drugs that are marketed in developed countries, but for other uses.

The group of experts should also study mechanisms for transfer of medicines and analysis of import/export laws that could facilitate the transfer of investigative or licensed products from developed countries to developing nations. The body should explore the nature of useful interactions and regulatory assistance for DRAs in countries with high levels of diseases such as AIDS, malaria and tuberculosis.

4. **New IP Instruments to Address Market Failure for Neglected Diseases.** Another issue the body should explore is how the IP systems in developed countries might stimulate innovation in areas where market failure has prevented

investment. In particular, the group should consider new incentives that stimulate research for priority diseases of developing countries to broaden the world of beneficiaries of biomedical innovation, including models such as transferable rights of market exclusivity. The experience of the United States with its Orphan Drug Act as well as pediatric exclusivity could shed further light on this issue.

5. **Technology-Transfer Capacity-Building: Voluntary and Compulsory Licenses.** Much has been said about the importance of compulsory licensing as a tool to transfer technology and make medicines more readily available. Generally however, technology transfer in the biomedical sector takes place through arms-length negotiations in which IP rights are licensed in exchange for royalty payments or other consideration. Licensing – whether voluntary or compulsory – is impossible where there is no possibility or incentive to obtain a patent, and this is the case for medicines in most of the developing and least developed world. A working technology-transfer system is predicated upon the existence of a system for defining, obtaining, and protecting the underlying property rights. Thus, the body should give thought to helping developing and least-developed countries strengthen their IP systems to promote technology transfer.
6. **Patents: Transparent Mechanisms for Sharing Research.** Much recent discussion has been generated on the need to provide free access to medical journals to research communities in developing countries as a way of bridging the health information gap. Much of this information is already available – for developed and developing countries alike – in no-cost (free) databases, including patent databases easily accessible on the Internet. Indeed, the great bulk of patent documentation – millions of pages every year – exists solely to project this information into the public domain. Furthermore, a combination of international cooperation and advances in information technology has put this once inaccessible information now potentially on the screen of any Internet user. An anti-patent policy ensures that valuable research and technological know-how is not patented, and is therefore not disclosed to the public.
7. **Appropriate Funding.** Where there has been little incentive in the past to invest in research for certain diseases, such as malaria and tuberculosis, the deployment of resources through financing instruments such as the Global Fund and enhanced bilateral assistance create incentives to invest in research where none existed in the past. The body should examine the need for more predictable and sustainable financing of healthcare from international assistance *and* from national Health Ministries.

Comments received by:
Special Assistant to the Secretary for International Affairs 10/27/03
Office of the Assistant Secretary for Planning and Evaluation, OS/HHS 9/17
U.S. Mission, USTR, Geneva, Switzerland 9/20/03
Food and Drug Administration/HHS 9/23/03
Office of Global Health Affairs/HHS, 9/20/03

Possible Candidates for IP Body Membership
(biosketches attached)

Ernest Berndt, Massachusetts Institute of Technology, Cambridge,
Massachusetts

Patricia Danzon, University of Pennsylvania, Philadelphia, Pennsylvania

Maria Freire, Global Alliance for TB Drug Development, New York, New
York

Carl E. Gulbrandsen, Managing Director, Wisconsin Alumni Research
Foundation, Madison, Wisconsin.

Chris Henschel, Medicines for Malaria Venture, Geneva, Switzerland

Murray Lumpkin, Food and Drug Administration, U.S. Department of
Health and Human Services, Washington, D.C.

Fabio Pammoli, University of Siena, Italy

Tomas Philipson, Food and Drug Administration, U.S. Department of
Health and Human Services, Washington, D.C.

Michael P. Ryan, Georgetown University, Washington, D.C.

Regina Luisa Wigdorovitz de Wikinski, Facultad de Farmacia y Bioquímica
Universidad de Buenos Aires, Argentina.

Richard Wilder, Law Firm of Sidley, Austin, Brown & Wood, Washington,
D.C.

Ernst R. Berndt
Alfred B. Sloan School of Management
Massachusetts Institute of Technology

Ernst Berndt is the Louis B. Seley Professor of Applied Economics at the Alfred B. Sloan School of Management, where he is Director of the National Bureau of Economic Research, Program on Technological Progress and Productivity Measurement.

Professor Berndt received his B.A., Honors, in Economics, from Valparaiso University, Indiana. He received a M.S. and Ph.D. in Economics from the University of Wisconsin Madison.

Prior to joining the Alfred B. Sloan School of Management in 1980, Dr. Berndt has worked as a Research Economist for the U.S. Government; an Assistant Professor at the University of British Columbia; Area Head of Economics, Finance and Accounting at Massachusetts Institute of Technology Sloan School. He has also been a Visiting Scholar of Economics at Massachusetts Institute of Technology and Visiting Professor of Applied Economics at Harvard Medical School.

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**Patricia Danzon
The Wharton School
University of Pennsylvania**

Patricia Danzon is the Celia Moh Professor at The Wharton School, where she is a Professor of Health Care Systems, and Insurance and Risk Management. Professor Danzon is also Chair of the Health Care Systems Department.

Professor Danzon received a B.A. First Class, in Politics, Philosophy and Economics, from Oxford University, England. She received a M.A. and a Ph.D. in Economics from the University of Chicago.

Prior to joining The Wharton School at the University of Pennsylvania in 1985, Dr. Danzon has worked as an Associate Professor at Duke University; a Senior Research Fellow at the Hoover Institution at Stanford; and a Research Economist at The Rand Corporation. She has also been a Visiting Professor of Business Economics at the University of Chicago and a Visiting Associate Professor at the University of California, San Diego.

Her major research interests involve the application of economics to understand the workings of private market and social policy for health care, insurance, and legal and regulatory systems.

Professor Danzon is an internationally recognized expert in the fields of health care, pharmaceuticals, insurance, and liability systems. She was recently elected to the Institute of Medicine of the National Academy of Sciences. She has served as a consultant on international health care issues to the World Bank, and U.S. Agency for International Development. In the U.S. her consulting experience includes work for the American Medical Association, the American Hospital Association, the Insurance Services Office, the Institute for Civil Justice, the Alliance of American Insurers and the Pharmaceutical Manufacturers' Association.

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Maria C. Freire
Chief Executive Officer
Global Alliance for TB Drug Development

Dr. Maria Freire was named Chief Executive Officer of the TB Alliance in September 2001. An internationally recognized expert in technology commercialization, Dr. Freire led the Office of Technology Transfer at the U.S. National Institutes of Health for seven years where she was responsible for all the patenting and licensing activities of the NIH, as well as for the Food and Drug Administration. Dr. Freire was also responsible for the development of Health and Human Services. Prior to her NIH appointment, Dr. Freire established and headed the Office of Technology Development at the University of Maryland at Baltimore and the University of Maryland, Baltimore County.

A native of Peru, Dr. Freire received a Ph.D. in Biophysics from the University of Virginia. She completed post-graduate work in immunology and virology at the University of Virginia and the University of Tennessee, respectively. She is active on a number of national and international boards and committees, and is the recipient of numerous awards, including the DHHS Secretary's Award for Distinguished Service, the 1999 Arthur S. Flemming Award and the 2002 Bayh-Dole Award. She has written and spoken extensively about science in the public interest and how society's most advanced technologies can be leveraged for global health priorities.

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Experience:

Managing Director 2000 - present	Wisconsin Alumni Research Foundation Madison, Wisconsin
Director of Patents & Licensing 1997 - 2000	Wisconsin Alumni Research Foundation Madison, Wisconsin
General Corporate Counsel 1992 - 1997	Lunar Corporation and Bone Care Intl, Inc. Madison, Wisconsin
Partner 1989 - 1992	Stroud, Stroud, Willink, Thompson & Howard Madison, Wisconsin
•	Practice concentration: patent prosecution and litigation
Partner 1987 - 1989	Haight & Hofeldt Madison, Wisconsin
•	Practice concentration: patent prosecution and litigation
Partner 1986 - 1987	Ross & Stevens Madison, Wisconsin
•	Practice concentration: patent prosecution and litigation
Associate 1981 - 1986	Ross & Stevens Madison, Wisconsin
•	General practice and litigation

Boards: Wisconsin Technology Council, Director
Cornell Research Foundation, Director

Teaching:

Patent Law	University of Wisconsin Law School	1990 - 99
Patent Prosecution	University of Wisconsin Law School	2001
Masters of Science in Biotechnology	Univ. of Wisconsin	2003

Education:

University of Wisconsin Law School	J.D. 1981
University of Wisconsin - Madison	PhD. 1978
St. Olaf College	B.A. 1969

Other:

Admitted to Patent Bar	1985
U.S. Army	1970 - 71

Professional Organizations: American Bar Association, Wisconsin Bar Association, Dane County Bar Association, American Intellectual Property Lawyers, Association of University Technology Managers, Licensing Executives Society, Cornell Research Foundation Board, Wisconsin Technology Council

Chris Hentschel

Chief Executive Officer, Medicines for Malaria Venture, Switzerland

Personal Profile:

Degree (Hons) in Biochemistry, King's College, London; postgraduate studies at the Imperial Cancer Research Fund, London, ETH, Zurich and NIH Bethesda, USA (Forgarty Fellow). International career in drug discovery and technology transfer management in the public and private sectors. Currently, Chief Executive Officer, Medicines for Malaria Venture (MMV). Senior Research Fellow, Emerging Technology Program, Wharton Business School, University of Pennsylvania, USA. Interests: emerging biotechnologies which can be harnessed for public good and for wealth creation.

