



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Office of International Affairs
Washington, D.C. 20201

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 be** 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 **must 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.

M.I.T., School of Management
East Building, 52
400 Main Street
Cambridge, MA 02142
U.S.A.
Tel: 1-617-253-2665
E-mail: ebemdt@MIT.EDU

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.

University of Pennsylvania
204 Colonial Penn Center
3641 Locust Walk
Philadelphia, PA 19104-6218
Tel: 215-898-0694
Fax: 215-573-2157
E-mail: beauvais@wharton.upenn.edu

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 **NM** appointment, Dr. Freier 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. Fleming** 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**.

Global Alliance for TB **Drug** Development
59 John Street, Suite 800
New York, New York 10038
U.S.A.
Tel: 212-227-7540
Fax: 212-227-7541
E-mail: Maria.Freier@tballiance.org

Carl E. Gulbrandsen

1506 Wood Lane
Madison, WI 53705

608.233.7674

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 Ph.D. 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.

Murray MacIntyre Lumpkin, M.D., M.Sc.

Dr. Lumpkin is a medical doctor and is presently the Principal Associate Commissioner of the United States Food and Drug Administration, U.S. Department of Health and Human Services, and the Senior Medical Officer in the Office of the Commissioner. In addition to the daily activities requested by the Commissioner and **Deputy** Commissioner, he is responsible for overseeing the Office of International Programs, the Office of Pediatric Therapeutics, the Office of Combination Products, and for coordinating the **FDA** responses to several national public health issues that cut across several of the programmatic centers at **FDA**. From January 2001 until November 2002, during the interim period between Commissioners, he served as the deputy to the acting commissioner.

His baccalaureate degree is from Davidson College (1975) and his medical doctorate degree from Wake Forest University (1979). His postgraduate medical education consisted of a three-year residency in **pediatrics** at the Mayo Clinic in Rochester, Minnesota and a two-year fellowship in pediatric infectious diseases at the Mayo Clinic. In 1984, he attended the London School of Hygiene and Tropical Medicine as a Fulbright Fellow and received an M.Sc. in Medical Parasitology from the University of London during that year. His professional certifications include **pediatrics** and tropical medicine.

He was recruited to the FDA in 1989 as Director of the Division of Anti-Infective **Drug** Products (DAIDP), and held this position until **1994**. He was responsible for the medical and scientific decisions, as well as the management of a 70-person staff of physicians, pharmacologists, chemists, microbiologists and project managers. The Division is charged with the primary oversight and approval responsibilities for drugs classified as antimicrobials (excluding drugs related to HIV and HIV-related diseases).

From 1994 to 2000, he served as Deputy Center Director (Review Management) for the Center for **Drug** Evaluation and Research. His main responsibilities included oversight and management of the five Offices of Drug Evaluation and their **now** fifteen new **drug** review divisions, the Office of Biostatistics, the Office of Post-marketing **Drug Risk** Assessment and the Advisory Committee Staff in **CDER**. Under his direction, these components provided statutory oversight of the following **three major phases** of the life of prescription and over-the-counter **pharmaceutical** products in the United States: (1) the oversight and management of **drugs** during their development (testing) phases in humans; (2) the evaluation of the adequacy of the scientific efficacy and safety **data** (the clinical benefit/risk analysis) to support approval of the product for sale in the United States once the formal **testing** phase is completed; and (3) the evaluation of the continued clinical benefit:risk profile of the product once it is **introduced** into the U.S. market and the management of **new risks** discovered post-marketing. He was **primarily** responsible for the **creation** and implementation of **leadership** and management **initiatives to ensure** that CDER met its product review performance goals established in conjunction with the Prescription **Drug** User Fee Act of 1992 (PDUFA), its reauthorization in 1997, and other CDER ORM provisions mandated in the Food and Drug Modernization Act of 1997 (including the provisions for creating economic incentives and for addressing clinical trial design and other scientific and ethical issues for pediatric research). Through the efforts of the **FDA** drug and biologic review teams, the reform of the new **drug** review process under **PDUFA** won the 1997 Ford Foundation / Harvard University "Innovations in American Government" award.

He has represented **FDA** on various international working groups and commissions. He was one of the initial members of **FDA's** representatives to the International Conference on Harmonization (a position he maintained for 10 years); and he was **FDA's** representative for nine **years** to the World Health Organization's **CIOMS** working groups on **drug** safety issues. He has represented **FDA** in numerous bilateral initiatives with various governments, including Canada, Great Britain, Singapore, Germany, France, the European Commission, and Australia. In 2000, he spent three months working at the European Agency for the Evaluation of Medicinal Products in London on a special initiative that encouraged bilateral exchanges of senior level leaders from both regulatory organizations or the world-wide development of a new antimicrobial.

Tomas Philipson
Food and Drug Administration
U.S. Department of Health and Human Services

Tomas Philipson is a Senior Economic **Advisor** to the Commissioner **for the Food and Drug Administration**. Dr. Philipson is **also** a Professor of Economics **and** The Law School **at** the University **of** Chicago, **Irving B. Harris Graduate School of Public Policy Studies**.

Dr. Philipson received a B.Sc. in Mathematics from Uppsala University, **Sweden**. He received **an** M.A. **in** Mathematics **from** Claremont Graduate School, and a Ph.D. in Economics from the University of Pennsylvania.

Prior to joining the Food and Drug Administration in 2003, Dr. Philipson has worked as an Associate Professor at the University of Chicago; a Visiting Assistant Professor at Yale University; an Assistant Professor at the University of Chicago and a Post-Doctoral Fellow at the University of Chicago.

Food and Drug Administration
5600 Fishers Lane, Room 14-89
Rockville, MD 20857
Tel: 301-827-3360
E-mail: tomas.philipson@fda.gov

Fabio Pammolli

University of Siena, Faculty of Economics 'Richard M. Goodwin', DSAS
Piazza San Francesco 7
1-53100 Siena
Italy
Telephone: +39 0577 232187
Fax: +39 0577 232188
E-mail: custom@unisi.it ; pammolli@unisi.it

Fabio Pammolli

Obtained his Ph.D. from the St. Anna School of Advanced Studies, Pisa. Since 1998 he is Associate Professor of Economics and Management at the Faculty of Economics Richard Goodwin of the University of Siena, Italy. His main research interests are in the Economics of Technical Change, Applied industrial Organization and Strategic Management, the Economic Analysis of the Pharmaceutical Industry, the Economic Analysis of the Biomedical Research System. Among others, he published on the Journal of Management and Governance, R&D Management, Journal of International Business Studies. He participated in research projects of the EU, DGXII (TSER, HCM), the Mellon Foundation (USA), the Monte de' Paschi Foundation, National Health Care Ministry, the Italian Research Council (CNR) and the Italian Ministry of Scientific Research (MURST). He is a member of the National Committee on Pharmaceutical Expenditure of the National Health Care Ministry.

Profile

Pammolli's area of scientific interest spreads over variety of issues related to research-based pharmaceutical industry. He analyses different processes occurring within it both from the perspective of micro- and macroeconomics; he also creates interesting benchmarks of intra- and inter-industry character devoted to competition. Among his major scientific concerns lie such issues as the new division of innovative labor within the industry and the economics of science.

Pammolli is an initiative leader of **EPRIS** (European Pharmaceutical Regulation and Innovation Systems), which is aimed at analyzing the development and shaping of the European pharmaceutical industry, with particular reference to its competitiveness, innovative performances, and growth. It analyzes the salient features of healthcare, research, and industrial systems in the European pharmaceutical industry, and their impact on industrial growth and competitiveness.

Pammolli contributed to large extent to works on a report for the Directorate General Enterprise of the EU Commission titled **Global Competitiveness in Pharmaceuticals – A European Perspective**. It provides a fact-based evidence that the European pharmaceutical industry is losing competitiveness compared to the US, as commented by EFPIA President, Jorge Gallardo. Shortly after the report had been published a 10-member group gathering representatives of the industry, EC Commission, governments and patients was set up, with a primal focus on possible ways of improvement of competitiveness of the European industry.

Dr. Pammolli has published extensively on issues surrounding innovation and technology changes and systems.

MICHAEL P. RYAN, PhD
McDonough School of Business
Georgetown University
Washington, DC 20057
tel (202) 687-2672; fax (202) 687-4031
ryanmp@georgetown.edu

Michael P. **Ryan**, PhD, teaches and conducts research regarding international political economy, management, **and** social responsibility at the Georgetown University McDonough School of Business where he specializes in the business, government, **and** ethics of intellectual property. He is the author of *Knowledge Diplomacy: Global ~~competition~~ and the Politics of Intellectual Property* (1998) and *Playing by the Rules: American Trade Power and Diplomacy in the Pacific* (1995). His co-authored *Knowledge Management: Technology, Intellectual Property, and Organization in the World Economy* will be completed in 2003; his *Knowledge Ethics: Intellectual Property and Social Responsibility in the World Economy* is underway.

Professor Ryan assisted the Hashemite Kingdom of Jordan's government with the drafting of **new** patent laws and is assisting the **King's** government, business community, **and** academy regarding intellectual property and technology strategy. He is **assisting** the university system of **South** Africa with its technology commercialization strategy **and** has worked with the government, business community, **and** academy in New Zealand regarding its biotechnology **and** bio-informatics strategy. He conducted for the government of **Peru** a study of the public administration of its intellectual property laws and policies. Professor **Ryan** recently lectured to Chinese engineers and public administrators in Beijing, Dalian, and Shenzhen under the auspices of its **Ministry** of Science **and** Technology. During the past few years he **has** also lectured in Argentina, Brazil, Bulgaria, Chile, Croatia, the Dominican Republic, **Japan**, Malaysia, the Philippines, Singapore, **South** Africa, and the West **Bank/Palestinian** Authority.

Professor **Ryan** teaches in the undergraduate, **MBA**, and executive education programs at **Georgetown**. His co-taught course on international business **and** the world economy **was** named **#1 by Business Week** among all executive MBA programs. At Georgetown Professor **Ryan** **established** the first intellectual property course for public affairs students in 1994 and for MBA students in 1998. He **has** been a guest lecturer at China University of Political Science and Law, a guest scholar at the Brookings Institution, and is a member of the Academy of International Business, the American Political Science Association, the American Society of International Law, and the Society for Business Ethics. He is a member of the Cosmos Club **and** serves on the board of trustees at the Rock Creek International School. He earned a PhD in political science at the University of Michigan, where he studied at its Law School and was a researcher in higher education at its School of Education, **and** also holds a master's degree in philosophy from the Ohio State University.

CURRÍCULO VITAE ABREVIADO

Nombre y Apellidos: REGINA LUISA WIGDOROVITZ DE WIKINSKI

Fecha de Nacimiento: 10 de Agosto de 1930. Argentina. D.N.I. N° 0018325

Domicilio: Santa Fe 2306 - 10B (1123) Capital Federal, Argentina.

Teléfono 4823-6726. Fax 4821-2493 E-mail: rwikinsk@ffyb.uba.ar

SITUACION ACTUAL

- Decana de la Facultad de Farmacia y Bioquímica UBA. Período 1998-2002 y 2002-2006. Dedicación Exclusiva.
- Prof. Emérita de la Universidad de Buenos Aires. Prof. Titular, Especialidad Química Clínica del Depto. de Bioquímica Clínica. Fac. de Farmacia y Bioquímica. UBA. Dedicación Exclusiva desde marzo de 1996 hasta mayo de 1999. Dedicación parcial desde mayo de 1999.
- Miembro de la Academia Nacional de Farmacia y Bioquímica. Sección Bioquímica y Ciencias Naturales,
- Calificada en el Prog. de Incentivos para Docentes-Investigadores del Ministerio de Educación: Categoría I.
- Directora de la Carrera de Especialización en Bioquímica Clínica. Área Química Clínica. Fac. de Farmacia y Bioquímica, UBA. Consejo de Dirección en colaboración con los Prof. Dres. M. A. Pizzolato, y G. Negri
- Directora de la Carrera de Especialización en Química Clínica de la Universidad Nacional de Misiones por convenio entre la UBA y la UNAM. Marzo de 1997-Diciembre 1999..Marzo de 2000- continúa.
- Integrante del Consejo de Administración de la Red de Hospitales Universitarios en representación de la Facultad de Farmacia y Bioquímica desde junio de 1993 (Resol. CS 3989)
- Miembro del Comité Académico de la Maestría en Salud Pública de la UBA.
- Miembro del Comité Académico de la Maestría en Microbiología Molecular del Instituto Malbrán-Universidad Nacional General San Martín.
- Miembro del Consejo Ejecutivo de CEDIQUIFA. Junio de 2003.
- Docente del Curso Superior para Médicos Especializados en Diabetes desde 1986. Continúa.

Richard Wilder

Mr. Wilder **is** a partner in the Washington office of the law **firm** of Sidley, Austin, Brown & Wood. There he **specializes** in intellectual property – both in terms of seeking **and** enforcing rights and in respect of trade and policy matters.

Before **returning** to the private practice of law, Mr. Wilder **was** Director of the Global Intellectual Property Issues Division in the World Intellectual Property Organization (WIPO). There he **was** responsible for WIPO programs dealing with diverse issues, including biotechnology, genetic resources, health care, traditional knowledge, folklore and human rights. Mr. Wilder also served in the **U.S. Patent and Trademark, Office of Legislative and International Affairs**. There he represented the U.S. Government in international negotiations on intellectual property issues.

Before **his** public service, Mr. Wilder practiced intellectual property law in corporate and **law firm** settings. There he advised clients in all areas of intellectual property, sought protection (including **drafting and filing** patent and trademark applications), conducted licensing negotiations, **and handled** dispute resolution involving intellectual property. In the area of dispute resolution, he handled litigated matters both in U.S. Federal Courts and before the U.S. International Trade Commission.

Mr. Wilder **has** taught law – including at the University of Malaya, Malaysia - **and** speaks and writes often in the field of intellectual property. Prior to his career in law, **Mr. Wilder** practiced **as an** engineer in the field of electrical power generation. **Mr. Wilder** has a degree in Mechanical Engineering **from** the University of Washington, Seattle, Washington **and a** law degree (Juris Doctorate) from the Franklin **Pierce** Law Center, Concord, New Hampshire.

Sidney Austin Brown & Wood LLP
1501 K Street, NW
Washington, **D.C.** 20005
Tel: 202-736-8000
Fax: 202-736-8711
E-mail: rwilder@sidley.com