Public Hearings | Intergovernmental Working Group on Public Health, Innovation and Intellectual Property

Proposals, Recommendations made

1<sup>st</sup> Public Hearing | December 2006 (31 submissions)

Daniele Dionisio | Coordinator, Access to Drugs

Available from: http://www.who.int/phi/public hearings/first/13Nov06DanieleDionisio.pdf

Title of submission: PROFIT RULES AND THE RIGHT TO APPROPRIATE ANTIRETROVIRAL TREATMENTS: SUITABILITY OF INCENTIVE-BOUND WHO-MEDIATED VOLUNTARY LICENSES FOR EQUITABLE LONG-TERM SOLUTIONS

Proposal(s) recommended for further exploration: WHO-mediated Incentive-bound voluntary license agreements (VLA)

Combined incentives for generic manufacturers to negotiate VLAs. These incentives should comprise: Generic ARVs exclusive bulk purchasing by international donors based on generic manufacturers' acceptance of WHO prequalification surveillance; fiscal relief by country governments for generic manufacturers; WHO brokerage in VL agreement negotiations.

Kevin Fisher | AIDS Vaccine Advocacy Coalition (AVAC)

Available from: <a href="http://www.who.int/phi/public\_hearings/first/13Nov06AVACFisherKevin.pdf">http://www.who.int/phi/public\_hearings/first/13Nov06AVACFisherKevin.pdf</a>

Title of submission: Re: Intergovernmental Working Group on Public Health, Innovation & Intellectual Property

Proposal(s) recommended for further exploration: Early stage sharing of intellectual property (IP) among developers, government institutions and academics:

AVAC has developed proposals for addressing this area – e.g. see: 'Intellectual property at the crossroads' in AVAC Report 2005. *No further explanation provided in the submission* 

Trevor M Jones | Professor CBE

Available from: <a href="http://www.who.int/phi/public-hearings/first/13Nov06TrevorMJonesCBE.pdf">http://www.who.int/phi/public-hearings/first/13Nov06TrevorMJonesCBE.pdf</a>

Title of submission: WHO - Hearings on R&D into drugs for developing countries. November 2006

### Proposal(s) recommended for further exploration: Public Private Partnerships

In particular, Medicines for Malaria Venture (MMV), the Global Alliance for Tuberculosis research (GATB), the Institute for One World Health (IOWH), the Foundation for New Diagnostics (FIND), Drugs for Neglected Diseases Initiative (DnDI), IAVI and EMVI

Eric Noehrenberg | International Federation of Pharmaceutical Manufacturers & Associations, IFPMA

Available from: http://www.who.int/phi/public\_hearings/first/14Nov06EricNoehrenberg.pdf

Title of submission: Submission on behalf of the Biomedical Industry Advisory Group: "The R&D process for pharmaceutical products, diagnostics and vaccines

Proposal(s) recommended for further exploration: PDPs, Advanced Purchase Commitment, Tropical Diseases Drug Act:

Legislative package similar to the Orphan Drug Act, that provides incentives to increase R&D for neglected diseases. Key features include a combination of "push/pull" mechanisms, such as R&D tax credits, grants, reduced regulatory fees, and fast track regulatory approval."

### **Global Fund for Tropical Diseases**

Fund that makes necessary finances available to countries and communities, so they can purchase new and existing drugs for neglected diseases

### Streamlining regulatory approval

Governments make sure existing treatments get to patients in need by providing timely and accurate assessments of treatment needs and by abolishing tariffs, and taxes on essential medicines.

Philip Stevens | Director, Health Programme, International Policy Network

Available from: <a href="http://www.who.int/phi/public\_hearings/first/14Nov06PhilipStevens.pdf">http://www.who.int/phi/public\_hearings/first/14Nov06PhilipStevens.pdf</a>

Title of submission: Submission to the WHO IGWG from the Civil Society Report on Intellectual Property, Innovation and Health

Proposal(s) recommended for further exploration: Transferable patent extensions, Orphan drug legislation, Open source, Private Public Partnerships, Improving Patent Offices (merging of patent offices at regional level or countries with slow and inefficient patent offices might introduce incentive-based pay schemes (combined with appropriate quality controls), or contract out services to the private sector (combined with clear quantity and quality controls), Improving drug regulation (Creating competing drug regulatory bodies and certifiers that set the standards of regulation at levels demanded by those making choices about drug regimens); Guaranteeing longer periods of data exclusivity

Buko Pharma-Kampagne

Available from: <a href="http://www.who.int/phi/public\_hearings/first/14Nov06BUKO">http://www.who.int/phi/public\_hearings/first/14Nov06BUKO</a> Pharma.pdf

Title of submission: Submission to WHO Public Hearing on public health, innovation and intellectual property

No specific proposal made/recommended

Dra. Lázara Martínez Muñoz

Available from: <a href="http://www.who.int/phi/public\_hearings/first/14Nov06LazaraMartinezMunoz.pdf">http://www.who.int/phi/public\_hearings/first/14Nov06LazaraMartinezMunoz.pdf</a>

Title of submission: SUGERENCIA PARA INCREMENTAR EL IMPACTO DE LOS RESULTADOS DEL

PROGRAMA I+D DE MEDICAMENTOS PARA ENFERMEDADES TROPICALES

Proposal(s) recommended for further exploration: Accelerated/fast-track drug registration/approval/regulation

- Strengthen the regulatory capacity of the regulatory authorities.
- Harmonize their work so as to facilitate the registration between countries region.
- Create a collaborative framework that helps to unite efforts regulatory specialists of south-south.
- Develop capacity for dialogue between regulators and regulated to identify constraints ('gaps') in projects from early stages and throughout the process.
- Develop legal documents, regulations, procedures etc that retain the quality, safety and efficacy, as well as transparency accelerated processing of products.
- Promote the creation of multidisciplinary teams and managing the development of capabilities in this area.

Colleen Daniels | Health Action International Europe (HAI)

Available from: <a href="http://www.who.int/phi/public\_hearings/first/14Nov06ColleenDanielsHAl.pdf">http://www.who.int/phi/public\_hearings/first/14Nov06ColleenDanielsHAl.pdf</a>

Title of submission: Public hearing on public health, innovation and intellectual property

Proposal(s) recommended for further exploration: Biomedical R&D Treaty, Medical Prize Funds,
Philadelphia Consensus Statement of Universities Allied for Essential Medicines (UAEM) Policies for
Health-Related Innovations (Various recommendations for how universities should promote equal access to the

fruits of university research and engage in and promote research and development for neglected diseases)

Anna Wang | Medicines for Malaria Venture

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Available from: http://www.who.int/entity/phi/public\_hearings/first/15Nov06AnnaWangMMV.pdf

Title of submission: Comment by the Medicines for Malaria Venture

Proposal(s) recommended for exploration: PDPs

James Love | Consumer Project on Technology (CPTech)

Available from: http://www.who.int/entity/phi/public hearings/first/15Nov06JamesLoveCPTech.pdf

Title of submission: Submission of CPTech to IGWG

Proposal(s) recommended for further exploration: Patent Pool and Prize Funds

Refers generally to incentive schemes that are not tied directly to high drug prices and lists relevant articles

Thomas Faunce | Senior Lecturer Medical School and College of Law, The Australian National University

Available from: <a href="http://www.who.int/entity/phi/public\_hearings/first/15Nov06ThomasFaunce.pdf">http://www.who.int/entity/phi/public\_hearings/first/15Nov06ThomasFaunce.pdf</a>

Title of submission: Toward a Multilateral Treaty on Safety and Cost-effectiveness of Medicines and Medical Devices

Proposal(s) recommended for further exploration: A treaty on the safety and cost-effectiveness of medicines and medical devices - multilateral treaty on reward of medicines and medical device innovation through:

Reward of medicines and medical device innovation through internationally harmonised assessment of safety, quality, efficacy, and cost-effectiveness, funded independently by a tax on global financial transactions. The Treaty would establish principles underpinning such assessments: for example, safety, quality, efficacy, equity of access, and a sustainable and responsible industry

Third World Network

Available from: <a href="http://www.who.int/entity/phi/public\_hearings/first/15Nov06ThirdWorldNetwork.pdf">http://www.who.int/entity/phi/public\_hearings/first/15Nov06ThirdWorldNetwork.pdf</a>

Title of submission: SUBMISSION ON THE WORLD HEALTH ASSEMBLY RESOLUTION WHA 59.24 AND THE RECOMMENDATIONS OF THE COMMISSION ON INTELLECTUAL PROPERTY, INNOVATION AND HEALTH (CIPIH

No specific proposal made/recommended

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Centre for Applied Philosophy and Public Ethics (CAPPE) | Australian National University - comment on wha59.24

Available from: <a href="http://www.who.int/entity/phi/public\_hearings/first/15Nov06CAPPEpogge.pdf">http://www.who.int/entity/phi/public\_hearings/first/15Nov06CAPPEpogge.pdf</a>

Title of submission: CAPPE Team Comment on WHA59.24

Proposal(s) recommended for further exploration: Full Pull Plan for the Provision of Pharmaceuticals (FPPPP):

A second type of pharmaceutical patent that rewards inventors not with monopoly pricing powers but in proportion to the invention's impact on the global burden of disease.

Any inventor firm is free to choose either the conventional patent or the new Patent-2. If it chooses the latter, the patented knowledge is treated as a public good, making the new medicine available for generic production worldwide.

#### Incentives:

- Pre-patent Incentives:
  - Patent-2 will incentivise research and development of drugs for poverty-related diseases that remain neglected under the current patent regime.
  - While traditional patents make it far more lucrative to develop treatments rather than vaccines, Patent-2 entails no such bias and focuses potential inventors solely on developing interventions that reduce the global burden of disease in the most cost-effective way.
- o Post-Patent Incentives:
  - To make one's drug accessible to even very poor people, by selling it below marginal cost of production or by giving technical and financial support for its manufacture by low-cost generic producers.
  - To ensure that patients are fully instructed in the proper use of one's drug, so that this drug has maximum public health impact.
  - To collaborate toward improving health systems of poor countries in order to enhance the impact of one's invention there.

International Partnership for Microbicides

Available from: <a href="http://www.who.int/phi/public\_hearings/first/15Nov06InternationalPartnershipforMicrobicides.pdf">http://www.who.int/phi/public\_hearings/first/15Nov06InternationalPartnershipforMicrobicides.pdf</a>
Title of submission: Submission to the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property

Proposal(s) recommended for further exploration: PDPs

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Ellen 't Hoen | Médecins Sans Frontières

Available from: http://www.who.int/phi/public\_hearings/first/15Nov06EllentHoenMSF.pdf

Title of submission: Towards a health needs driven framework for R&D and access to medicines

Proposal(s) recommended: Delinking, patent pools, prize funds for R&D and proposals for a convention on R&D

Nicoletta Dentico | Drugs for Neglected Diseases Initiative (DNDi)

Available from: <a href="http://www.who.int/phi/public\_hearings/first/15Nov06NicolletaDenticoDNDi.pdf">http://www.who.int/phi/public\_hearings/first/15Nov06NicolletaDenticoDNDi.pdf</a>

Title of submission: Building a global strategy for policy change in neglected disease research

Proposal(s) recommended for further exploration: PDPs, Public sector funding, new financial incentives from collaborative management of intellectual property rights (like patent pools), and other proposals that are not linked to return on investment, but rather to health outcomes

Miriam Naarendorp | Ministry of Health, Suriname

Available from: http://www.who.int/entity/phi/public\_hearings/first/15Nov06MiriamNaarendorpMOH.pdf

Title of submission: Public Hearings on Innovation and Intellectual Property

No specific proposal made/recommended

Kevin Outterson | Boston University & West Virginia University

Available from: <a href="http://www.who.int/phi/public\_hearings/first/15Nov06KevinOutterson.pdf">http://www.who.int/phi/public\_hearings/first/15Nov06KevinOutterson.pdf</a>

Title of submission: Access to Global Disease Innovation

Proposal(s) recommended for further exploration: Various proposals mentioned, including PDPs, Grants Differential pricing (patent buyout)

For example, purchase of non-OECD patent licenses from pharmaceutical companies at a price which reflects the foregone R&D cost recovery in low- and medium-income markets and submission into a patent pool.

Kathryn Taylor | International AIDS Vaccine Initiative

Available from: http://www.who.int/phi/public hearings/first/15Nov06KathrynTaylor.pdf

Title of submission: Comment by the International AIDS Vaccine Initiative

Proposal(s) recommended for further exploration: PDPs, Advance Market Committments

Guilherme Patriota | Permanent Mission of Brazil in Geneva

Available from: <a href="http://www.who.int/phi/public\_hearings/first/15Nov06GuilhermePatriota.pdf">http://www.who.int/phi/public\_hearings/first/15Nov06GuilhermePatriota.pdf</a>

Title of submission: WHO PUBLIC HEARING ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL

PROPERTY RIGHTS

No specific proposal made/recommended

Debra Hayes | Academic research

Available from: <a href="http://www.who.int/phi/public\_hearings/first/15Nov06DebraHayes.pdf">http://www.who.int/phi/public\_hearings/first/15Nov06DebraHayes.pdf</a>

Title of submission: Abstract

No specific proposal made/recommended

Dalindyebo Shabalala | Center for International Environmental Law

Available from: http://www.who.int/phi/public\_hearings/first/15Nov06DalindyeboShabalala.pdf

Title of submission: THE WHO&INTELLECTUAL PROPERTY IN BILATERAL FREE TRADE AGREEMENTS

No specific proposal made/recommended

Caroline J Gallant | Universities Allied for Essential Medicine

Available from: http://www.who.int/phi/public\_hearings/first/15Nov06CarolineJGallant%20.pdf

Title of submission: PHILADELPHIA CONSENSUS STATEMENT

Proposal(s) recommended for further exploration: Philadelphia Consensus Statement of Universities

Allied for Essential Medicines (UAEM) Policies for Health-Related Innovations (Various recommendations on how universities should promote equal access to the fruits of university research and engage in and promote research and development for neglected diseases)

Andres Mejia-Vergnaud | Instituto Libertad y Progreso ILP

Available from: http://www.who.int/phi/public\_hearings/first/15Nov06lLPAndresMejia.pdf

Title of submission: SUGERENCIAS PARA EL INTERGOVERNMENTAL WORKING GROUP ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY (IGWG) DE LA ORGANIZACIÓN MUNDIAL DE LA SALUD.

No specific proposal made/recommended

Francisco Padilla Olivares | Centre National de Coopération au Développement

Available from: <a href="http://www.who.int/phi/public\_hearings/first/15Nov06FranciscoPadillaOlivares.pdf">http://www.who.int/phi/public\_hearings/first/15Nov06FranciscoPadillaOlivares.pdf</a>

Title of submission: Public hearing on public health innovation and intellectual property

Proposal(s) recommended for further exploration: Prizes, Patent Pool, Open Source

Tracy Haller | Novartis International AG.

Available from: <a href="http://www.who.int/phi/public\_hearings/first/15Nov06TracyHallerNovartis.pdf">http://www.who.int/phi/public\_hearings/first/15Nov06TracyHallerNovartis.pdf</a>

Title of submission: Public Hearing on Public Health, Innovation and Intellectual Property

Proposal(s) recommended for further exploration: PDPs, Economic incentives to promote innovation, including grants, tax credits for research and development expenditures, roaming patent extensions, dedicated advance purchase funds, streamlined approval procedures

European Generic Medicines Association (EGA)

Available from: <a href="http://www.who.int/phi/public\_hearings/first/15Nov06EuropeanGenericMedicinesAssociation.pdf">http://www.who.int/phi/public\_hearings/first/15Nov06EuropeanGenericMedicinesAssociation.pdf</a>

Title of submission: EGA's RESPONSE TO THE WHO CONSULTATION ON PUBLIC HEALTH, INNOVATION

AND INTELELCTUAL PROPERTY

No specific proposal made/recommended

Mirta Levis | Asociacion Latinoamericana de Industrias Farmaceuticas

Available from: <a href="http://www.who.int/phi/public\_hearings/first/15Nov06MirtaLevis.pdf">http://www.who.int/phi/public\_hearings/first/15Nov06MirtaLevis.pdf</a>

Title of submission: ASOCIACION LATINOAMERICANA DE INDUSTRIAS FARMACEUTICAS

No specific proposal made/recommended

Heeseob Nam | KFHR and IPLeft

Available from: http://www.who.int/phi/public hearings/first/15Nov06HeeseobNam.pdf

Title of submission: Submission by KFHR and IPLeft for WHO Public Hearing on PHI

Proposal(s) recommended for further exploration: Establishment of a review center that evaluate patents issued by national patenting offices, ensuring that problematic patents are filtered out of the system.

## Public financing of R&D:

The cost for public R&D should be funded by a certain proportion of the total budget of social health insurance, or a certain proportion of its expenditure on medicine (for example, 1-2%).

M Angélica Sánchez V | Asilfa

Available from: <a href="http://www.who.int/phi/public\_hearings/first/15Nov06AngelicaSanchez.pdf">http://www.who.int/phi/public\_hearings/first/15Nov06AngelicaSanchez.pdf</a>

Title of submission: Trip's Plus para Chile y América Latina

No specific proposal made/recommended

Peter Mansfield | Healthy Skepticism Inc

Available from: http://www.who.int/phi/public hearings/first/15Nov06MansfieldPeter.pdf

Title of submission: British Medical Journal editor Fiona Godlee has proposed that pharmaceutical manufacturers be banned from researching their products

### Proposal(s) recommended for further exploration: Delinking

Government agencies should be pay separately via iterative open competitive public tenders for each of the following pharmaceutical companies' funcions: manufacturing, research, promotion, and education.

# 2nd Public Hearing: Section 1, Draft Global Strategy and Plan of Action | November 2007 (43 submissions)

Jacqueline Bonisteel | Academia/Research, Intern, University of Ottawa

Available from:

http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_JacquelineBonisteel\_Full\_Contribution.pdf

Title of submission: WHO's Second Public Hearing on Public Health Innovation and Intellectual Property

No specific proposal made/recommended

Robert Reinhard | Civil Society, San Francisco Department of Public Health Research, USA

Available from:

http://www.who.int/phi/public hearings/second/contributions section1/Section1 RobertReinhard Full Contribution n.pdf

Title of submission: RE: Draft global strategy and plan of action on public health, innovation and intellectual property - A/PHI/IGWG/2/2 (Draft Global Strategy)

Proposal(s) recommended for further exploration: Additional research funds, PDPs

Philip Stevens | On Behalf of a Coalition of 24 Civil Society Groups, UK

Available from:

http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1 PhilipStevens\_Full\_Contribution\_pdf

Title of submission: CIVIL SOCIETY RESPONSE TO THE DRAFT PLAN OF ACTION

Proposal(s) recommended for further exploration: R&D inventory:

An inventory should be undertaken to catalogue extistent R&D activities, both public and private, targeted on 'neglected' diseases, to ensure that work is not duplicated.

Harvey Bale | International Federation of Pharmaceutical Manufactures and Associations

Available from:

http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_HarveyBale1\_IFPMA\_Full\_Contribution.pdf

Title of submission: Pharmaceutical and Vaccine Research and Development for the World Medical Needs

No specific proposal made/recommended

Richard Barker | Association of the British Pharmaceutical Industry

Available from:

http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_RichardBarker\_ABPI\_Full\_Contribution.pdf

Title of submission: Global Health and the Pharmaceutical Industry

Proposal(s) recommended for further exploration: PDPs and exploration of partnerships with NGOs, IOs and Universities, sensitive pricing and licensing in LDCs and DCs

Jeremiah Norris | Director, Center for Science in Public Policy, Hudson Institute, USA

Available from:

http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_Jeremiah%20Norris\_Hudson%2 Olnstitute\_Full\_Contribution.pdf

Title of submission: An Analysis of The World Health Organization Secretariat's Draft Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property

No specific proposal made/recommended

Harvey Bale (2<sup>nd</sup> submission) | International Federation of Pharmaceutical Manufactures and Associations

Available from:

http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_HarveyBale2\_IFPMA\_Full\_Contribution.pdf

Title of submission: COMMENTS ON IGWG DRAFT GLOBAL STRATEGY

Proposal(s) recommended for further exploration: Advance Market Commitments (AMCs), PDPs, Expanded Funding Mechanisms (such as Global Fund to Fight AIDS, Tuberculosis and Malaria)

**Tropical Disease Acts in industrialized countries:** 

Similar to 'Orphan Drug Acts', a Tropical Diseases Drug Act could be a legislative package intended to provide a favorable framework of incentives to increase R&D for drugs targeting diseases of the developing world.

Such a package would include both research incentives (R&D tax credits, research grants, lower regulatory fees, fast-track approval) and market incentives (e.g. advanced purchasing commitments).

### Reducing taxes on health products for neglected diseases:

Reducing taxes on both imported and domestically produced drugs avoiding inflating the price of drugs that are mainly free of patent or donated and relieving poor people from paying additional money for potentially free drugs.

Gene Copello | Executive Director, The AIDS Institute, USA

Available from:

http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_Gene\_Copello\_AIDS\_Institute\_F ull\_Contribution.pdf

Title of submission: Public Comment on the Recommendations of The World Health Organization Intergovernmental Working Group (IGWG) on Public Health, Innovation and Intellectual Property

No specific proposal made/recommended

Durhane Wong-Rieger | Consumer Advocare Network, Canada

Available from:

http://www.who.int/phi/public hearings/second/contributions section1/Section1 Advocare Full Contribution.pdf

Title of submission: CURRENT ISSUES IN INTELLECTUAL PROPERTY: A PATIENT PERSPECTIVE

Proposal(s) recommended for further exploration: Free-market incentives, e.g. Orphan Drug Act,
Differential pricing for new therapies offered to low GDP countries; Medical Research & Development
Treaty (MRDT); Pooled advance purchase commitments:

Governments, foundations, and international alliances commit to purchasing specified quantities of vaccine at contracted prices and then give it to the poorest countries (at affordable prices)

Adrian Koning | Canadian Organization for Rare Disorders

Available from:

http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_CORD\_Full\_Contribution.pdf

Title of submission: INTELLECTUAL PROPERTY AND PUBLIC HEALTH: A PATIENT PERSPECTIVE ON

CURRENT ISSUES

Proposal(s) recommended for further exploration: Free-market incentives, e.g. Orphan Drug Act, Differential pricing for new therapies may be offered to low GDP countries, Medical Research & Development Treaty (MRDT), Pooled advance purchase commitments

Governments, foundations, and international alliances commit to purchasing specified quantities of vaccine at contracted prices and then give it to the poorest countries (at affordable prices)

Thomas Pogge | Incentives for Global Health, USA

Available from:

http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_Thomas\_Pogge\_Incentives\_for\_Global\_Health\_Full\_Contribution.pdf

Title of submission: Track2 Team Detailed Comment on A/PHI/IGWG/2/2 (Draft Global Strategy and Plan of Action)

Proposal(s) recommended for further exploration: Track2 (Now known as 'Health Impact Fund' – included in proposals examined by the EWG)

Wellcome Trust | Charitable Foundation, UK

Available from:

http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_Wellcome\_Trust\_Full\_Contribution.pdf

Title of submission: WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property: Draft Global Strategy and Plan of Action

Proposal(s) recommended for further exploration: Increased funding for PDPs (more funding for developing country clinical trial sites)

Marc Wortmann | Executive Director, Alzheimer's Disease International, UK

Available from:

http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_Marc\_Wortmann\_ADI\_Full\_Contribution.pdf

Title of submission: WHO comments

No specific proposal made/recommended

Jo Harkness | International Alliance Patients' Organizations, UK

Available from:

http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_IAPO\_Full\_Contribution.pdf

Title of submission: WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual

Property: Draft Global Strategy and Plan of Action

No specific proposal made/recommended

Lawrence Kogan | Institute for Trade, Standards, and Sustainable Development, USA

Available from:

http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_ITSSD\_Full%20Contribution.pdf

Title of submission: ITSSD Response to the Draft Global Strategy and Plan of Action

Proposal(s) recommended for further exploration: General Public License (GPL) model of open source:

"Copyleft": Software authors who would otherwise possess or be entitled to exclusive private property rights in their expressed creations affirmatively waive those rights, including the right to profit from them, when contributing their work to the software collective. They do so in exchange for the right to receive attribution, as a matter of contract (or license). They then leverage that resulting legal contract right to compel future creators of derivative works to waive also their otherwise exclusive private property rights. This ensures that they, too, will not profit from their creations. As a result, the software standard remains 'open' indefinitely, with the effect of forcing more code into the open community.

### **Berkeley Software Distribution License (BSD) model of open source:**

Businesses are permitted to build upon free software to create proprietary software. This means that, the BSD License allows proprietary commercial use, and the software released under the license can be incorporated into proprietary commercial products. In addition, any works based on and/or derived from the free software may be released under its own proprietary license.

Kevin Outterson | Associate Professor of Law, Boston University

Available from:

http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_Kevin\_Outterson\_Boston\_Uni\_F ull\_Contribution.pdf

Title of submission: A Request for Clarification Concerning the Proper Scope of the IGWG's Work to Improve Access to Patented Medicines

No specific proposal made/recommended

Tracy Haller | Novartis, USA

Available from:

http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_Novartis\_Full\_Contribution.pdf

Title of submission: Comments – Draft Global Strategy and Plan of Action

Proposal(s) recommended for further exploration: PDPs

Myrl Weinberg | President, National Health Council, USA

Available from:

http://www.who.int/phi/public hearings/second/contributions section1/Section1 Myrl Weinberg National Health
Council Full Contribution.pdf

Title of submission: - no Title

No specific proposal made/recommended

European Generic Medicines Association | Belgium

Available from:

http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_EGA\_Full\_Contribution.pdf

Title of submission: Intergovernmental Working Group on Public Health, Innovation and Intellectual Property:

EGA Submission to Section 1: Draft Global Strategy and Plan of Action

No specific proposal recommended

Daniele Capezzone, Benedetto Della Vedova, Veaceslav Untila & Kelsey Zahourek | European Parliamentarians and the Property Rights Alliance, Italy

Available from:

http://www.who.int/phi/public hearings/second/contributions section1/Section1 Capezzone Full Contribution.pd <u>f</u>

Title of submission: Comments on the Draft Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property

No specific proposal made/recommended

Ronald Cass | Center for the Rule of Law, USA

Available from: <a href="http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_Cass-CRL..pdf">http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_Cass-CRL..pdf</a>
Title of submission: Comments on Draft Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, A/PHI/IGWG/2/2

No specific proposal made/recommended

Sangeeta Shashikant | Third World Network, Malaysia

Available from:

http://www.who.int/phi/public hearings/second/contributions section1/Section1 ThirdWorldNetwork Full Contribution.pdf

Title of submission: Global Strategy and Plan of Action on Public Health, Innovation and Intellecutal Property (A/PHI/IGWG/2/2): Preliminary Comments by Third World Network

No specific proposal made/recommended

Caroline Gallant | Universities Allied for Essential Medicine, Canada

Available from:

http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_Gallant\_Full\_Contribution.pdf

Title of submission: WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual

Property Response to Section I - Draft Global Strategy and Plan of Action

Proposal(s) recommended for further exploration: Philadelphia Consensus Statement of Universities Allied for Essential Medicines (UAEM) Policies for Health-Related Innovations:

Various recommendations how universities should promote equal access to the fruits of university research and engage in and promote research and development for neglected diseases

Lila Feisee | Biotechnology Industry Organization, USA

Available from: <a href="http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_FeiseeLila-BIO.pdf">http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_FeiseeLila-BIO.pdf</a>

Title of submission: The Submission of the Biotechnology Industry Organization (BIO) to the World Health Organization Second Public Hearing on Public Health, Innovation and Intellectual Property

No specific proposal made/recommended

Richard Kjeldgaard | Pharmaceutical Researchers and Manufacturers of America

Available from:

http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_KjeldgaardRichard-PhRMA.pdf

Title of submission: Comments of PhRMA on the Draft Global Strategy and Plan of Action of the

Intergovernmental Working Group on Public Health, Innovation and Intellectual Property

Proposal(s) recommended for further exploration: Advance market commitments, Specialized market mechanisms (Orphan Drug exclusivity), Research and development tax incentives, Continued cooperation among the private sector, the academic community, the public sector, and nongovernmental organizations (In particular Tropical Disease Research (TDR) program, the Global Alliance of TB Drug Development, the Medicines for Malaria Venture (MMV) and other innovative programs that promote R&D for diseases disproportionately affecting the developing world)

Measures in the Proposed Work Program that Should Not Be Pursued: Patent Pools, Free Trade

Agreement, Duplication of the Work of the WTO and WIPO, An Independent Research & Development Treaty,

Proprietary Data of Companies in Compound Libraries and Comparable

Meri Koivusalo | National Research and Development Centre for Welfare and Health, Finland

Available from: <a href="http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_KoivusaloMeri-STAKES.pdf">http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_KoivusaloMeri-STAKES.pdf</a>

Title of submission: Contribution to the public hearing on Intergovernmental Working Group on Public Health, Innovation and Intellectual Property Rights

Proposal(s) recommended for further exploration: Coordination of PDPs; Global regulatorion of financing of research and development and gathering resources in support of global measures.

"The global plan of action could and would benefit from serious exploration of different options for Treaties and Conventions, for example, in terms of securing sufficient support to research and development on the basis of health needs and/or in ensuring national policy space for health."

Jean-Frederic Morin | The Innovation Partnership, Canada

Available from:

http://www.who.int/phi/public hearings/second/contributions section1/Section1 MorinJeanFrederic-tlP.pdf

Title of submission: Submission to WHO's Second Public Hearing on Public Health Innovation and Intellectual Property

Proposal(s) recommended for further exploration: Patent Pool

Peter Munyi | HAI Africa on behalf of the African Civil Society Coalition, Kenya

Available from: <a href="http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_Munyi%20Peter-AfricanCivilSocietyCoalition.pdf">http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_Munyi%20Peter-AfricanCivilSocietyCoalition.pdf</a>

Title of submission: The African Civil Society Coalition on IGWG1[1]: Submission on the Intergovernmental Working Group (IGWG) draft Global Strategy and Plan of Action

No specific proposal made/recommended

Peter Munyi | Health Action International Africa, Kenya

Available from: <a href="http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_MunyiPeter-HAI\_AFRICA.pdf">http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_MunyiPeter-HAI\_AFRICA.pdf</a>

Title of submission: Submissions on the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property's Draft Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property

No specific proposal made/recommended

Randall Rutta | Easter Seals, USA

Available from: <a href="http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_RuttaRandall-EasterSeals.pdf">http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_RuttaRandall-EasterSeals.pdf</a>

Title of submission: Public Comment on the Recommendations of the World Health Organization Intergovernmental Working Group (IGWG) on Public Health, Innovation and Intellectual Property

No specific proposal made/recommended

Ellen t'Hoen | Médecins Sans Frontières - Campaign for Access to Essential Medicines, France

Available from: <a href="http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_tHoenEllen-msf.pdf">http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_tHoenEllen-msf.pdf</a>

Title of submission: Second Public Hearing on Public Health, Innovation and Intellectual Property Submission to Section 1 – Draft Global Strategy and Plan of Action

Proposal(s) recommended for exploration: R&D treaty, prize funds, patent pools or other mechanisms that have a pro-health approach to priority setting and financing of R&D and the management of IPs. Delinking

Wayne Taylor | McMaster University, Canada

Available from: <a href="http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_TaylorWayne.pdf">http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_TaylorWayne.pdf</a>
Title of submission: Capacity building in developing countries, particularly in terms of regulatory, compliance, auditing or inspection regimes.

No specific proposal made/recommended

Paul Herrling | Novartis International AG, Switzerland

Available from: <a href="http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_HerrlingPaul-Novartis.pdf">http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_HerrlingPaul-Novartis.pdf</a>

Title of submission: R&D and sustainable, predictable Financing of R&D for Neglected Diseases

Proposal(s) recommended for exploration: Global Funding mechanism:

Creation of a major pool of funds by mechanisms similar to e.g Global Fund, GAVI, International Finance Facility, supported by Governments, Foundations and Cahrities: Wellcome Trust, BMGF, Development Banks etc. (There could be one such pool for each neglected disease or a pool for all neglected diseases subdivided into sections with the appropriate expertise for each of them)

Janet Trunzo | The Advanced Medical Technology Association, USA

Available from: <a href="http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_TrunzoJanet-AdvaMed.pdf">http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_TrunzoJanet-AdvaMed.pdf</a>

Title of submission: Comments of the Advanced Medical Technology Association on the World Health
Organization's Draft Global Strategy and Plan of Action of the Intergovernmental Working Group on Public
Health, Innovation and Intellectual Property

Proposal(s) recommended for further exploration: PDPs

Harald Zimmer | VFA/German Association of Research-based Pharmaceutical Manufacturers

Available from: <a href="http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_Wagner-Ahlfs-HAI\_Europe.pdf">http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_Wagner-Ahlfs-HAI\_Europe.pdf</a>

Title of submission: Submissions to Section 1 - Draft Global Strategy and Plan of Action

Proposal(s) recommended for further exploration: Delinking, Advanced Market Commitments, PDPs, Open Licencing of goods developed by public institutions

Frederick Abbott & Jerome Reichman | Florida State University College of Law & Duke University School of Law. USA

Available from:

http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_Abbott&Reichman.pdf

Title of submission: Strategies for the Protection and Promotion of Public Health Arising Out of the WTO TRIPS Agreement Amendment Process

Proposal(s) recommended for further exploration: Patent Pools, Patent buyouts, PDPs

Spring Gombe | Knowledge Ecology International, Switzerland

Available from: <a href="http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_GombeSpring-KnowledgeEcologyInternational.pdf">http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_GombeSpring-KnowledgeEcologyInternational.pdf</a>

Title of submission: Comments of Spring Gombe, Health Policy Analyst, Knowledge Ecology International: Draft Global Strategy on Public Health, Innovation and Intellectual Property (WHO Doc A/PHI/IGWG/2/2)

No specific proposal made/recommended

Manon Ress | Knowledge Ecology International, Switzerland

Available from: <a href="http://www.who.int/phi/public\_hearings/second/contributions\_section2/Section2\_ManonRess-PatentPool.pdf">http://www.who.int/phi/public\_hearings/second/contributions\_section2/Section2\_ManonRess-PatentPool.pdf</a>

Title of submission: IGWG Submission on Collective Management of Intellectual Property -- The Use of Patent Pools to Expand Access to Needed Medical Technologies

Proposal(s) recommended for further exploration: Patent Pool

Xuanhao Chan | FIP/International Pharmaceutical Federation, Netherlands

Available from: <a href="http://www.who.int/phi/public\_hearings/second/contributions\_section2/Section1\_ChanXuanhao-ntml">http://www.who.int/phi/public\_hearings/second/contributions\_section2/Section1\_ChanXuanhao-ntml</a>

FIP.pdf

Title of submission: Comments from FIP

No specific proposal made/recommended

Mohga Kamal-Yanni | Oxfam International, UK

Available from: <a href="http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_Kamal-Yanni-Oxfam.pdf">http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_Kamal-Yanni-Oxfam.pdf</a>

Title of submission: Oxfam International Submission to IGWG Draft Global Strategy and Plan of Action

Proposal(s) recommended for further exploration: Various mechanisms, including Tobin tax, carbon taxes, Advanced Market Commitments

Felix Rozanski | Director, Asociación de Derechos Intelectuales, Argentina

Available from:

http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_Felix\_Rozanski\_ASDIN\_Full\_Contribution.pdf

Title of submission: Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG)

No specific proposal made/recommended

Milan Hosta | Director, Asthma & Sport Organization, Slovenija

Available from:

http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_Astma&Sport\_Full\_Contribution.pdf

Title of submission: Submission to the Second Public Hearing of the World Health Organization (WHO) Intergovernmental Working Group on Public Health, Innovation and Intellectual Property

## No specific proposal made/recommended

Brendan Barnes | European Federation of Pharmaceutical Industries and Associations, Belgium Available from:

http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_EFPIA\_Full\_Contribution.pdf

Title of submission: EFPIA Comments on Draft global strategy and Plan of Action on Public Health, Innovation and Intellectual Property

No specific proposal made/recommended

## 2nd Public Hearing: Contributions from Member States

Maria do Céu Machado - High Commissioner for Health, Portugal, on behalf of the European Union Available from:

http://www.who.int/phi/public\_hearings/second/contributions\_section1/Section1\_EU\_Full\_Contribution.pdf

Title of submission: EU answer to the 2nd Public Hearing of the IGWG on Public Health, Innovation and Intellectual Property

Proposal(s) recommended for further exploration: PDPs, TDR (Special Programme for Research and Training in Tropical Diseases), Global Fund to fight against AIDS, TB and Malaria, International Financing Facility for Immunisation (IFFIm), AMC (Advance Market Commitment) and UNITAID.

Sub-regional Meeting Consensus Document, Rio de Janeiro, Brazil, 3-5 September 2007

Available from: <a href="http://www.who.int/phi/public\_hearings/second/regional\_consultations/Sub-regional\_Consensus\_Document.pdf">http://www.who.int/phi/public\_hearings/second/regional\_consultations/Sub-regional\_Consensus\_Document.pdf</a>

Title of submission: Argentina, Brazil, Bolivia, Chile, Costa Rica, Cuba, Ecuador, El Salvador, Honduras, Mexico, Peru, Suriname, Uruguay and Venezuela: WHO Doc A/PHI/IGWG/2/2

No specific proposal made/recommended

UK Government - Response to the Report of the Commission on Public Health, Innovation and Intellectual Property Rights, September 2007

Available from: <a href="http://www.who.int/phi/public\_hearings/second/regional\_consultations/United\_Kingdom\_DFID.pdf">http://www.who.int/phi/public\_hearings/second/regional\_consultations/United\_Kingdom\_DFID.pdf</a>
Title of submission: The UK Government Response to the Report of the Commission on Public Health, Innovation and Intellectual Property Rights

Proposal(s) recommended for further exploration: PDPs, GAVI, International Financing Facility for Immunisation (IFFIm), Patent Pools, MMV, Advanced Purchasing Mechanisms, Open Source, Equitable Pricing in LDCs

## 2nd Public Hearing: Reports from Regional Consultations (6 submissions)

AFRO - Regional Consultation on Public Health, Innovation and Intellectual Property, Brazzaville, Congo, 3–5 September 2007

Available from: <a href="http://www.who.int/phi/public\_hearings/second/regional\_consultations/RC\_AFRO.pdf">http://www.who.int/phi/public\_hearings/second/regional\_consultations/RC\_AFRO.pdf</a>

No specific proposal made/recommended

AMRO/PAHO- Regional Consultation on Public Health, Innovation and Intellectual Property, Ottawa, Canada, 22-23 October 2007

Available from: <a href="http://www.who.int/phi/public\_hearings/second/regional\_consultations/RC\_AMRO.pdf">http://www.who.int/phi/public\_hearings/second/regional\_consultations/RC\_AMRO.pdf</a>

No specific proposal made/recommended

EMRO - Regional Consultation on Public Health, Innovation and Intellectual Property, Cairo, Egypt, 15–16 August 2007

Available from: <a href="http://www.who.int/phi/public\_hearings/second/regional\_consultations/RC\_EMRO.pdf">http://www.who.int/phi/public\_hearings/second/regional\_consultations/RC\_EMRO.pdf</a>

No specific proposal made/recommended

EURO - Regional Committee for Europe, Fifty-seventh Session, Belgrade, Serbia, 17–20 September 2007

Available from: <a href="http://www.who.int/phi/public\_hearings/second/regional\_consultations/RC\_EURO.pdf">http://www.who.int/phi/public\_hearings/second/regional\_consultations/RC\_EURO.pdf</a>

No specific proposal made/recommended

SEARO - Regional Consultation on Public Health, Innovation and Intellectual Property, Male, Maldives, 24-25 Oct. 2007

Available from: <a href="http://www.who.int/phi/public\_hearings/second/regional\_consultations/RC\_SEARO.pdf">http://www.who.int/phi/public\_hearings/second/regional\_consultations/RC\_SEARO.pdf</a>

No specific proposal made/recommended

WPRO - Informal Inter-Country Consultation on Public Health, Innovation and Intellectual Property, Manila, Philippines, 5-7 September 2007

Available from: <a href="http://www.who.int/phi/public\_hearings/second/regional\_consultations/RC\_WPRO.pdf">http://www.who.int/phi/public\_hearings/second/regional\_consultations/RC\_WPRO.pdf</a>

No specific proposal made/recommended