“The IP System, R&D and Access -- and What is Needed”

“Open Forum”
Commission on Intellectual Property Rights, Innovation and Public Health (CIPIIH)
Geneva, June 1, 2005

H. Bale, IFPMA
CIPIH Needs to Take a Holistic Approach to Innovation

<table>
<thead>
<tr>
<th>Techniques/Technologies</th>
<th>Disease Scope</th>
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<tbody>
<tr>
<td>Prevention</td>
<td>Global diseases</td>
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<tr>
<td>Diagnostics</td>
<td>Diseases prevalent in developing countries</td>
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<tr>
<td>Medical Devices</td>
<td>Vaccine-preventable diseases (e.g., rotavirus)</td>
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<tr>
<td>Pharmaceuticals</td>
<td>Diseases for which there are not yet cures or vaccines</td>
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<tr>
<td>Vaccines</td>
<td>Diseases showing increased resistance</td>
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<tr>
<td>Biotechnology</td>
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<tr>
<td>Traditional Medicine</td>
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</table>
Further Innovation Issues

• Are treatments/cures/vaccines or even diagnostics *Available*?

• *Are they Accessible* to patients who need them?

• *Are they Affordable* – at any price – to people who need them?
What is Innovation in Pharmaceuticals, Vaccines and Biotechnology?

« *Innovation* in pharmaceuticals encompasses many different options, going from the development of a *completely new medicine* for the treatment of a disease otherwise incurable, to *modifications of known pharmaceutical formulations to improve benefits for the patients*, such as less invasive administration route or a simpler administration schedule »

~100 Discovery Approaches

7,000,000 Compounds Screened

Preclinical Pharmacology

Preclinical Safety

Clinical Pharmacology & Safety

Patent Application

Discovered

Exploratory Development

Full Development

Phase I

Phase II

Phase III

Idea

11 - 15 Years

Drug

1 - 2 Products

专利保护－新药研发投入的保障
Key Characteristics of R&D-Based Pharma/Vaccine/Biotech Industry

- **Knowledge intensive**: bio, chemistry, IT...
- **Highly Regulated**: Clinical trial, grant of product license, patent grant, marketing regulations, quality inspections, reporting requirements, prices (frequently)
- **Long** product development cycles: 8-15 yrs.
- Numerous product pipeline **failures**: risk
- **Large financial commitments**: $200 mil to > $1.0 bil per new compound
- **Collaboration with public sector** (e.g., NIH)
Need for Adequate and Effective IP Protection (IPP)

- Patents: regulatory delays in major markets leave effective patent life of less than 10 years under the 20-year TRIPS rule (Number of OECD countries partially offset via protection supplementary to TRIPS level.)
- Clinical data protection provided for by TRIPS: “data exclusivity”
- Trademark protection against infringement and counterfeiting
There is no single global “IP System”

<table>
<thead>
<tr>
<th>Highly-Developed Strong IPP:</th>
<th>Recently-Developed Strong IPP:</th>
<th>Recent Adoption of Strong IPP:</th>
<th>TRIPS-Level IPP:</th>
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<tbody>
<tr>
<td>European Union</td>
<td>China</td>
<td>Poland</td>
<td>India</td>
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<tr>
<td>Japan</td>
<td>Korea</td>
<td>Hungary</td>
<td>Brazil</td>
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<td>New Zealand</td>
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<td>United States</td>
<td>Jordan</td>
<td>Estonia</td>
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<tr>
<td>Canada</td>
<td>Morocco</td>
<td>Latvia</td>
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<td></td>
<td>Taiwan</td>
<td>Lithuania</td>
<td>Below TRIPS Level of IPP</td>
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<td></td>
<td>et al.</td>
<td>Malta, Cyprus</td>
<td>Bangladesh, Other developing and least developed countries</td>
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<td></td>
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<td>(Also, they chose to “opt-out” of use of “flexibilities” of the TRIPS Para 6 accord.)</td>
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(Canada eliminated compulsory licensing in 1992; also provides mechanism for Doha Para 6)
No single IP System... but there are trends based upon:

- Informatics and computing revolution
- Genomics, Proteomics
- Emerging convergences of technology, based on knowledge and IP for future bioscience solutions
“As the Future Catches You”
-- Juan Enriquez, Harvard U.

Convergence & Acceleration:
– IT Revolution: Computers, Internet, etc.
– Bioinformatics/Biocomputing Revolution: Lasers, Robotics, Nanotechnology
– Molecular Revolution: Genomics, Proteomics, Combinatorial Chemistry
“As the Future Catches You” (2001)
-- Enriquez

- As new disciplines and technologies emerge... you don’t win the game by just producing gobs of knowledge. You also have to protect it and apply it...

- Which is why patents are a good barometer of creativity... tenacity... ability to articulate an idea... and capacity to build knowledge.

- Patents are a good window... (although not the only window) on who might triumph... and who might lose... over the course of the next two decades.
“Not all patents are good... Or valuable.... But being unable to generate patents... IS VERY BAD..... to compete globally... one has to patent globally” (J. Enriquez)

<table>
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<tr>
<th>Year</th>
<th>Country V</th>
<th>Country M</th>
<th>Country B</th>
<th>South Korea</th>
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<tbody>
<tr>
<td>1985</td>
<td>15</td>
<td>35</td>
<td>30</td>
<td>50</td>
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<tr>
<td>1998</td>
<td>29</td>
<td>77</td>
<td>88</td>
<td>3,362</td>
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A Few Implications

• IP needs to be part of any coherent health and economic -- as well as science -- policy.
• Some emerging countries will become successful global players in developing innovative biopharmaceuticals – South Korea, India, China, Singapore.
• Patents, data exclusivity and trademark protection are, or will be, an important part of the economic and legal structure in developing countries making the transition.
But…IPP Alone is not Sufficient and Needs Complementary Actions

- “Orphan disease” legislation: developed country “push/pull” mechanisms are in place
- Important public scientific research -- NIH
- WHO/TDR: focus on diseases endemic in developing countries
- PPP’s: MMV, GATB, DNDi, IAVI, MVI
- Need to Create sustainable demand: e.g., Advance-purchased commitments
Industry Needs to Continue Doing More – How?

• Collaborate with public, academic and NGO institutions to develop needed medicines where markets are currently lacking: MMV, GATB, etc.

• Work similarly with others in helping to overcome barriers to access to existing therapies and vaccines: GAVI, Global Fund for AIDS, TB and Malaria
Concrete Actions: Access to Tropical Diseases Medicines

- **Leprosy**: since 2000, USD 35 million worth multidrug therapy donated through WHO and the Global Alliance to Eliminate Leprosy (GAEL)
- **Onchocerciasis**: 40 million doses of Mectizan donated annually in 34 countries
- **Lymphatic Filariasis**: 96 million tablets of albendazole donated in 40 countries
- **Trachoma**: 16 million treatments donated in 11 countries
Current Concrete R&D Actions

- Novartis Institute for Tropical Diseases in Singapore
- AstraZeneca Research Institute in Bangalore
- GSK Tropical Research Institute in Tres Cantos, Spain
Further Information

Background on IP issues, Partnerships, Neglected diseases

www.ifpma.org

www.biag.org