

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

“Open Forum”

Commission on Intellectual Property Rights,  
Innovation and Public Health (CIPRH)

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# CIPIH Needs to Take a Holistic Approach to Innovation

## Techniques/Technologies

- Prevention
- Diagnostics
- Medical Devices
- Pharmaceuticals
- Vaccines
- Biotechnology
- Traditional Medicine

## Disease Scope

- Global diseases
- Diseases prevalent in developing countries
- Vaccine-preventable diseases (e.g., rotavirus)
- Diseases for which there are not yet cures or vaccines
- Diseases showing increased resistance

# 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?

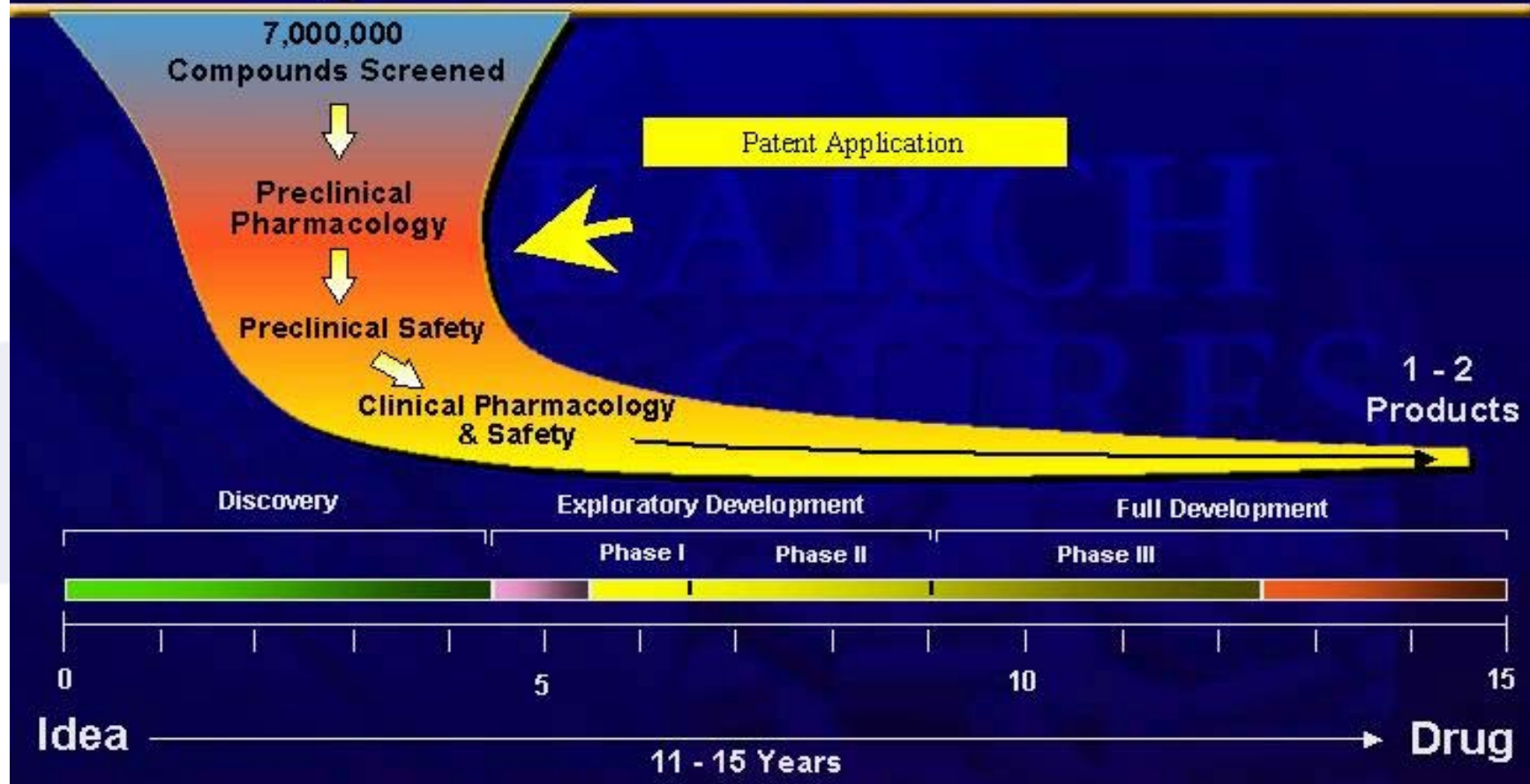
# What is Innovation in Pharmaceuticals, Vaccines and Biotechnology?

« *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 »

EU Working Group on Pharmaceuticals and Public Health,  
Report, March 2000.

~100 Discovery Approaches

专利保护—新药研发投入的保障





**Comprehending  
the R&D Process  
in  
Pharmaceutical,  
vaccine,  
Biotech,  
Diagnostics and  
Devices Sectors**

[www.biag.org](http://www.biag.org)

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**Biomedical Industry Advisory Group (BIAG)**



# 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’

| <b>Highly-Developed Strong IPP:</b>  | <b>Recently-Developed Strong IPP:</b>   | <b>Recent Adoption of Strong IPP:</b>   | <b>TRIPS-Level IPP:</b>  |
|--|---|---|--|
| <p><b>European Union</b><br/><b>Japan</b><br/><b>Australia</b><br/><b>New Zealand</b><br/><b>Switzerland</b><br/><b>United States</b><br/><b>Canada</b></p> <p>(Canada eliminated compulsory licensing in 1992; also provides mechanism for Doha Para 6)</p> | <p><b>China</b><br/><b>Korea</b><br/><b>Mexico</b><br/><b>Chile</b><br/><b>Singapore</b><br/><b>Jordan</b><br/><b>Morocco</b><br/><b>Taiwan</b><br/><b>et al.</b></p> | <p><b>Poland</b><br/><b>Hungary</b><br/><b>Czech Republic</b><br/><b>Slovakia</b><br/><b>Slovenia</b><br/><b>Estonia</b><br/><b>Latvia</b><br/><b>Lithuania</b><br/><b>Malta, Cyprus</b></p> <p>(Also, they chose to “opt-out” of use of “flexibilities” of the TRIPS Para 6 accord.)</p> | <p><b>India</b><br/><b>Brazil</b><br/><b>South Africa</b><br/><b>Argentina</b><br/><b>Thailand</b></p> <hr/> <p><b>Below TRIPS Level of IPP</b></p> <hr/> <p><b>Bangladesh, Other developing and least developed countries</b></p> |

*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)**

*1985: US Patents Granted*

- Country V: 15
- Country M: 35
- Country B: 30
- **South Korea: 50**

*1998: US Patents Granted*

- Country V: 29
- Country M: 77
- Country B: 88
- **South Korea: 3,362**

# 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](http://www.ifpma.org)

[www.biag.org](http://www.biag.org)

