TRAINING COURSE
12-14 February 2009
Main Campus, University of Pretoria

INTELLECTUAL PROPERTY RIGHTS
AND
PHARMACEUTICAL PRODUCTS
AND PROCEDURES

Global Trends
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United States Patent and Trademark Office

Global Trends in Pharmaceutical Intellectual Property Rights
Is it a choice of IP or Public Health?

VS

Or can we have both?
Topics for Today

- IP and Public Health Innovation
- IMPACT: Counterfeits and Public Health
- IGWG: Public Health, Innovation and Intellectual Property
- IGM: Pandemic Preparedness
### Disease Burdens

**Emerging and Re-Emerging Infectious Diseases: 1996-2004**

- Ebola and Marburg
- Congo hemorrhagic fever
- Influenza H5N1
- Hendra virus
- Lassa fever
- Monkeypox
- Nipah virus
- New variant Creutzfeldt-Jakob disease
- Rift Valley fever
- SARS coronavirus
- Venezuelan equine encephalomyelitis
- Yellow fever
- West Nile fever

**Source:** Interfarma (Brazilian Research-based Pharmaceutical Manufacturers Association)

### Pharmaceutical Market

**Source:** Interfarma (Brazilian Research-based Pharmaceutical Manufacturers Association)

<table>
<thead>
<tr>
<th>Key Markets</th>
<th>US$ Bil</th>
<th>% of the total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. UNITED STATES</td>
<td>$ 274.4</td>
<td>45.1</td>
</tr>
<tr>
<td>2. JAPAN</td>
<td>$ 56.7</td>
<td>9.3</td>
</tr>
<tr>
<td>3. FRANCE</td>
<td>$ 34.0</td>
<td>5.6</td>
</tr>
<tr>
<td>4. GERMANY</td>
<td>$ 31.9</td>
<td>5.2</td>
</tr>
<tr>
<td>5. UK</td>
<td>$ 20.5</td>
<td>3.4</td>
</tr>
<tr>
<td>6. ITALY</td>
<td>$ 20.5</td>
<td>3.4</td>
</tr>
<tr>
<td>7. SPAIN</td>
<td>$ 16.3</td>
<td>2.7</td>
</tr>
<tr>
<td>8. CANADA</td>
<td>$ 15.5</td>
<td>2.5</td>
</tr>
<tr>
<td>9. CHINA</td>
<td>$ 10.7</td>
<td>1.8</td>
</tr>
<tr>
<td>10. SOUTH KOREAN</td>
<td>$ 8.9</td>
<td>1.5</td>
</tr>
<tr>
<td>11. BRAZIL</td>
<td>$ 8.4</td>
<td>1.4</td>
</tr>
<tr>
<td>12. MEXICO</td>
<td>$ 8.1</td>
<td>1.3</td>
</tr>
<tr>
<td>12 BIGGER</td>
<td>$ 505.9</td>
<td>83.2</td>
</tr>
<tr>
<td>TOTAL MARKET</td>
<td>$ 608.1</td>
<td>100.0</td>
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</table>
### Top 10 Medical Breakthroughs of 2007

1. Circumcision dramatically reduces HIV transmission  
2. Molecular test for Metastatic Breast Cancer  
3. First Human Vaccine against Avian Influenza  
4. Help for dieters: Alli  
5. New diabetes genes  
6. Continuous birth control: no more periods  
7. New relief for fibromyalgia: Lyrica  
8. Early-stage test for lung cancer  
9. New source of Stem Cells  
10. Benefits of Vitamin D


### Top 10 Medical Breakthroughs of 2008

1. First Neurons Created from ALS Patients (methods and products)  
2. Inflammation vs. Cholesterol (CRP and statins)  
3. Scarless surgery  
4. Genomes for the Masses  
5. New Genes for Alzheimer’s  
6. Five-in-one Vaccines (diptheria, tetanus, pertussis, polio, haemophilus influenzae type B)  
7. Gene Screens for Breast Cancer  
8. Blood test for Down syndrome  
9. Seasick Patch for Cancer Patients  
10. Stem-Cell Trachea Transplant

Trade and Public Health

- TRIPS flexibilities
  - Article 1
  - Article 27.2 and 27.3
  - Article 30
  - Article 31
  - 2001 WTO extension until 2016 for least developed countries (LDCs)
  - Doha Ministerial Declaration and the August 30, 2003 letter
    - Specifically mentions HIV/AIDS, malaria, tuberculosis, and other epidemics

Trends in Data Protection

- TRIPs Article 39.3: (Undisclosed Information) Requires States to protect undisclosed test or other data, the origination of which involves considerable effort, that is submitted to governments to obtain marketing approval for pharmaceutical and agricultural chemical products must be protected against “unfair commercial use” and against disclosure.
### Art. 39.3 Unfair Competition Protection

<table>
<thead>
<tr>
<th>Many countries have/are providing a period of time against non-reliance</th>
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<tbody>
<tr>
<td>For new pharmaceutical chemical entities</td>
</tr>
<tr>
<td>Japan – 8 years</td>
</tr>
<tr>
<td>China, Korea – 6 years</td>
</tr>
<tr>
<td>EU – 8+2+1 years</td>
</tr>
<tr>
<td>U.S., Guatemala, Mexico, Australia, New Zealand, Egypt, Singapore, Chile (among others) – 5 years</td>
</tr>
</tbody>
</table>

### Patent vs. Data Protection

**Patent Protection**
- Protects:
  - The pharmaceutical product; or
  - The method of making the pharmaceutical product; or
  - The method of using the pharmaceutical product

**Data Protection**
- Protects:
  - The test or other data generated by the innovator in clinical studies to prove safety and efficacy;
  - Does not provide protection for a competitor who produces their own phase I, II & III clinical data

Patent Protection and Undisclosed Information Protection are Separate IP Protections Under TRIPS and Protect Different Subject Matter
Counterfeit Drugs Harm Society

Types of Counterfeit Drugs:
- Identical copies containing same ingredients, formulas and packaging, by other than the original manufacturer
- Look-alikes—high quality packaging with little or no active ingredients or harmful substitutes
- Rejects—rejected by authentic manufacturer
- Re-labels—past expiration date
- Devices—aortic pumps, implants, test kits, etc.

Pharmaceutical Production: Sterile, Uniform, Safe, and Efficacious
Counterfeit Pharmaceutical Production: ???

Public Health, Innovation and Intellectual Property

- World Health Organization
  - Inter-Governmental Working Group (IGWG)
  - Inter-Governmental Meeting (IGM) on Pandemic Preparedness
IGWG: Global Strategy

- Encourage the application and management of IP to maximize health-related innovation and access.
  
  Source: http://www.who.int/mediacentre/events/2008/wha61/issues_paper1/en/

IGWG: IP Resources and Capacity Building

- Promote Capacity Building
- Promote Health Representative participation in IP and Trade negotiations
- Strengthen IP training and education
- Facilitate access to and innovation in traditional medicine
- Take account of TRIPS flexibilities and public health in national legislation and international negotiations
**IGWG: Delivery and Access**

- Increase investment in health-delivery infrastructure and financing of health products
- Improve ethical review and regulation of health product quality, safety, and efficacy
- Promote competition to increase access and affordability

**Complementary Incentives**

- Award Schemes
- Career Recognition for Health-related Innovations
- Priority Voucher Program – US FDA

IGM: Avian Influenza

- Global Influenza Surveillance Network in operation since 1952
- Twice annual seasonal influenza candidate vaccine strain recommendations
- 250 million seasonal doses
- 4 Collaborating Centers, 3 Reference Laboratories, and 122 National Influenza Centers (94 countries)
IGM: Pandemic Preparedness

- Indonesia suspended sample sharing in December 2006
- Half of all human cases occur in Indonesia
- Indonesia stated concern regarding fairness, equity and transparency of benefit and sample sharing in current system

IGM Today

- GISN currently operational; some Indonesian samples shared
- Ongoing negotiations at WHO to resolve remaining issues
- Conflicting views on benefits
  - Shared to all based on public health needs or tied to virus sharing
Questions?

Thank you!