Balancing Innovation and Competition Through Intellectual Property Policies in the Pharmaceutical Sector

China Pharmaceutical University
Nanjing, China
September 2, 2013

Teresa Stanek Rea
Acting Director, United States Patent and Trademark Office
Acting Under Secretary for Intellectual Property, United States Department of Commerce
Pharmaceutical Patents Granted by U.S. PTO
(Recorded by Origin of Priority Document 8/23/2013)

<table>
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<tr>
<th>FY</th>
<th>U.S. All</th>
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<td>-39%</td>
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8/30/2013
Drug Discovery and Commercialization

- PRE-DISCOVERY: 5,000–10,000 compounds, 3–6 years
- Drug Discovery: 250
- Preclinical: 5
- Clinical Trials:
  - Phase 1: 20–100 volunteers, 6–7 years
  - Phase 2: 100–500 volunteers, 6–7 years
  - Phase 3: 1,000–5,000 volunteers, 6–7 years
- FDA Review: 0.5–2 years
- Scale-up to MFG.: INDEFINITE
- Post-Marketing Surveillance: INDEFINITE

Source: PhRMA®
• CPU owns 507 Patents for Technology Transfer

• CPU has Filed 11 Patent Applications with the U.S. PTO since 1990, with 5 granted, 5 pending, and one abandoned.
Senator Birch Bayh
# Medicine Patent Filings in China

## 2009-2010 Medicine Patent Applications (N)

<table>
<thead>
<tr>
<th>Category</th>
<th>2009-2010 Medicine Patent Applications (N)</th>
<th>% of Total Applications</th>
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<tbody>
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<td>Chemical Medicine</td>
<td>6206</td>
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<td>Biological and Biochemical Medicine</td>
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Source: 2010 and 2011 China Statistics Yearbook on High Technology Industry
“Orange Book”

http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm
### Example from the Orange Book

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http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=021880&Product_No=001&table1=OB_Rx
Article 26(3) of China’s Patent Law

• “The written description shall contain a clear and comprehensive description of the invention or utility model so that a technician in the field of the relevant technology can carry it out; …”

• “说明书应当对发明或者实用新型作出清楚、完整的说明，以所属技术领域的技术人员能够实现为准；…”
Comparisons with Chinese Practice

- SIPO 1993/2001 Examination Guidelines – 4.1, Chapter 10 of Part 2 ("Sufficiency of Disclosure")
  - For an application for a chemical product invention, the use and technical effect of the product shall be **sufficiently** disclosed.

- SIPO 2006/2010
  - For an application for a chemical product invention, the use and/or technical effect of the product shall be **completely** disclosed.

  - "there must be *sufficient disclosure*, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed.” (In Re Vaeck, 947 F.2d 488 (Fed. Cir. 1991))

  - "The information contained in the disclosure of an application must be *sufficient* to inform those skilled in the relevant art how to both make and use the claimed invention.”
Comparisons with Chinese Practice

- For a new pharmaceutical compound...
  - SIPO
    - 1993 - The effective amount, method of application or method of formulation shall be described to such an extent that a person skilled in the art can carry it out.
    - 2001/2006/2010: There should be qualitative or quantitative laboratory test data (including animal test) or clinical test sufficient to prove that the technical solution can achieve the forecasted technical solution or effect.
  - US/1991: There must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed. In Re Vaeck (1991).
Drug Discovery and Commercialization
Comparisons with Chinese Practice

• SIPO
  – 1993: Prerequisite for supplementing use and effect after the filing date
    [is]...it must be a use or effect that has been implied in the original
    specification so that a person skilled in the art is able to deduce
    directly; or it is use that can be deduced directly from the prior art.
  – 2001: Prerequisite for supplementing use and effect after the filing date
    [is]...it must be a use or effect that has been implied in the original
    specification so that a person skilled in the art is able to deduce
    directly; or it is use that can be deduced directly from the prior art.
  – 1993 & 2001: Any embodiment submitted after the filing date can only
    be used as a reference by the examiner for assessing novelty,
    inventiveness, and practical applicability.
  – 2006/2010: Embodiment and experimental data submitted after the
    filing date shall not be taken into consideration.

• US (1971) Post-filing evidence "can be used to substantiate any doubts as
  to the asserted utility since this pertains to the accuracy of a statement
  already in the specification." In re Marzocchi (439 F.2d 220 1971)
First Chinese Patent Applicant in the United States

Dr. Jin Fuey Moy (梅振魁; Mei Zhenkui, 1862-1924)
THANK YOU

谢谢！