Developing Countries in the Globalization of Pharmaceutical Patenting

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2016 Dr. Sam-Chung Hsieh Memorial Lecture
Stanford University Library
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Globalization of Pharmaceutical Patenting

Ming Liu and Sumner La Croix, “A cross-country index of intellectual property rights in pharmaceutical inventions,” Research Policy 44 (February 2015)

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General Issues: Conflicts over Intellectual Property

1. Benefits: Incentives to innovation
   • Permit appropriation of knowledge

2. Costs: Restrict access and use of innovations
   • Allow owner to control

→ Conflicts over ownership and use of knowledge
Specific Issues: Conflicts over Drug Patents

1. High research costs
   • Expensive and low success rate, hence concern with appropriation

2. Long lag times
   • Long periods from invention to commercialization, hence concern with using full terms (or more)

3. Easy replication
   • Minimal technological barriers, hence search for legal means of appropriation

4. Low functional substitutes
   • Terms of access have widespread significance

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Globalization of Pharmaceutical Patents:
Key Issues

• Potential Benefits
  – Innovation
  – Foreign investment
  – Licensing (inward and outward)
  – Product launch

• Potential Costs
  – Higher prices (across board or key therapeutic areas)
  – Stress on health budgets

• \textit{Expected benefits > expected costs}: allow drug patents
• \textit{Expected benefits < expected costs}: do not allow drug patents
  \rightarrow Abilities to harness benefits and mitigate costs distributed unevenly (“N/S”)
Is it an invention?
  Yes
  ↓
Can this sort of invention be patented?
  Yes
  ↓
  Non-patentable subject matter (no patent)
  No
  ↓
Examination
Is it “new,” is it “inventive,” is it industrially “useful?”
  Yes
  ↓
Patent Granted
  No
  ↓
Application rejected (no patent)
Is it an invention?
  Yes

Can this sort of invention be patented?
  Yes
  Examination
  Is it “new,” is it “inventive,” is it industrially “useful?”
    Yes
    Patent Granted
  No

No
  Non-patentable subject matter (no patent)

No
  Application rejected (no patent)
From Application to Patent

Is it an invention?  
Yes  

↓

Can this sort of invention be patented?  
Yes

↓

Examination

Is it “new,” is it “inventive,” is it industrially “useful?”  
Yes

↓

Patent Granted

No  

No  

Non-patentable subject matter (no patent)

No  

Application rejected (no patent)

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National Income and Pharmaceutical Patents

(Per Capita GDP, USD2005) vs. (Year of Introduction)

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Nuances, Details, Fine Print...

- Not immediate (transition periods)
- Not retroactive (as if the world started in 1995)
- Variation in national styles of implementation (when and how drug patenting introduced; subsequent reforms)
**The Long Shadow of Initial Choices**

FDA approved drugs (1996-2004) in Brazil and India

Sampat and Shadlen, “TRIPS Implementation and Secondary Pharmaceutical Patenting in Brazil and India,” *Studies in Comparative International Development* 50 (June 2015)

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The Importance of 1995

Priority Date of First Patent by Year of Drug Launch


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Primary vs. Secondary Patents
Growing Importance of Secondary Patents

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Patent application covering XYZ

1994 – 2014

XYZ is the base compound, covered by a “primary” patent

Patent covering XYZ*

2000 – 2020

Approval of XYZ* for marketing

2003

XYZ* is a modification of XYZ, covered by both the primary patent and a new “secondary” patent

Secondary patents and exclusivity terms

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“Sequential accumulation of patents on alternative dimensions of existing molecules and drugs, to extend periods of market exclusivity.”
Responding to the Challenges of Secondary Patents

Litigation

Examination

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Case Study: Glivec in India

Events
2006, IPO rejected application for crystalline form of Glivec’s base molecule (imatinib mesylate)
• Provision against secondary patents a ground for rejection
• Novartis appeal (also Constitutional Court)
• Supreme Court upheld rejection (2013)

Result
No patent protection for Glivec in India
• Outrage (Novartis et al)
• Ecstasy (MSF et al)
## Gleevec/Glivec in Comparative Perspective

<table>
<thead>
<tr>
<th></th>
<th>USA</th>
<th>India</th>
<th>Brazil</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary</td>
<td>Applied for (1993); granted + extensions</td>
<td>Pre-1995; not eligible</td>
<td>Granted (pipeline)</td>
</tr>
<tr>
<td>Secondary</td>
<td>Granted, challenged, settled</td>
<td>Denied (Section 3d and pre-grant opposition)</td>
<td>Denied</td>
</tr>
<tr>
<td>Comment</td>
<td>Unsuccessful LCM/Evergreening</td>
<td>Timing (+/- 2 years....)</td>
<td>Unsuccessful LCM/Evergreening</td>
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</tbody>
</table>
But Examination is Resource-Intensive
Comparative Grant Rates

Conclusions

• A new world order
• Effects depend on national implementation
• Still in global period of transition
• Asymmetric abilities to harness benefits and mitigate costs
• Addressing gap in global governance