Intellectual Property and Access to Vaccines

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The Value of IP

In our current system, IP benefits:

- The private sector: By protecting large capital investments to achieve return on investment, and

- The public sector: By helping to mobilize the funds necessary to develop safe and effective products
Case Study
Hepatitis B Vaccine and Korea
History of HBV vaccine

- 1962 – identification of hepatitis antigen in Korea
- 1968 – characterization of HBsAg
- Mid-1970s – first HBV vaccine based on human plasma (producers in US, Europe, Asia)
- Mid-1980s – HBV vaccines based on recombinant DNA technology (two Large Pharma companies): now the world’s most widely used vaccine.
Price History

- **1980s** – limited use of vaccine in developed countries. Very little use in developing countries (Korea, China, Taiwan). Too expensive (~$18 per dose).

- **1986** – founding of the International Task Force. Price drops to <$1 per dose

- **1992** – World Health Assembly calls for universal childhood immunization

- **1999** – Gates Foundation establishes Children’s Vaccine Fund. Price drops to <$0.30 per dose.
IP for rDNA HBV

- Institut Pasteur
- Biogen, NV
- Regents of the University of California
- These patents were filed only in US, Europe, and a few other countries.
- Many other patents including for isolation, purification, etc.
Three key patents

<table>
<thead>
<tr>
<th>Assignee</th>
<th>Invention</th>
<th>Date</th>
</tr>
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<tbody>
<tr>
<td>Pasteur</td>
<td>Nucleotide sequence coding HBsAg, vector containing sequence, process for producing sequence and HBsAg</td>
<td>29 Aug 1980</td>
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<tr>
<td>Biogen</td>
<td>Recombinant DNA molecules expressing HBcAg and HBsAg</td>
<td>31 March 1982</td>
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<tr>
<td>UC</td>
<td>Synthesis of human virus antigens, e.g., HBsAg, by yeast ((Saccharomyces cerevisiae)).</td>
<td>21 June 1988, 7 June 1995</td>
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Korea and HBV vaccine

- 1984 – Company A and Company B introduce plasma-derived vaccine
- 2005 – Company A to introduce rDNA vaccine (*Hansenula*)
How did Korea develop rDNA vaccines?

- Company A developed technology on its own (*Sacch.*).
- Company B entered joint venture with a company that controlled *Hansenula*.
- Company C formed joint venture with a company that had access to technology (*Sacch.*).
- Companies focused on countries where key patents not filed (Asia and Mideast).
Strategy

- Pursue joint ventures to facilitate learning
- Focus on countries outside US and Europe to avoid patent concerns, regulatory costs, and other market entry costs.
- Obtain acceptance by several national governments (primarily in Asia)
- Upgrade national regulatory systems
- Obtain WHO certification
A General Framework

Biotechnology Innovation
Six determinants of biotechnology innovation

- Support for R&D
- Ability to manufacture new biotech products
- The creation of domestic markets
- The development of export markets
- Creation of systems to protect IP
- Creation of systems for drug and vaccine regulation
### HBV & Determinants

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<th>Support for R&amp;D</th>
<th>The government accorded high priority to biotechnology. Strong support for overseas training and domestic research.</th>
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<tr>
<td>Manufacturer</td>
<td>Government encouraged development of biotechnology industry.</td>
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<td>Domestic market</td>
<td>Government accorded high priority to HBV immunization.</td>
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<td>Export market</td>
<td>Government encouraged export markets. Companies worked with public sector entities (ITFHBI). Marketed directly to countries.</td>
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<td>IP</td>
<td>Avoided countries where key patents in force. Sought new IP.</td>
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<td>Regulation</td>
<td>Government built up KFDA. WHO provided guidance.</td>
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Conclusions

- IP did not impede access of HBV in developing countries
- Lack of interest on part of Large Pharma
- Lack of resources by other potential suppliers – longer time-to-develop
- Need to develop regulatory systems
- LACK OF MARKET
Key Conclusions

- The development of new vaccines takes place in a complex space framed by six determinants of innovation.

- IP is important but probably less so than regulatory issues and market development.
Questions for the future

- **R&D**: Increasing difficulty of vaccine development. The continued dominance of Big Pharma in R&D?
- **IP**: TRIPS – global and equal treatment, product patents?
- **Regulation**: Continuous increase in regulatory hurdles?
- **Markets**: Will there be markets?
- **Manufacturing**: Least important issue?
IP Issues in the future

- Global dominant patents
- Blocking of second comers
- Level of developing country commitment
- Large Pharma need for joint ventures in developing countries
- ?
Acknowledgement

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