Vaccine Partnerships and Intellectual Property Management

Elizabeth J. Haanes, Ph.D.
IP Concerns in the Vaccine Space

• Strategic planning should begin early and should focus on partnering rather than exclusion

• Learn the patent landscape...and avoid third-party patent “thickets”

• In the vaccine space, IP strategies need to be global
  – International IP protection: TRIPS
  – Government rights and responsibilities

• What to expect from your patent counsel
Partnerships

- Who are the players in vaccine development partnerships?
- What do they contribute?
- What are their goals?
- How does IP help or hinder achieving those goals?
- How can we make it work better?
The PLAYERS

- “the bug”
- Individuals and populations at risk from “the bug”
- Basic (e.g. academic) researchers
- Governments
- NGOs
- Financers
- Corporations
Basic Researchers

- Mainly universities, but also intramural government research (e.g., NIH)
- Often the initial source of discoveries
- Research often government funded
- Patenting of government funded discoveries:
  - U.S.: Bayh-Dole Act
  - Equivalent provisions in other countries
- Spurs university/industry partnerships which cycle more funds into research
Governments

- Intramural and extramural funding of basic research and patenting of discoveries
- Responsible for public health and biodefense
- Regulatory authority over vaccine licensure
Non-Governmental Organizations

- Interest in promoting global health
- Non-profit motivation
- Huge source of research funding, especially in the vaccine space
- May or may not have independent research and/or clinical trial capabilities
- Unlikely to have manufacturing capabilities
Financers

- Fund high-risk commercial endeavors with hopes of large return on investment
- Fund start-up and early-to-mid-stage private companies in the development of innovative new vaccines
- High risk, but not without careful due diligence – IP protection is important
Startup and Early-Stage Corporations

• Often spin-offs from academic institutions
• Innovative technologies in search of financial investment
• Early development of an IP strategy can be a key to securing investments
Established Corporations

- Expertise, infrastructure, and capital to develop, test, and manufacture vaccines
- Expertise in clinical trials and regulatory affairs
- May or may not have robust discovery research arms
- Often depend on in-licensing of technologies from academia and early-stage corporations for pipeline
- Generally have established products which generate profits
Something for Everyone

Partnership

- Safe, effective commercial vaccines
- Global cooperation to provide affordable vaccines to areas with greatest need
- Biodefense

Finances
- Governments
- Large corporations
- NGOs

Universities
- Small corporations
- Large corporations

IP Protection

Extended IP Protection

New Innovation

Funding
Partnerships: the Road to Health and Profit

• Develop a strategic plan, incorporating IP considerations, that maximizes goals and facilitates establishment of partnerships
• Understand the patent landscape throughout vaccine development
• Cut through patent thickets with communication and cooperation
• Use IP strategy as a business tool rather than an impediment
Learn the Landscape…
…and Stay Out of the Thickets
## Survey/Map the Patent Landscape

<table>
<thead>
<tr>
<th>Protect ideas</th>
<th>increase value</th>
</tr>
</thead>
</table>

### Your IP
- Owned
- Licensed (exclusive vs. nonexclusive)
- Options
- “Provisional” or “unrealized”

### Partner IP
- Current strategic partners
- Potential strategic partners
  - Search / analyze
  - Due diligence for acquisition / license

### Competitor IP
- FTO collection / analysis
- Opinions (FTO, noninfringement, invalidity)
- Identify gaps (“opportunities”) and potential design-arounds
Freedom-to-Operate

DNA/RNA
Vector system
Expression Platform
Polypeptide Engineering
Propagation
Purification
Formulation

Excipients
Adjuvants
Stabilizers

Vaccination Methods
Delivery devices

Commercial Vaccine Formulation
Patent Right = A Right to Exclude or a Right to Collect Damages

- In certain circumstances, a patent grant provides a right to exclude others from practicing the claimed subject matter
- In other circumstances, a patent grant provides the right to seek compensation, but not the right to exclude
A Right to Exclude ≠ A Right to Make

- A patent does not give patent owner an affirmative right to make, use, or sell anything.

- A patent claim can be subordinate to a broader, dominant patent claim (e.g., genus vs. species).

- Holder of subordinate patent may need license to practice its own technology.

- Must compare claims of dominant patent (not disclosure) to what your company is doing or plans to do (e.g., make, use, sell).
FTO Analyses

• Obtain broad overview of third-party patents at a very early stage
• Tailor analysis to geographic scope
• Obtain more detailed analyses as vaccine product development progresses
• Perform regular updates
Some Free Tools for Patent Searching

- Great resources, but can’t replace analysis by expert patent counsel
- Most national patent offices now have full text of patents online

www.patentlens.net

http://ep.espacenet.com

USPTO Patent Full-Text and Image Database

http://patft.uspto.gov/
Coping With Valid Patent Claims

• License
  – Often cross-licensing one’s own patents is useful in negotiations
  – Direct competitors—licensing may not be an option

• Clinical Research Exemptions

• Design Around
  – Usually only possible with early identification of relevant patents
  – Not possible with very broad claims, but broad claims more likely to be invalid
“Patent Thickets”

• Bundles of patents which must be considered prior to commercializing a product

• For example, malaria antigens: 167 patent families owned by 75 assignees were identified.
## Other Areas That May Be Prone to Patent Thickets

- Adjuvants
- Cell lines for propagating viral vaccines
- Protein expression systems for subunit vaccines
- Anything having to do with influenza
Everyone Into the (Patent) Pool?

- A **patent pool** is an arrangement in which two or more patent owners agree to license certain of their patents to one another and/or to third parties.
- Patent pools have been used in a variety of industries
  - sewing machines and aircraft
  - software and consumer electronics products such as DVDs, MPEG, Blue-Ray discs, and high definition DVDs.
<table>
<thead>
<tr>
<th><strong>Everyone Into the (Patent) Pool?</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>•</strong> Patents in a pool should cover <em>complementary</em> technologies, as opposed to <em>competing</em> technologies.</td>
</tr>
</tbody>
</table>
| **•** Ideally, an independent standard-setting body would establish criteria, guidelines, or standards for what technology can be included in a patent pool.  
  – World Health Organization? |
| **•** The pooled patents should be available on a nonexclusive basis. |
| **•** The pooled patents should be available separately from the individual patent holders on a nonexclusive basis. |
Can Patent Pools Work for Vaccines?

- Patent pools proposed for SARS (WHO) and malaria (PATH malaria vaccine initiative), did not come to fruition

- UNITAID is considering patent pools for drugs to fight HIV, malaria, and TB

- EMILA (the Essential Medical Inventions Licensing Agency)
  - A non-profit Licensing Agency proposed by Knowledge Ecology International (KEI) to support the creation of patent pools that facilitate manufacture and sale of medical products and vaccines
Think Globally, Act Globally

- Rights to government-funded inventions
- Compulsory licenses under TRIPS
- Research exemptions
Government-Sponsored Research

- In the U.S.: Bayh-Dole Act (35 U.S.C. §§ 200-212)
  - Government lacks the incentives to develop and commercialize technology innovations
  - Act allows non-profit organizations and small businesses to acquire rights to intellectual property arising out of government funded research
  - many other developed and developing countries are establishing, or have established, similar laws.
Limitations to Rights Conveyed Under Bayh-Dole

- U.S. retains "a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world"
  - Scope of “non-exclusive license” not yet tested

- “March-in rights”: the ability to require a patentee to grant a license under various circumstances such as:
  - (1) no effective steps have been taken to achieve practical application of the invention
  - (2) unmet health or safety needs
    - U.S. has not yet exercised “march-in rights”
Compulsory Licenses under TRIPS Article 31

• May be granted for:
  – lack of working of a patent
  – Government-funded inventions
  – failure or inability of a patentee to meet demand for a patented product
  – where refusal to grant a license leads to the inability to exploit important technological advances

• Typically limited to domestic use
Doha Declaration -- 2001

- Compulsory licenses to a third party manufacturer for the purpose of protecting public health -- exporters to least developed countries also included

- Allows for license for exportation to least developed countries rather than primarily domestic usage as normally required by Art. 31 of TRIPS

Clinical and Experimental Use Exemptions

- Use of a patented product or process in experiments related to regulatory approval of a drug is exempt from infringement.

- Provisions provided in most countries:
  - China: *Sankyo v. Wansheng* (Beijing No. 2 Intermediate People’s Court, Dec. 2006)
  - Europe: Art. 10(6) of Directive 2004/27/EC, scope varies among EU states
  - India: India Patents Act Art. 107A
  - U.S. 35 U.S.C. § 271(e)(1)
What Should You Expect From Your IP Counsel?

1. A thorough understanding of your technology and your business plan
2. Knowledge of the vaccine industry -- to understand what your competitors are doing
3. Smart, cost-effective patent procurement and patent leverage
4. Consistent, high quality representation throughout product development and commercialization
5. The ability and willingness to explain how the rapidly evolving legal landscape could affect your business
6. Regular reevaluation of your IP strategy
Thank You!

- Acknowledgments:
  - Jorge A. Goldstein, Ph.D.
  - Eric K. Steffe
  - Vaccine clients of SKGF