Unlocking Intellectual Property: Principles for Responsible Negotiation

November 16, 2012
Webinar speakers

**Panelists**

- **Maria Freire**
  President
  Foundation for the NIH

- **Robert Cook-Deegan**
  Research Professor, Genome Ethics, Law & Policy
  Institute for Genome Sciences and Policy, Duke University

- **David Lubitz**
  Partner
  Schaner & Lubitz, PLLC

**Moderator**

- **Margaret Anderson**
  Executive Director
  FasterCures
The Summit:

- Held July 2012
- Small, expert-led working group from academia, government, venture philanthropy and patient advocacy groups, and consulting and law firms
- Focused on developing guiding principles for responsible licensing and promoting adoption of these practices to best support innovation

Key Findings:

- It is not about the IP, it is about how it is being used
- There is a fundamentally new landscape in biomedical research resulting from the emergence of venture philanthropy and patient advocacy groups
- We need an IP management system that addresses this emerging ecosystem, not reflects the current one
Introducing the Principles

UNLOCKING INTELLECTUAL PROPERTY:

Principles for Responsible Negotiation

Principles for Getting Started

KNOW YOURSELF AND YOUR FEAR

Negotiating

TACKLE THE TOUGH STUFF EARLY

After Negotiations

BE A LEARNING AND SHARING SYSTEM

“Build your IP plan into your business strategy and face it head on. Intellectual property negotiations are almost always important and often inevitable.”
Principles for Getting Started

Know Yourself and Your Fear

• **Identify and calibrate your expectations.** Recognize that in some cases getting on base might be just as important as hitting a home run. While IP is not always about the money (e.g., it is also about research outcomes), IP is primarily about the money. If you are an academic institution, remember that you are the outward emissary of the university’s ideas, not just a profit center.

• **Know your limits,** that is, what your organizations absolutely can or cannot allow.

• **Do not let fear paralyze you.** Entering into and negotiating agreements based on fear of litigation or fear of not maximizing revenue is not productive... not doing the deal or slowing progress is a far bigger loss to the patient and the public than lower potential economic return.

Anticipate the Road Ahead

• **Build your IP plan into your business strategy and face it head on.** Intellectual property negotiations are almost always important and often inevitable. Make conscious decisions, even if the final decision is to take no action. Remember that your decision(s) can affect whether your counter-party becomes a repeat player.

• **Identify authentic partners** who can bring value-adding assets to the table, help frame objectives that are important to each party, and participate for the long-term, if required. Then assume good intentions.

• **Go into negotiations with knowledge of the players, the “market,” and the context.** There is no substitute for deep intelligence. Educate yourself about customer preferences and professional standards to ensure they are adequately considered in your business plan.

• **Set a timeline for finalizing decisions** but anticipate that re-negotiation might be necessary as events transpire.
Negotiating

Tackle the Tough Stuff Early

- Make sure you have the right people at the table at the right time, for example, researchers, investors, technology transfer officers, or patient advocates.
- Make informed decisions about what you need to protect and why based on actual risks, not perceptions.
- Set the bar high for justifying exclusivity in licensing. Expect some friction if you demand exclusivity.
- Build in “use it or lose it” requirements (interruption licenses).
- Recognize that some things are more valuable when shared, for example, data, resources, materials, animal models, and, under specific, well-controlled conditions, even access to patients or research subjects.

Avoid Unnecessary Complication

- Don’t re-invent the wheel if you don’t have to. Large, successful organizations frequently rely on standard agreements, such as Material Transfer Agreements. If it works for them, it probably will for you as well.
- Take advantage of existing guidelines and reports intended to improve practices, such as Stanford’s “Nine Points to Consider,” NIH’s “Best Practices,” and OECD’s “Guidelines.”
- Be as transparent as the process allows. For example, don’t keep your plans to secure patents from your partners.
- Impose licensing requirements that are compatible with the market. Focus on maintaining market-oriented negotiation outcomes.
- Aim for speed to market and speed to use. If your partner can’t comply, figure out why, or search for another partner. Drag increases costs and adds to uncertainty.
After Negotiations

Be a Sharing and a Learning System

• **Learn from your mistakes and create an institutional record** for future deals and dealers.

• **Remember that what worked once might not work the next time.** Be flexible and recognize the need for agility in your policies.

• **Share what works.** Let the broader community know what (and how and why) different strategies were successful for you.

“Overly restrictive licensing and unrealistic expectations can deter innovation or improvement by controlling the exchange of information and materials for research or the ability to improve the patented product.”
Questions of the Future

- What will be the impact of the increasingly cumulative nature of products (both therapeutics and diagnostics) on IP protection and use?
- Is sharing – data, patients, evaluation models – the way of the future?
- Will venture philanthropies more often be the drivers of litigation in the emerging ecosystem?
Controversy over research and clinical genetic testing: “Gene patents”

- Secretary’s Advisory Committee on Genetics, Health and Society, 2010
  - Website
  - Duke’s 8 case studies of 10 clinical conditions - *Supplement to Genetics in Medicine*, April 2010
Scenarios

• Patent, no license (no conflict): Tay-Sachs
• Patent, nonexclusive licenses (no major conflict): CF, Huntington’s, colorectal cancer
• Patent, exclusive licenses:
  o Transient controversies: HFE, Long-QT, Canavan
  o Sole provider: BRCA, SCA, Alzheimer’s
“Clearing the market” of genetic tests: patent enforcement

<table>
<thead>
<tr>
<th>Condition</th>
<th>Gene(s)</th>
<th>No. of labs that stopped testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alzheimer’s</td>
<td>APOE</td>
<td>9</td>
</tr>
<tr>
<td>Breast &amp; ovarian cancer</td>
<td>BRCA1/2</td>
<td>9</td>
</tr>
<tr>
<td>Muscular dystrophy</td>
<td>dystrophin</td>
<td>5</td>
</tr>
<tr>
<td>Hemochromatosis</td>
<td>HFE</td>
<td>4</td>
</tr>
<tr>
<td>Spinocerebellar ataxia</td>
<td>SCA genes</td>
<td>4</td>
</tr>
<tr>
<td>Canavan disease</td>
<td>ASPA</td>
<td>4</td>
</tr>
</tbody>
</table>

68% of patents from academic institutions, 59% note federally funded research  
Cho et al. *J Molec Dx* 2003
Academic institutions

• >2/3 of Dx patents are held by academic research institutions (Huys et al.)
  • Blocking claims in 16 of 22 conditions; most held by academic institutions

• ~3/4 of patents held by academic institutions (Athena Dx exclusive licenses)

• Many laboratories that withdrew genetic tests are at universities (Penn, Boston University, Baylor, UCLA)

• Pervasive infringement in research
Myriad Case resources

- Gold & Carbone case study: *Genetics in Medicine April 2010 supplement*
- Shobita Parthasarathy: *Building Genetic Medicine*
- SACGHS Case studies (Compares colon to breast/ovarian cancer family testing): *Genetics in Medicine April 2010 suppl*
- BRCA case Web pages:
  - [http://www.genome.duke.edu/centers/cpg/Myriad/](http://www.genome.duke.edu/centers/cpg/Myriad/)
  - [http://www.genome.duke.edu/centers/cpg/BRCA-resources/](http://www.genome.duke.edu/centers/cpg/BRCA-resources/)
Cystic fibrosis and CFTR

• Patented by the University of Michigan (U of M) and Hospital for Sick Children (HSC)
  o Obvious diagnostic importance
  o Possible therapeutic importance
    • Gene transfer
    • Target for drug discovery
Initial discussions on licensing

- Anticipation of potential licensees:
  - Clinics, hospitals wanting to perform CF testing
    - In-house diagnostic testing vs. kit manufacture
    - Anticipation of other CFTR mutations
  - Companies wanting to develop CF therapeutics
    - Which gene transfer vector would be most effective?
- Inclusion of CF Foundation during discussions
  - Non-exclusive licensing for diagnostics
Types of CFTR licenses

- **CFTR licenses**
  - Therapeutic license
    - May allow sub-licensing
  - Diagnostic license
  - Diagnostic kit manufacture
    - “Most favored nation” clause
  - In-house genetic testing
    - Cheaper, lower royalties, more negotiable
Sub-licensing through CFF

• CFF-funded research projects more efficient
  o CFF pays for license, not research funds
  o Expedites research by a few months
  o CFF pays lower license fee than other licensees
  o License fee paid annually only for active research projects
• Benefits the U of M
  o CFF handles administrative aspects of licensing
  o Aids goal of helping the public
Unexpected sidelight: humanitarian sub-licensing through One World Health

- Diarrheal disease kills 1.5 million children/year
- CFTR may be relevant
- Humanitarian licensing: OneWorld Health handles sub-licensing (U of M does not expect $ back)
  - Complies with global health technology licensing for humanitarian purposes proposed in many guidance documents for managing intellectual property
Success story: Kalydeco® (ivacaftor)

• CF patients with p.G551D mutation in CFTR
  o Present in ~1200 CF patients in the U.S.
• Partnership between CFF and Vertex Pharmaceuticals
• Many potential patent barriers:
CFTR licensing model

Pros:
• “Stayed out of the way”
• Generated revenue stream for patent holders
• Protected IP
• Engagement of key stakeholders
• Model for successful gene patent licensing

Cons:
• License fees
• Complex license negotiations
• May not work for all gene patents:
  o Savvy patient advocacy organization
  o Profit margin for “orphan disease” therapeutics
Who really did the work?

- Mollie Minear, Ph.D.
- Kaeleen Boden (summer undergrad fellow)
- Cristina Kapustij (research associate)
- Subhashini ("Shubha") Chandrasekharan, Ph.D.
- Chris DiRienzo, M.D., M.P.P.
- Julia Carbone, J.D. (S.J.D. candidate)
- E. Richard Gold, J.D.
Resource documents

- “Nine Points”
  http://www.autm.net/AM/Template.cfm?Section=Nine_Points_to_Consider1
- NIH “Best Practices”
- OECD Licensing Guidelines
  www.oecd.org/sti/biotechnology/licensing
Disease Foundation Perspectives On IP Issues In Venture Philanthropy
Disease Foundations have two goals

- Finding cures for a particular disease
- Advancing scientific understanding of the disease and its complications to:
  - Identify targets (causes) that lead to cures and therapies
Disease Foundations fund

• Academic researchers – for target identification and research tools
• Companies that have promising technologies – cures and therapies

Generally, Disease Foundations don’t want to own IP created with their money, but they do want researchers in the field to have rights to the IP funded by them in order to move as quickly as possible toward cures, therapies, and target discovery.
Academic research funding by Disease Foundations

Generally, there are four IP trends and issues in connection with such funding:

1) Research only (i.e. non-commercial) licenses in tools and other technology that are sublicensable to third party researchers - which third parties can benefit from the sublicenses?

2) Facilitating research consortia - establishing the rules of the road for members through policies and confidentiality agreements

3) Transfer of research data and tissue samples to third party repositories for distribution to researchers - on what terms will third party researchers gain access to such data and tissue samples?

4) March-in rights – when should funders be able to come in, take, and then push promising technologies that are not being licensed?
Disease Foundation funding of Contract Research Organizations

• Funding for narrow-scope projects – e.g. target identification and research tools

• Foundations may obtain ownership of, or at least license rights to, the result – not because Foundations want ownership per se, but because CROs are used to assigning ownership rights to customers

• Results are made available to third party researchers (on an at-cost basis) - critical point for Foundations - through the CRO or through a third party repository

• Issues include – (1) ensuring that the results created by the CRO do not infringe on third party intellectual property rights, and (2) who can benefit from reduced cost results, i.e. can researchers at for-profits take advantage of the low-cost result?
Funding of for-profits by Disease Foundations

• Generally, there is one big IP issue and a couple of minor ones when Disease Foundations fund companies

• The Big Issue – Interruption license
  o The Problem - If a technology funded by a foundation is stalled because of changed company research priorities or the inability of a company to take a technology forward for lack of funding . . .
  o The Solution (part 1) - then the funder can march-in with exclusive rights to the technology and find a new willing licensee
  o The Solution (part 2) - The first company is given the opportunity to share in the reward if the technology results in a product through a return that is based on sales of the product
  o Alternatives to the problem, e.g. the foundation’s money back, even with interest or other financial penalty, are much less satisfactory for the Disease Foundation

• Minor issues – Publication and research licenses
  o Publication - Disease Foundations, which are approved for tax exemption by the IRS, want to push research results into the public domain. It is consistent with their missions and consistent with IRS rules approving disease foundation grants to for-profit companies
  o Research licenses – Disease Foundations like to obtain research only (i.e. non-commercial) licenses in funded technology for use by other researchers
In comparison with government funders and academic institution grantees, with respect to IP issues, Disease Foundations are:

- More focused on cures, therapies, and targets than on ownership of IP
- More activist on access to IP – they want researchers to share and interruption rights
- More impatient to get the deal done – their timelines for negotiation tend to be much shorter

In comparison with company grantees and private sources of funding, Disease Foundations are:

- More focused on cures, therapies, and targets than on ownership of IP
- More activist on use of IP – they want interruption rights and publication of results
Q&A

Panelists

Maria Freire
President
Foundation for the NIH

Robert Cook-Deegan
Research Professor,
Genome Ethics, Law & Policy
Institute for Genome Sciences and Policy,
Duke University

David Lubitz
Partner
Schaner & Lubitz, PLLC

Moderator

Margaret Anderson
Executive Director
FasterCures
What is next for IP at FasterCures?

- *Unlocking Intellectual Property: Principles for Responsible Negotiation* is now available on the Web site
- PANEL – “License to drive (innovation): IP strategies to support, not slow, progress” at Partnering for Cures
- Augmenting TRAIN Central Station to include more content and resources devoted to issues of IP in the life sciences, including the emerging role of venture philanthropies
View an archive of this Webinar
www.fastercures.org/train
• PARTICIPATE in outcomes-oriented dialogue on solving the challenges that slow medical progress
• DISCOVER new and scalable models for improving research efficacy and efficiency
• PARTNER with others who share your goals and could advance your programs
• CONSULT with strategy and regulatory experts onsite – for FREE – on tailored advice on your initiatives
• PRESENT your transformative multi-sector partnership/project to potential collaborators and supporters

Registration information available at: www.parterneringforcures.org
IT TAKES TOO LONG.

1 OF EVERY 10,000
OF RESEARCH PROJECTS FAIL BEFORE THEY GET TESTED IN HUMANS.
15 YEARS
THAT'S HOW LONG IT TAKES TO TURN A SCIENTIFIC DISCOVERY INTO A NEW MEDICAL SOLUTION THAT COULD IMPROVE AND SAVE LIVES.

TIME = LIVES

15 YEARS
$1 BILLION
1 IN 3 AMERICANS
LIVES WITH A DANGEROUS OR DEBILITATING DISEASE FOR WHICH THERE ARE NO CURES, AND FEW MEANINGFUL TREATMENT OPTIONS.

IT COSTS TOO MUCH.

$100 BILLION
PER YEAR SPENT ON R&D.
AND YET, ONLY 35 NEW DRUGS APPROVED IN 2011.

ONLY 5¢
TO BRING ONE NEW THERAPY FROM LAB TO MARKET.

IT'S ABOUT SAVING LIVES.

WE ALL KNOW SOMEONE WHO COULD USE A FASTER CURE.

FasterCures
@fastercures

follow
like
read
add
link
watch

connect