BCRF Intellectual Property

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on behalf of
Breast Cancer Research Foundation

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Outline

➢ BCRF Background
➢ Why an Intellectual Property policy?
  • CFF, Kalydeco, $3.3 billion, $300,000 for patient
➢ The process of establishing a policy.
➢ The Policy
  • IP to be assigned to BCRF
  • Return to BCRF
  • Drug Research Collaborative
➢ Benefit from an Intellectual Property policy.
➢ Challenges, pitfalls, examples, case studies.
  • Is it worth it? Revenue? Benefits that can’t be quantified?
  • Revenue that comes to universities is not that big (Shannon Greer)
Breast Cancer Research Foundation

➢ Founded in 1993 with a singular mission to fund research

➢ Has had some form of Intellectual Property policy since...early 2000s?

➢ Major overhaul in 2013

➢ Revenue from Intellectual Property to date: $0
Why an IP Policy?
Why an IP Policy?

➢ Potential for financial returns
  • Fund more research, reinvest in the mission, help more people
  • CFF invested $75M in Kalydeco, approved in 2012, returned $3.3B in 2014

➢ Ensure potentially useful technologies make it to patients

➢ Encourage commercialization

➢ To align with other funders

➢ Understanding why you need/want an intellectual property policy will help you capitalize on the returns (qualitative and quantitative).
How to develop your policy

➢ Keep your focus on the why
➢ Use the HRA resources that Shannon and Michael already presented
➢ Don’t be afraid of “simple policies.”
➢ Organize your policy in to sections or chunks.
➢ Use a pro-bono law firm if you have one!
<table>
<thead>
<tr>
<th></th>
<th>BCRF</th>
<th>Komen</th>
<th>Avon Breast Cancer Crusade</th>
<th>American Cancer Society</th>
<th>Cancer Research Institute</th>
<th>Damon Runyon Cancer Research Foundation</th>
<th>Leukemia and Lymphoma Society</th>
<th>Lymphoma Research Foundation</th>
<th>National Multiple Sclerosis Society</th>
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<tbody>
<tr>
<td><strong>Addressing infringement</strong></td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Society and Beneficiary must inform one another of suspected infringement of patent or proprietary rights in the Invention.</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Joint funding by non-gov’t third party</strong></td>
<td>N/A</td>
<td>If other organization has IP policy which conflicts, will negotiate rights in good faith.</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Will confer, in good faith, to arrive at mutually satisfactory disposition of rights.</td>
</tr>
<tr>
<td><strong>Joint funding with US Government</strong></td>
<td>N/A</td>
<td>Deference to Government policy upon written notice by agency or</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
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10 Points of Evaluation

➢ ownership of IP generated under the grant award
➢ notification requirements
➢ patenting requirements
➢ handling of infringement actions
➢ joint funding with non-government third parties
➢ joint funding with the U.S. Government
➢ income, payment and royalty terms
➢ requirements to commercialize inventions
➢ audits and reporting requirements
➢ permitted non-commercial use of inventions.
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Ownership, Notification, and Patenting

➢ Generally agree the beneficiary/beneficiary’s institution owns to the invention.
  • Only exceptions when the institution does not have a policy

➢ “As early as possible” vs “within 3 months of conception”
  • Avoid lapse or abandonment of patent or patent application

➢ Option reverts to BCRF if beneficiary chooses not to pursue protection

➢ There has never been an institution without some kind of policy.

➢ Can you really enforce this? Can you enforce something you don’t know about?

➢ Can BCRF actually pursue the patent protections?
  • Need time – review by SAB, gathering information from institution, submitting applications
  • Institutions have asked for royalties.
Income and Royalty

- **Licensing Costs**
  - No payments until licensing costs are recouped.

- **Threshold**
  - Start payment after first $250,000

- **Royalty structure**
  - 10% of net royalties

- **Cap**
  - No cap

- This seems fairly standard?

- This seems relatively arbitrary. But BCRF grants are $250,000/year so maybe that’s where it comes from?

- Royalty structure: percent of investment vs. flat percent.

- 5x cap in some agreements, which is reasonable. But homerun clause?
Royalty Structure

➢ Percentage of investment
  • Example 1: Total cost for invention was $1M. BCRF gave $250,000 so BCRF gets 25% of the profits.
  • Example 2: BCRF gives a $250,000 grant for a risky project very early in development. Nobody else thinks it’s going to work. That $250,000 allowed the investigator to demonstrate proof of concept which got him/her another $250,000 from somewhere else. They were able to leverage that in to another $500,000 that eventually got the product to market. Does BCRF still only get 25%? Without BCRF this product would not exist. BCRF invested at a critical time that was necessary for success. Shouldn’t the early investor receive a larger piece of the returns?

You’ve developed an IP policy, what next?

➢ Remember why you developed an IP policy in the first place
   • (hopefully it wasn’t for revenue...)
➢ Develop a plan to capture relevant invention information.
➢ Do you want to actively request invention information? Or wait for them to be reported to you?
➢ How would you like the invention information reported to you?
   • Every institution has a different template.
   • Create your own with the questions you need answered to turn around for your stakeholders.
     • More business related and commercialization plans if the goal is revenue?
     • More scientific or patient-focused questions to use for fundraising appeals or demonstrate foundation impact?
Is it worth it?

➢ BCRF has never received any royalty.
➢ Hours spent developing the policy in 2013?
➢ Each year BCRF spends at least 5 hours/week in August and September negotiating policies plus added administrative time for each unique policy.
➢ BCRF is currently negotiating a policy with a single institution for over 3 months.
  • This has caused several grants to be delayed in activation.
➢ BCRF passively received a handful of invention notification each year which are largely briefly reviewed and filed.