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# Taking IP to the bank: Tech transfer pitfalls to avoid

Anne Marie Clark, CAS, examines some common pitfalls suffered by organizations, that are less familiar with all of the workings and considerations required for successful tech transfer to the business community.

**I**n the previous issue of *The Patent Lawyer Magazine*, we looked at statistics documenting the rise of tech transfer at universities and institutions throughout the world. In this article, we'll examine some common pitfalls suffered by organizations, often research units within universities, that are less familiar with all of the workings and considerations required for successful tech transfer to the business community. The varying degrees of global tech transfer success underscore the inherent risks involved throughout the process, no matter the groups involved. The university to business tech transfer route can be especially tricky as academics favor immediate publication of a new discovery or invention, with corporations and university tech transfer offices requiring discretion until the intellectual property (IP) is adequately protected.

## Considerations for licensing and tech transfer

Grant applications, conference abstracts, blogs, meeting presentations and poster sessions, journal article submissions and publications can all constitute disclosure. Academics with limited business or patenting experience may not always consider the potential impact early disclosure can have on future patent applications and licensing arrangements. Businesses sometimes lack the technical understanding to effectively evaluate market potential of a new technology, and universities frequently underestimate the importance of protecting intellectual property. Negotiations around IP licenses can often be challenging, with equity decisions, reversionary IP rights, and board

positions on any spin-off companies constituting potential points of conflict during negotiations.

A common type of tech transfer occurs between start-up companies formed as the result of university research efforts and other, usually larger, companies. These larger companies are either looking to purchase or license new technology that the start-up controls, or looking to partner with the start-up to nurture the development of the technology at a more rapid rate. The startup will follow a fairly typical pattern when looking to leverage its IP: first, consider the patent landscape, then the competitive landscape. Next, determine if the IP answers an unmet need. Where all of these criteria can be met, there is an opportunity (*see Figure 1 overleaf*). However, this business-to-business tech transfer presents its own obstacles. The most common is inadequate depth and scope of due diligence by either party before or during the tech transfer. Companies can waste significant time and money when they pursue a business arrangement only to find that the IP is already covered elsewhere.

When companies proceed with a licensing agreement without knowing or weighing the true IP landscape, expensive and time-consuming problems can occur. Businesses that carry out IP searches that are too narrow will miss relevant data. Perform too broad of a search, and the relevant data will be lost in the vast number of results. Either of these can lead a business to greenlight projects that are at risk for future legal challenges.

Other issues arise when the discovering business has assets that are covered by IP that is not properly assigned or otherwise not fully documented, resulting in IP that is not adequately controlled for the tech transfer to advance. The technology recipient should always ensure that potential collaborators, such as visiting scientists or contractors, have all necessary supporting agreements in place, and are in fact the registered patent assignee of the IP in question. All associated trademarks should have been filed and granted, and there should be no current requests for *ex parte* reexaminations that might hinder the business arrangement.

Once the above questions have been answered, then the originating company must negotiate how much IP

## Résumé

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to retain, whether to license the idea, create a strategic alliance, or permanently transfer IP ownership. For a detailed outline of the licensing process businesses typically go through for the tech transfer considerations discussed earlier in this article (see Figure 2). Below, we'll look at some cases where insight from a professional searcher collaborating with a patent attorney might have altered the strategy of competing parties in some famous patent litigation where licensing agreements were already in place.

**Case Study 1: Discovery of HIV**

A classic example of research collaboration where ownership of the resulting IP was in question and debated in court occurred during the AIDS epidemic of the 1980s. Researchers at the Pasteur Institute in France believed they had found the virus that caused AIDS. They disclosed their findings publicly the same day they applied for a British patent on their research. They then sent samples of this virus to a team of researchers headed by Dr. Robert Gallo of the National Cancer Institute (NCI) with stipulations stating the only allowable use was for research purposes, and prohibiting disclosure, commercial or industrial use without permission. NCI, under the leadership of Dr. Gallo, filed an application and secured a patent for a procedure to detect the antibodies of the AIDS virus on behalf of the United States a few months later. The French researchers claimed their US patent application was ignored by the USPTO in favor of the American patent<sup>1</sup>.

The US bodies went on to license production of these blood testing kits to several organizations, the royalties of which were being collected by the United States. The Pasteur Institute sued the United States for royalties associated with the licensing agreements, and to get proper credit for their contributions to the discovery. The United States Claims Court ruled the contract between the parties did not adhere to the Contract Disputes Act of 1978 (CDA) and dismissed the complaint without prejudice for lack of jurisdiction<sup>2</sup>. The United

States Court of Appeals for the Federal Court reversed and remanded the lower court's decision, finding the contract did not fall under the CDA because there was no buyer or seller, and that the transfer was donative in nature<sup>3</sup>.

One of the most widely publicized patent disputes ever, the case was finally settled in unprecedented fashion, with President Ronald Reagan and the then-newly elected French Prime Minister, Jacques Chirac, becoming involved in negotiations. The settlement called for shared credit, included an outline of each country's contributions with approval from the principal investigators from both sides, and called for 80% of all royalties to be donated to an AIDS research and education foundation<sup>4</sup>.

**Case Study 2: CRISPR/Cas9**

One prominent example of legal complications stemming from universities fighting to protect their IP is the ongoing CRISPR controversy. Researchers at the University of California, Berkeley, led by lead author Jennifer Doudna, and the Broad Institute of the Massachusetts Institute of Technology (MIT), led by molecular biologist Feng Zhang, both claim rights to the CRISPR/Cas9 gene-editing technology. The cutting edge technology, which allows researchers to cut into DNA and insert new genetic code at a specific point using RNA as a guide for the Cas9 enzyme, was first announced by Dr. Doudna's team in the August 2012 issue of Science<sup>5</sup>.

Some months later, in March of 2013, Dr. Doudna and her collaborators filed for a patent to protect their invention. However, half a year later, notably after the passage of the America Invents Act (AIA), which moved the United States to a first-to-file patenting system, Dr. Zhang applied for a similar patent to cover his CRISPR/Cas9 research. He used the new fast track option provided by the AIA and on 15 April 2014, patent US8697359 was awarded to Dr. Zhang and the Massachusetts Institute of Technology.

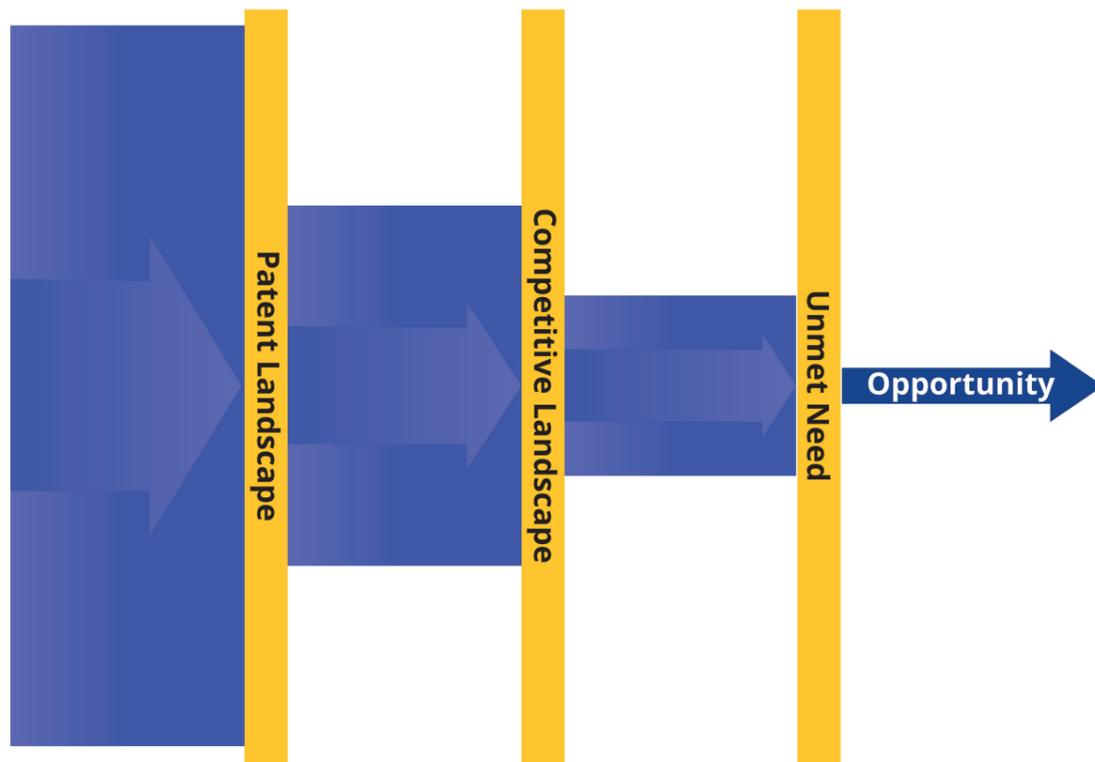
The case is as yet undecided, but it has captured the attention of researchers, corporations and info pros across the world. Global corporate players like Bayer, Novartis and most recently Monsanto lined up to license the technology from both UC, Berkeley and the Broad Institute in anticipation of a specific outcome to capitalize on the technology. Novartis, having bought a stake in companies with licenses with UC, Berkeley, is interested in leveraging the technology toward their CAR-T work to develop cancer weapons. Bayer reached an agreement with ERS Genomics, a startup created to monetize patents held by Emmanuelle Charpentier, who is listed as a co-inventor on the Doudna CRISPR patent. Monsanto just recently announced it had finally struck a licensing deal of its own – with the Broad Institute – to use the CRISPR technology to add or remove genes to plants more rapidly than previously possible<sup>6,7</sup>.

Clearly, there will be winners and losers in these licensing deals depending on how the interference trial plays out. Will Monsanto and others who have banked on the strength of the Broad Institute's position have to pay millions in royalties to Dr. Doudna's team? Has Novartis put their chips in the right corner with UC, Berkeley? Would these companies have been wise to wait until the dust settled (a process which could take years)? Will the benefits of getting a jump on research relying on CRISPR/Cas9 outweigh the losses likely to result from the aftermath if a company chose the wrong strategic partner? These are the sorts of pitfalls universities, startups, and potential collaborators must seek to avoid when navigating the IP landscape to ensure the best possible outcome for their technology transfer monetization efforts.

Universities and spin-off companies may not yet be equipped to cover all of the IP considerations necessary for successful transfer of their burgeoning research, but the bases must be covered to move forward. With any tech transfer arrangement, having a professional IP searcher engaged in the process can help smooth the way. Doing

sufficiently broad and thorough IP searches at key points will ensure due diligence is performed and can avoid long and costly problems later in the process. Many institutions rely on search services like Science IP to do this groundwork on their behalf. This can be the best bet to ensure your IP is protected and is not dominated by existing IP controlled by another entity, or that a licensing agreement will trigger no legal challenges like those expected to arise from the CRISPR controversy.

<sup>1</sup> Altman, L.K. (December 14, 1985) "French Sue U.S. Over AIDS Virus Discovery." The New York Times. <http://www.nytimes.com/1985/12/14/world/french-sue-us-over-aids-virus-discovery.html> Accessed Sept. 13, 2016.  
<sup>2</sup> Institute Pasteur v. United States, 10 Cl. Ct. 304 (July 7, 1986) United States Claims Court. Accessed Sept. 16, 2016.  
<sup>3</sup> Institute Pasteur v. United States, 814 F.2d 624 (March 9, 1987) United States Court of Appeals for the Federal Court. Accessed Sept. 16, 2016.  
<sup>4</sup> Altman, L.K. (April 1, 1987) "U.S. and France End Rift on Aids." The New York Times. <http://www.nytimes.com/1987/04/01/us/us-and-france-end-rift-on-aids.html>. Accessed Sept. 13, 2016.  
<sup>5</sup> Hesman Saey, T. (August 24, 2016) "CRISPR Inspires New Tricks to Edit Genes." Science News. <https://www.sciencenews.org/article/crispr-inspires-new-tricks-edit-genes>. Accessed Sept. 1, 2016.  
<sup>6</sup> Lev-Ari, A. (August 24, 2016) "Licensing Agreements for CRISPR/Cas9 Genome Editing Technology Patent." Leaders in Pharmaceutical Business Intelligence Group. <https://pharmaceuticalintelligence.com/2016/08/24/licensing-agreements-for-crisprcas9-genome-editing-technology-patent/> Accessed Sept. 16, 2016.  
<sup>7</sup> Chatsko, M. (September 27, 2016) "Monsanto Finally Licenses the Most Important Biotech Discovery of the 21st Century." The Motley Fool. <http://www.fool.com/investing/2016/09/27/monsanto-finally-licenses-the-most-important-biotech.aspx>. Accessed September 27, 2016.



Source: CAS

Figure 1: IP considerations in the innovation-to-opportunity workflow.



Figure 2: Business development in-licensing process with IP considerations, clockwise. SWOT – strengths, weaknesses, opportunities, and threats.