

UNLOCKING INTELLECTUAL PROPERTY:

Principles **for** Responsible Negotiation

The ability to obtain patents for discoveries and inventions made in the biomedical sciences has been a crucial tool in advancing

R&D in the areas of drugs and devices as well as in the newer subfields of genomics and proteomics. According to the U.S. Constitution, the purpose of the U.S. patent system is “to promote the Progress of Science and useful Arts . . .” The patent system provides incentives for innovation, promotes disclosure of discoveries, and protects investments.

However, intellectual property (IP), and the systems that support and advance it, also have been blamed for achieving the opposite at times—in particular, slowing innovation and promoting secrecy. For example, patents can deter downstream innovation if they are overly broad or if complimentary patents have diverse owners. Patent holders can also shelve their inventions at a cost to society. Some licensing and enforcement practices of patent holders

similarly draw criticism. 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.

For several years, *FasterCures* has heard from many of its colleagues in the worlds of philanthropy, nonprofit disease research, industry, and academia that IP issues are often a significant roadblock in moving discoveries toward diagnosis and treatment. Further discussions revealed that these difficulties are related to a number of emerging and persistent trends, including: misaligned expectations among parties, entry of new actors into IP negotiations (i.e., nonprofit disease groups and disease-focused philanthropists), new parameters for the precompetitive

space in the drug development process, a changing financial environment, and the cumulative and complementary nature of scientific advances.

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Institutional relationships are evolving, with emerging collaborative models moving further upstream into the precompetitive space and more high-value joint research efforts being undertaken. The current IP landscape contains new players, new paradigms, new relationships, and new funding structures. The entrance of nonprofit disease groups has raised not only expectations but also scrutiny. There are more people watching.

While academic and for-profit IP negotiations have been the topic of study and assessment for some time, the unique role and expectations of the newest entrants, the nonprofit disease research community, deserve attention. This community has different expectations for IP than its industrial and academic partners. Nonprofit disease groups, motivated primarily by the needs of their constituencies, do not weigh profits and publications—which drive investments and rewards in industry and academia—as heavily. These nonprofits tend to want to enhance the freedom to operate to more rapidly advance scientific innovation toward cures and therapies for diseases, versus the limiting model more prevalent in the current IP environment. Therefore, while each sector is working toward a common solution, missions, resources, and expectations differ. While

some larger disease nonprofits have succeeded in negotiating IP that serves the needs of all parties, other groups are still learning.

FasterCures believes that a set of guiding principles and points to consider can serve as a useful tool for all parties in biomedical research, in particular nonprofit disease groups and philanthropists negotiating IP with academic, industrial, and other nonprofit partners. To develop these principles, *FasterCures* convened a small expert panel in July 2012. The group reviewed data and several published cases pertaining to patenting, licensing, and litigation, shared its collective experiences, and examined several reports and guideline documents relevant to patenting and licensing, such as Stanford University's "Nine Points to Consider in Licensing University Technology," the National Institutes of Health's (NIH) "Best Practices for the Licensing of Genomic Inventions," and the Organisation for Economic Cooperation and Development's (OECD) "Guidelines for the Licensing of Genetic Inventions." The principles that emerged stand on the foundation that has been built and tested by others. They are intended to provide guidance for organizations new to IP negotiation as well as to serve as a set of useful values for more experienced organizations.

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. And, 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. Be prepared to consider, factor in, and articulate your nonmonetary goals, such as the advancement of scientific research, as consistent with your tax-exempt mission and status.

- **Know your limits, that is, what your organizations absolutely can or cannot allow.** Conduct a readiness assessment by identifying your assumptions and the issues that will affect the negotiations. Also know that there is a difference between internal policy, which can be altered or amended in appropriate circumstances, and external legal requirements or prohibitions, which cannot.
- **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. In fact, few lawsuits actually transpire and progress to a final decision; a handful of highly publicized cases are more outliers than the norm. If the desired result is based on research impact as well as monetary returns, 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.** Intellectual property negotiations are almost always important and often inevitable. Make conscious decisions, even if the final decision is to take no action.
- **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. Be clear about why the stakeholders are involved and the value they are expected to add. Think through which stakeholders are needed to foster innovation, and only exclude a stakeholder group—especially nonprofits—after careful thought. Remember that your decision(s) can affect whether potential counterparts become repeat players.
- **Make informed decisions about what you need to protect and why** based on actual risks, not perceptions. Look at each situation individually, recognizing your assumptions and identifying both your own biases and those of other stakeholders. Then define a strategy with your partner(s) that is the most realistic and effective way to promote your innovation.
- **Set the bar high for justifying exclusivity in licensing.** If exclusivity is warranted, understand why, clarify who controls it, and assess whether it is justified throughout the life of the patent. Expect some friction if you demand exclusivity.

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

- **Build in “use it or lose it” requirements** (interruption licenses). If you have invested in the IP and the owner is not exercising the rights to use the invention and make it widely available, or if they are using it in a way that impedes progress, ensure you have a way to take it to a party where its value can be maximized. Likewise, if you are not going to commercialize or exercise rights, you should be willing to give them to someone else.
- **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. Clearly define your requirements for sharing by all parties, and consider how parties will be encouraged to share or be penalized if they don't.

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 LEARNING AND SHARING 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.

Looking Forward

FasterCures recognizes that every negotiating situation is unique and does not advocate a singular approach to negotiations. These principles were developed not as fundamental truths, but rather as a starting framework that sets an expectation for behavior. There may be good reasons for parties to diverge from these principles, but negotiators should carefully consider and be able to justify such departures. Individual organizations may also identify additional principles to guide its actions based on specific needs, missions, or fiduciary responsibilities.

The shifting roles of industry and universities, and the emergence of venture philanthropy, patient advocacy, and other disease nonprofits, has reignited IP management as an inflection point in the collaboration that embodies the drug development process from bench to bedside. We need to recognize the effects that the emergence of a new field of stakeholders has on IP management and common practices, and mold an IP learning system that reflects these shifts, encourages the sharing of good ideas, and facilitates the use of best practices.

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