

Creating and demonstrating value in the intellectual property of biotechnology companies

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Biotechnology companies are attractive targets for certain larger companies that are looking to diversify or to complement their existing businesses. However, after the excitement of joining the golden age of biotechnology subsidies, someone at the acquiring company invariably asks for scrutiny of the target's intellectual property. If you are that potential target, it is important to know what an acquiring company may deem valuable and how to position yourself to demonstrate that value. This article focuses on the issues that are important to an acquiring company, and outlines general strategies for both creating valuable intellectual property and demonstrating a strong intellectual position.

Issues important to an acquiring company

An acquiring company will focus on the return on investment. A current revenue stream is desirable, but acquiring companies appreciate that much of the biotechnology industry is still in its infancy. Thus, they will evaluate the position that the target may provide in both current and future markets and should, and probably will, ask:

Target products and market

- What are the target's current and anticipated products, services and markets?
- What unique features will cause buyers to pick the target's goods/services or select a competitor's instead?

Target IP

- What intellectual property rights does the target currently have? What rights is it in the process of obtaining that will offer exclusivity?
- What rights are being licensed in and out by the target?
- Does the target currently have IP synergistically useful to the acquiring

company's other businesses?

- Do those rights provide an actual competitive advantages?

Competitors

- Who are the competitors?
- What are their intellectual property positions?
- How will their rights affect the target's freedom to operate?

Target employees

- Who are the key employees?
- What are their (current and prior) employment contract obligations with respect to ownership issues, prior employee 's' rights, severance and non-compete clauses?

Value

- How valuable are the intellectual property rights that the target owns, or licenses, including how strong and broad are these rights?
- Do reasonable forecasts suggest that value will be maintained over time, decay quickly, or grow?

The target should be asking these questions of itself long before any acquiring company expresses interest, and by doing so can increase its value and market position, justify a higher price for its goods and services, and perhaps raise share prices. Further, companies within the scope of US Sarbanes-Oxley requirements may be required to address these issues.

Creating and demonstrating a strong intellectual property position

Information without implementation is useless, and a biotechnology target should use the answers to the questions above to better position itself by taking three primary steps.

Plan

First, the biotechnology company needs an overarching intellectual property plan, and should have this plan in place before any suitors approach. To formulate an intellectual property plan, the company needs to appreciate that there is value not only in patents, but also in copyrights, trademarks and trade secrets. For example, there are occasions in which it is a better strategy not to patent but to keep an invention a trade secret and, for bioinformatics companies, it is important to make use of European database protections and protection under the US Digital Millennium Copyright Act.

The company must also appreciate that passive possession of IP rights affords nothing. The IP plan must detail how to use the rights. Accordingly, a company should consider license, litigate and enter into ►►

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strategic deals to serve its goals. For example, it is often cheaper to license in a technology than to develop around it. Conversely, a biotechnology company may need to protect its own position at times by attacking the position of competitors, e.g., by litigation or opposition or reexamination proceedings.

Action

Second, the biotechnology company must implement its plan efficiently. Avoid the temptation to acquire a long list of patents and patent applications that are weak or unduly narrow. Sophisticated acquiring companies conduct due diligence beyond issues such as the chain of title and payment of requisite fees. For both issued patents and pending applications, they will consider the breadth of the claims and the value of subject matter that was surrendered during prosecution. For pending applications, acquirers will also consider outstanding rejections. Further, it is not uncommon for an acquiring company to conduct its own prior art search to see if the patents could easily be invalidated or avoided; one of the first things reviewed are other publications by the inventors or known to the inventors, which not only may raise the issue of invalidity, but also in the US the spectre of invalidation due to inequitable conduct.

An acquiring company may reduce its offer or consider entering the space as a competitor if it thinks that the rights are of little value. Thus, the target should:

- *Develop a process to evaluate new inventions and sources of creativity.* Intellectual property should not be dealt with on an *ad hoc* basis. Create a sensible system for allowing employees to share their creativity with management, and for management to have the opportunity to evaluate the intellectual property in the context of the business's needs and goals. Representatives from business, R&D and legal should be selected to form an intellectual property committee, with one appointed 'tsar' or CIPO (Chief IP Officer).
- *Obtain patents with claims that are clear, easily understood and as broad as possible.* Breadth and clarity benefit the patent holder. Unnecessarily complex claims can seem narrow and reduce apparent

value or be unintelligible to a future US jury and judge who often lack technical backgrounds.

- *Repeatedly remind the inventors of the importance of collecting relevant prior art and maintaining current landscape awareness.* Patent Offices around the world have been criticised for failing to devote enough resources to uncover relevant prior art. This may lead to the issuance of overbroad, and possibly invalid, patents. Also, knowing what others are patenting now can help better guide both research directions and patenting strategies.
- *Check the portfolio on a regular basis for compliance with deadlines, chains of title and payment of necessary fees and annuities.* There is no easier mistake to fix, if found early enough, or for a suitor to catch (and then kill or discount the deal) than a cloud on title or an abandoned patent.
- *Make strategic and reasoned decisions with respect to where to obtain worldwide rights.* To obtain or even seek protection costs money. Before rights are sought in foreign countries, a target should ask whether, within the life of the right, there is a realistic chance that a competitor would consider acting in that jurisdiction and whether the target would consider enforcing the rights there.
- *Understand the degree to which each patent and patent application could be used to help your market position with respect to current and future products, and/or how it could affect a competitor's business.* After an inventor informs a company that she has an idea, the company should first determine what would be the value of a patent on that invention. At a minimum, unless the patent is in an area in which the company or competitor may move in the future, then no patent should be sought.
- *Prune the portfolio as circumstances change.* New technologies will render some pending patent applications and issued patents (and trademarks) worthless. Do not devote resources to obtaining or maintaining no longer worthy rights.

Landscape

Third, the biotechnology target needs to

be intimately familiar with that which can affect its IP value. It must create two types of landscapes: (i) a landscape of the competition's products and services; and (ii) a focused intellectual property landscape that extends beyond competitors to include universities, individuals or any other owner of relevant rights.

Appreciating the landscape of the competition's products is necessary to understand both whether the competition is infringing any of the target's current rights, thereby identifying potential revenue streams for licenses and/or opportunities to enforce the target's rights, as well as to determine whether there are opportunities for collaborations or joint ventures. A history of strategic enforcement and active licensing is critical because it establishes that the biotechnology company's intellectual property rights are treated seriously in the marketplace.

Understanding the intellectual property landscape is important to identify the directions of movement, 'white space' of new opportunities for the target, as well as to prompt ideas for the target's own research. Further, the target will learn of potentially dominating patents, which the target may design around, challenge or license. Efficient review of and action upon the rights of others is important because it both demonstrates an efficient business model, and, if the rights of others are successfully challenged, can open new areas in which to operate.

Having taken the three steps outlined above, the target will be able to answer the acquiring company's questions and address the fundamental issue of why the target is valuable. The target will also be able to defend the strength and enforceability of its intellectual property, as well as to explain why, in the context of the intellectual property rights and businesses of others, the target has a desirable position. With this information in hand, an acquiring company will have a greater incentive to purchase the target and to do so at a higher price. ■