

# Understanding Your Patent Portfolio

## Reducing Risk Through Due Diligence

by Leslie Gladstone Restaino

**T**he explosion of life sciences innovation and the globalization of the marketplace have heightened the importance of intellectual property (IP) in biotech business transactions. More than 70% of the total market value of Standard and Poors 500 companies derive from intangible assets (1). The success of life sciences companies depends not only on continuing innovation and business acumen, but also on the strength of their corporate portfolio of intellectual property rights. Any party acquiring an interest in intellectual property rights (whether by license, strategic alliance, or as an investor in or acquirer of life sciences entities), should conduct a due diligence analysis to ensure that the technology underlying the transaction in fact has its purported value and is properly protected. This is particularly critical because IP assets can have a significant affect on predicted cash flow, product development, and income. Any assessment of the transaction is insufficient without proper IP consideration. Often, IP is considered late in the game and in only a cursory manner, leading to significant negative results.

The purpose of a due diligence analysis involves assessment of potential risks and benefits related to the transaction, including identifying risks that may undermine the value of the technology and developing strategies for overcoming such risks. The analysis must confirm that a



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purported technology owner actually owns the intellectual property rights to the technology, has the right to transfer it, can use the technology without substantial risk of treading on third-party intellectual property rights, and that intellectual property rights are valid and enforceable.

### THE IP PORTFOLIO: WHO OWNS WHAT?

Patents notably constitute the predominant form of intellectual property right in a life science transaction. A patent is a right to exclude others from making, using, or selling an invention for a specified period of time. The scope of patent protection is defined by the “claims” of the patent. In ascertaining the strength of an intellectual property portfolio,

particularly a patent right, you must first gather the materials necessary to make this assessment (See “Portfolio Review Materials” box).

The first due diligence inquiry is ascertaining who owns the subject technology. Under United States patent law, patents are issued by default in the name of their inventor(s). Unless there is an agreement to the contrary, each joint inventor shares an undivided interest in the rights to the entire patent irrespective of the individual inventor’s contribution to the totality of the invention defined by the patent. A due diligence assessment should identify whether the inventor(s) have properly assigned the technology to the entity purporting to own the patent rights. The United States Patent Act states that the transfer of rights from an inventor(s) to an assignee may be formally perfected by means of an assignment recorded in the United States Patent and Trademark Office (USPTO), and such assignment materials are publicly available from the USPTO ([www.uspto.gov](http://www.uspto.gov)).

Certain common problem issues associated with inventor assignments should be considered carefully. For example, when multiple inventors are involved, one or more assignments often are not executed when, in fact, assignments from all are necessary. Otherwise, an inventor with no assignment obligations may be considered a joint owner with the

assignee and may grant a separate license without the assignee's consent. That could develop into a problem, particularly when the inventors left a company under bad terms. Assignment pitfalls may be avoided, however, by having the rights of all inventors consolidated into a single entity.

The next inquiry is whether the conditions of any agreements underlying development of a technology and other related agreements have been satisfied. This is particularly critical because the life sciences industry often relies on licensing strategies to maximize income and leverage competitive market penetration. Therefore, a technology licensee must have sufficient rights in the technology. For example, if an investor is interested in second- and later-generation products, the underlying license agreement must give the licensee rights to all intellectual property improvements. A life sciences company cannot use or encumber a licensed technology absent an agreement granting it that right. Moreover, certain obligations in an underlying license agreement, if not satisfied, may terminate an underlying license.

For example, a license agreement may contain a *best efforts* clause placing an obligation on a licensee to manufacture and market the technology. In the event that a licensee has not used its best efforts to promote the technology, there may be a risk that the licensor can properly terminate the license. All licenses and other underlying agreements should be scrutinized to ascertain whether a technology may be transferred. License agreements commonly contain provisions that the use of the technology in question be restricted to a specified field of use, geographic territory, or other similar terms.

#### **FREEDOM TO OPERATE**

Due diligence does not end, however, once it is established that a subject company owns specific patents and other intellectual property. The risk of using the technology must be evaluated as well — to avoid being sued by a third party as soon as that technology

is commercialized. The purpose of such analysis is to confirm that there are no third-party patent rights hindering use of the technology. In other words, the company using the technology must have *freedom to operate*.

At the outset, the product or method that a life sciences company plans to commercialize must be identified. Then research to identify third-party patents and patent applications in similar areas of technology is conducted. The scope of claims contained within these patents is assessed and then compared with a commercialized product or method to identify situations in which it may be prudent for the commercializing company to take a license from an existing holder of patent rights. Prior litigations relating to both patents and their subject technology are reviewed, as well as any prelitigation correspondence alleging infringement and/or offering a license.

In the event that third-party patent rights appear to affect commercialization of the technology, it is crucial to determine whether those patent claims are valid. Often, patent claims are found invalid and unenforceable by prior art or otherwise. Where third-party patents exist, any party intending to use the technology should consider obtaining noninfringement and/or invalidity opinions from qualified legal counsel in order to avoid a potential finding of willful infringement and a trebling of patent damage awards.

#### **DETERMINING THE STRENGTH OF IP PROTECTION**

IP assets frequently are a barrier to entry by competitors or potential competitors. When<sup>12</sup> entering a market defined by established or pending IP assets, the strength of the IP portfolio should be examined. In other words, can the IP stand up or break through the picket fence of IP assets, or can the IP be readily rendered useless? Another important inquiry examines the strength of the intellectual property portfolio.

Intellectual property includes composition (e.g., pharmaceuticals or genes) and process patents, as well as

formulae, training manuals, manufacturing techniques, product packaging, technical data sheets, product specifications, databases, and production facilities. Those should be examined for their ability to enhance market share, increase profit margins, and help secure a position in a new market. To maximize value, the technology owner of a patent should have identified objectives to achieve with intellectual property protection and have aligned intellectual property goals with the actual products and business strategy. For example, a life sciences company may expand intellectual property protection activities beyond its core technologies, such as compositions and methods of creating them, to business methods specific to the life sciences industry.

In ascertaining the strength of the IP portfolio during due diligence, a review is conducted of the patent prosecution files to determine whether all filing deadlines have been met and when prior art is identified where materially relevant, it needs to have been provided to the foreign patent office. It should also be determined whether all prior art searches have been conducted, and if so, what the results were. Known prior art must be disclosed to the USPTO. However, there is no duty to seek out prior art

#### **PORTFOLIO REVIEW MATERIALS**

**Assignments and security interests** in the patent

**Correspondence** relating to pending or threatened claims of infringement or patent opinion invalidity

**Legal opinions** concerning the technology

**Patent prosecution files**, often referred to as the "file wrapper," describing and claiming the technology

**Prior art**, such as patent, academic and industry publications, white papers, and marketing materials

**Product descriptions**

**Related litigation files**

**Research notebooks** and other evidence relevant to proving the date of invention

Any and all **underlying licenses**

for subsequent disclosure. Furthermore, the strength of a patent is increased with the disclosure of prior art. It is becoming more likely that a court will uphold the validity of a patent over a given piece of prior art when that piece of prior art was properly disclosed to the USPTO during prosecution. Failure to disclose known prior art to the patent office may, under some circumstances, lead to the unenforceability of the patent for inequitable conduct. The strength and resilience of a patent may thus be measured in part based on the amount and type of prior art disclosed to the USPTO.

For life sciences technology, it is also important to assess whether patents satisfy the written description and enablement requirements of US patent law. If these requirements are not satisfied, a patent may be invalid. To contain sufficient *written description*, the patent specification must describe the invention with sufficient specificity such that someone with skill in the relevant technology would understand that the inventor has "possession" of the invention when the patent application was filed.

*Enablement* requires that a patent specification contain sufficient description of how to make and use the invention. For example, if a patent specification contains sufficient information to enable a skilled chemist to produce a particular compound by giving detailed information on how to produce analogous compounds, but it makes no reference to the compound in question, the written description requirement has not been met even though the description may be enabling.

The strength of a patent portfolio may also be measured in part by the presence or absence of evidence tending to prove patent-related matters. Accordingly, a company should take care to preserve evidence of inventorship and/or ownership. One reason is that a company may be forced to defend the validity of a patent in a litigation proceeding by proving that its inventors were the first to invent the technology. This includes notebooks, data banks, draft

publications, presentations, and any other evidence that shows conception of the invention, diligence in reducing the invention to practice, and actual physical reduction to practice itself.

### RISK REDUCTION

Any due diligence analysis should be conducted with three main objectives in mind. The analysis should identify any potential risks that may reduce the value of the technology. Those conducting due diligence should also develop strategies and defenses to reduce the severity of such risks. Further, conducting a comprehensive and detail-oriented approach, a due diligence analysis can enhance the value of the rights associated with a technology.

In addition, the due diligence investigation may take place in connection with a particular type of transaction, such as an offering of securities or the sale of a company. In such circumstances, the party conducting due diligence needs to keep in mind additional specific purposes of the investigation. They may include establishing a due diligence defense to minimize potential securities law liability under Section 11 of the Securities Act of 1933 or confirming the purchase price in an acquisition (2). In these circumstances, the party conducting due diligence should consult with its legal advisors as to the proper standards to be applied and the kinds of records that should be kept.

### REFERENCES

1 Haller M, Gold E. *Avoiding Transaction Peril: Value-Based IP Due Diligence*. PriceWaterhouseCoopers, Washington DC. [www.pwcglobal.com/gx/eng/ins-sol/publ/ipvalue/pwc\\_3.pdf](http://www.pwcglobal.com/gx/eng/ins-sol/publ/ipvalue/pwc_3.pdf).

2 US Securities and Exchange Commission. *Securities Act of 1933*. [www.sec.gov/divisions/corpfin/33act/index1933.shtml](http://www.sec.gov/divisions/corpfin/33act/index1933.shtml). 🌐

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