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Preventive Medicine for Patent Portfolios:

Getting More Out of IP Due Diligence

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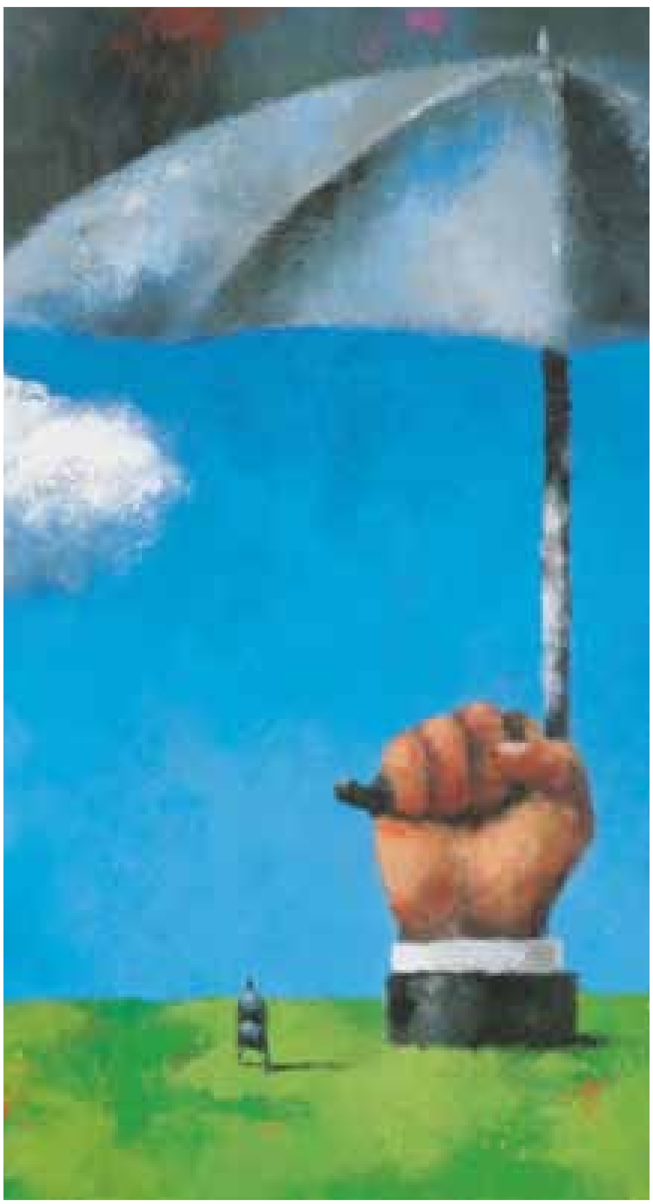

It is common for venture capitalists to perform intellectual property (IP) due diligence on a target company or opportunity, but after the "patient" is examined and the checklist complete, few use the work-up as an opportunity to make the patient healthier over the long haul. This article addresses key strategies for getting more value from IP due diligence and using the results to strengthen patent portfolios and freedom to operate positions.

IP due diligence is performed in connection with a variety of transactions, from mergers and acquisitions, securities offerings and loan securities, to VC and earlier-stage investments. A key difference that sets VC investments apart from other transactions is that VC-related diligence takes place at an earlier stage in the life of the target enterprise when there is still time to fix problems, strengthen IP positions and practices, and enhance the overall value of the enterprise. For this reason, it is important to approach IP due diligence with the following in mind: (a) use experienced IP attorneys and other professionals to perform the diligence; (b) design a strategy for the investigation that is precisely tailored to the target and the business environment in which it operates; (c) determine whether the patent claims are strong and well aligned with the target's business goals; (d) probe below the surface of the recorded patent assignments to scope out ownership conflicts; and (e) strategically assess the prospects for third-party patent infringement (freedom to operate). Even if the patient receives a clean bill of health at the end of the work-up, be proactive about using the results and intelligence from the investigation to further strengthen the portfolio so that it can remain vigorous and valuable for years to come.

If outside counsel will be retained to perform the due diligence investigation, make sure that a seasoned IP lawyer is actively leading the team, preferably someone with experience in all three pillars of the body patent — patent prosecution, licensing and litigation.

Assembling the Right Team

If outside counsel will be retained to perform the due diligence investigation, make sure that a seasoned IP lawyer is actively leading the team; preferably someone with experience in all three pillars of the body patent — patent prosecution, licensing and litigation. Too often, diligence work is pushed down to junior attorneys and professionals who have not yet acquired the experience and instincts to spot issues that really matter in terms of business strategy and enterprise value. A lawyer has to have lived in the trenches for a while before he or she can effectively analyze the data, spot the key issues and make an accurate assessment of IP health. If a seasoned lawyer is not actively involved, the telltale spot on the x-ray may be missed, the investment may be made, and later, regrettably, the patient may be too sick to deliver the promised or hoped for results.

Tailoring the Work-up to the Patient

A good doctor takes a full patient history before starting an examination to establish meaningful background and context. The same applies to IP due diligence. It is important for IP professionals to take the time at the beginning of the diligence project to understand the core fundamentals of the target's business and the competitive environment in which it operates. Only then can the diligence project be designed and tailored to produce meaningful and valuable information. For example, if the target is a biotech, pharmaceutical or medical device company that will invest millions or even billions of dollars in developing and launching its products, then patent protection and a strong, exclusive market position are essential to realizing a return on investment.[1] For other industries, patents are less important. For example, in the aerospace materials business, money is made by winning bidding contests and securing government contracts. Patents are not a factor in this process. Thus, in the aerospace world, patents are "nice to have" if there is a private sector market for the product, but they are usually not a "must have."

It is also important to have a good understanding of the territorial scope of the target's current and future business goals. There is no worldwide patent or patent system. Patents are territorial. Thus, if the target's business is limited to a particular geographic region, then the IP due diligence can be limited to that region. But if foreign markets are important, then the diligence should expand beyond the U.S. Typically, a patent portfolio will include filings in the U.S., the economic leaders of the European Union, and Japan. More and more, it is important to have filings in emerging markets, such as China, India and South Korea.

The Patent Portfolio Review

Look for Good Alignment of Patent Claims to the Target's Business Objectives

The patent portfolio review starts with the task of assembling a schedule of all patents and pending applications purportedly held by the target. This is usually accomplished with assistance from the target and by independent confirmation based on searches of well-known patent databases.

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1 In the U.S., a patent provides its owner with the right to exclude others from making, using, offering for sale, selling or importing the subject matter of the patent claims. 35 U.S.C. § 271(a). Further, a patent owner may prevent others from actively inducing the combination of components outside of the U.S. in a manner that would infringe the patent if such combination occurred within the U.S; and if the claims cover a process, the patent owner has the right to exclude others from using, offering for sale, selling, or importing products made by the process. 35 U.S.C. §§ 271(f) and (g).

Once the schedule is assembled, then the meaningful work begins. Triage the patent assets into categories of importance based on their relation to the target's business goals. Determine which patent assets relate to current or first-generation product offerings, second-generation product development, third-generation, and so on. Then, based on a balance between prudence and cost, skilled IP lawyers should study the claims of the critical categories of patent assets to determine how closely the claims are aligned to the target's business goals and whether the claims are strong enough to keep competition away. Generally, it is important to have a variety of claims covering different categories of patentable subject matter (such as compositions of matter, articles and methods of manufacture, and methods of use) because each of these categories has a different set of strengths and weaknesses when it comes time to assert the patent claims against competitors. Similarly, the claims should be of varying scope. Broad claims, while tantalizing, are more vulnerable to validity attacks by competitors. In the litigation context, the most valuable claim in any patent is the claim that covers the competitor's product and nothing more.

For the more important assets in the portfolio, it is a good idea to obtain the results of any prior art searches conducted by the target, and any prior art analyses, conclusions, reports and opinions pertaining to the patentability of pending applications and the validity of issued patents. If the target has done little or no prior art searching, then, for mission-critical patent assets, the VC should consider commissioning a prior art search to get a better handle on the value of the portfolio. There are many patent search firms that can provide prior art search services for reasonable rates. However, it is very important that the results be analyzed by a skilled patent lawyer, preferably one well versed in the law of patent claim construction.

Finally, if the VC decides to go forward with the investment, then the diligence lawyer should communicate his or her observations and conclusions in reasonable detail to the lawyers who will be handling the portfolio for the company going forward. If there were deficiencies or shortcomings in the nature and scope of the patent claims, now is the ideal time to remedy them through claim amendments, the filing of continuing applications, the preparation and filing of new applications, and in some cases, the commencement of patent reissue and reexamination proceedings.

Even in industries where speed to market is essential, companies can benefit from obtaining patent protection on their innovations. Indeed, filing for patent protection need not add additional time to market. In the United States, at least, a "provisional" patent application may be quickly prepared and filed before the product-release date. A provisional application is essentially a placeholder. It allows the inventor to file a simple description of the invention and how to make and use it. The inventor then has one year from the filing date of the provisional application to file a formalized patent application meeting all of the patent office's requirements. While the provisional is on file in the patent office, it is treated as confidential and no one outside of the patent office may access it. The key benefit of a provisional filing is that it establishes a date of invention, giving the company priority over others who may try to copy the innovative product once it hits the market or is otherwise disclosed. Even if the product launches in the marketplace before a patent application is filed, the situation can be remedied in the U.S., at least, because an inventor has one year from the first public disclosure, sale or offer for sale to file a patent application. However, in many foreign countries, including those of the European Union, publicly disclosing an innovation surrenders the inventor's ability to obtain a patent at all. As a result, if foreign patent protection could prove valuable, a company must file for patent protection prior to launching a product or otherwise disclosing the invention.

Ideally, to maintain the health and vitality of the company's patent portfolio over time, a system of reviewing the portfolio, aligning the patent claims to business objectives, and filing on new inventions will take place periodically over the life of the company. This is best done by appointing a patent committee made up of representatives from R&D, business development and legal who will continue to nurture the portfolio by ensuring that the company is harvesting new inventions frequently and effectively from all sources and by taking measures to continually feed and strengthen the core patent assets, while pruning away assets that are no longer important to the business, for example by selling or licensing those assets to other entities.

Probe below the Surface for Conflicting Ownership Interests

All IP due diligence includes analysis of the target's ownership of its IP assets. Does the target own what it thinks it owns? This task usually entails a search of the assignments recorded in publicly available databases at the United States Patent and Trademark Office (USPTO), the World Intellectual Property Organization (WIPO) for international applications filed under the Patent Cooperation Treaty (PCT), and other national patent offices. The search will uncover all recorded assignment instruments that convey ownership interests in the asset of interest. By analyzing the results of the search, a skilled professional will be able to trace the chain of ownership to confirm that there is a clean chain of title from inventor to the target. All too often, however, the diligence stops there. For the important core patent assets, the diligence process should delve beneath the surface to uncover any conflicting ownership interests that are not discoverable from a review of the public chain of title. This is highly important because under U.S. law, at least, joint inventors each own an interest in the invention and in any patent flowing from it, which, absent an agreement to the contrary, entitles each joint inventor to use or license its interest in the patent without having to obtain approval from or account to the other inventor(s), and further, all co-owners of a patent must voluntarily join in a suit to enforce the patent.[2] Accordingly, joint ownership surprises can lead to disastrous results, such as an alleged patent infringer locating an unnamed joint inventor and obtaining a license from the joint inventor to continue to practice the patent.[3] In other cases, patent rights have been lost entirely when an unnamed group of inventors challenged the original ownership rights and prevailed.[4] The earlier inventorship/ownership issues are discovered, the more flexibility there is for resolving the matter in an acceptable manner. If the discovery occurs at a late stage when the value of an invention is fully realized, it can be more difficult to negotiate an acceptable resolution. If the issue goes to court, and through the passage of time, documents and witnesses go missing, it may be impossible to prove inventorship, with the result that ownership rights could be severely compromised or lost.

2 See, e.g., Schering Corp. v. Roussel-UCLAF SA, 104 F.3d 341, 41 USPQ2d 1359 (Fed.Cir. 1997); Ethicon Inc. v. United States Surgical Corp., 135 F.3d 1456, 45 USPQ2d 1545 (Fed. Cir. 1998).

3 Ethicon Inc. v. United States Surgical Corp., 135 F.3d 1456, 45 USPQ2d 1545 (Fed. Cir. 1998).

4 E.g., Yeda Research and Development Co. Ltd. v. Imclone Sys. Inc., et al., 443 F. Supp.2d. 570 (2006).

Generally, it is important to have a variety of claims covering different categories of patentable subject matter (such as compositions of matter, articles and methods of manufacture, and methods of use) because each of these categories has a different set of strengths and weaknesses when it comes time to assert the patent claims against competitors.

Prior to the time that the first assignment is executed from inventor to company, there are events that typically occur that can result in conflicting ownership claims to the patent rights. In many cases, especially in the field of life sciences, the invention arises from the collaborative efforts of several individuals, sometimes resident at more than one institution. The collaborations can be formal or informal. An interview with the named inventors should be conducted to inquire about early collaborations and the potential for unnamed co-inventors. In addition, the diligence lawyer should collect all written agreements that might contain conflicting ownership provisions. Unfortunately, such provisions can lurk in a number of different types of agreements, from funding and grant agreements to nondisclosure agreements, consulting agreements, material transfer agreements, sponsored research agreements and license agreements.

If the invention and/or patents were licensed from a university or other research institution that relies on government grants, special care should be taken to ensure that the institution adequately secured an assignment of the inventors' rights in the invention and that the inventors did not, knowingly or unknowingly, assign their rights in the invention to another entity. Earlier this year, the Supreme Court addressed the issue of patent ownership in the context of federally funded inventions under the Bayh-Dole Act in the case of *Stanford University v. Roche*.[5] Affirming the basic tenet of patent law that "rights in an invention belong to the inventor" unless and until the inventor assigns the rights to another entity, the court held that the Bayh-Dole Act is not a panacea for lax assignment practices in that it "does not automatically vest title to federally funded inventions in federal contractors or authorize contractors to unilaterally take title to such inventions."

The technology of the patents-in-suit was developed by researchers at Stanford and Cetus Corporation. Cetus is known for its development of PCR, a DNA amplification technique that revolutionized the field of biotechnology. Together, Stanford and Cetus developed PCR-based methods and kits for quantifying HIV in patient blood samples. Dr. Mark Holodniy, a research fellow at Stanford, was at the center of the controversy. When Holodniy joined Stanford, he signed a Copyright and Patent Agreement (CPA), which stated that he "*agree[d] to assign*" his inventions resulting from his employment to Stanford. Because Holodniy had limited PCR experience, his supervisor at Stanford directed him to conduct some research at Cetus to learn PCR and develop an assay for HIV. At Cetus, Holodniy signed a Visitor's Confidentiality Agreement (VCA) that stated that he "*will assign and do[es] hereby assign*" his inventions made "as a consequence of his access" to Cetus. Later, Roche bought Cetus and all rights that Cetus obtained through agreements like Holodniy's VCA.

After about nine months at Cetus, Holodniy returned to Stanford, where he continued to work with his colleagues there on the development and validation of an HIV assay. Stanford filed a series of patent applications covering the invention, and in the process, acquired written assignments from all of the named co-inventors, including Holodniy. Roche, on the other hand, began marketing the technology in HIV kits that it currently sells worldwide. Stanford eventually sued Roche for patent infringement.

The Federal Circuit reviewed the terms of the dueling assignment clauses and concluded that the CPA

5 Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc., et al., 131 S. Ct. 2188, 180 L. Ed. 2d I, 2011 U.S. Lexis 4183 (U.S. 2011).

If the invention and/or patents were licensed from a university or other research institution that relies on government grants, special care should be taken to ensure that the institution adequately secured an assignment of the inventors' rights in the invention and that the inventors did not, knowingly or unknowingly, assign their rights in the invention to another entity.

constituted nothing more than a promise to assign rights to Stanford in the future, whereas the VCA effected a present assignment of Holodniy's future inventions to Cetus. Consequently, Cetus immediately gained equitable title to Holodniy's inventions, which converted automatically to legal title in the patent application as of its filing date. Because Cetus's legal title vested first, Holodniy's subsequent assignment to Stanford during patent prosecution did not transfer title to Stanford. Stanford argued that the Bayh-Dole Act negated Holodniy's assignment to Cetus because it empowered Stanford to acquire title to the invention. The Federal Circuit disagreed, and held that Stanford lacked standing to sue Roche for patent infringement because "it is well settled that all co-owners normally must join as plaintiffs in an infringement suit."[6]

The Supreme Court reviewed the case and affirmed the decision of the Federal Circuit. Accordingly, VCs should exercise heightened scrutiny when evaluating IP assets from federal contractors. As Justice Breyer remarked, "a potential purchaser of rights from the contractor, say a university, will not know if the university itself possesses the patent right in question or whether, as here, the individual, inadvertently or deliberately, has previously assigned the title to a third party."[7]

Incidentally, the decision in *Stanford v. Roche* undercuts the position firmly adhered to by all or nearly all universities that patent rights springing from federal funds cannot be assigned by the university to a third party such as a company with plans to commercialize the invention. Until this day, the most that a company could expect to get from a university was an exclusive license. Now, with the Supreme Court's pronouncement that the Bayh-Dole Act "does not automatically vest title to federally funded inventions in federal contractors or authorize contractors to unilaterally take title to such inventions," there is room for companies to negotiate directly with university inventors for assignments of their inventions.

The Freedom to Operate Review

IP due diligence usually includes some level of investigation of the relevant patent rights of competitors to avoid exposure to liability for patent infringement. This investigation can range from simply reviewing the freedom to operate (FTO) opinions of the target company's lawyers to a full-blown, worldwide search and analysis of all relevant patents. The former approach takes a lot on faith, whereas the latter approach can be extraordinarily expensive and time-consuming. Accordingly, a middle ground often involves searching and reviewing the relevant patents held by those competitors of the target who have the wherewithal to assert their patents and potentially block the target from activities that fall within the scope of the asserted patents.

The FTO patent search can be carried out by a professional search firm or directly by diligence counsel. In either case, it is important that patent lawyers with sound knowledge of the law of patent claim interpretation analyze the results of the FTO search. If a potentially problematic patent is found, the target company has many options. It can drop the product altogether, attempt to alter the product so that it is no longer covered by the patent claims ("design

6 Board of Trustees of the Leland Stanford Junior University, et al. v. Roche Molecular Systems, Inc., 583 F.3.1 832, 8480, 2009 U.S. App. LEXIS 21465, *37 (Fed. Cir. 2009)

7 Board of Trustees of the Leland Stanford University, 131 S. Ct. at 2201, 180 L. Ed. at 19, 2011 U.S. LEXIS at *38.

around"), take a license under the patent, attack the validity of the patent in a patent office reexamination or opposition proceeding or before a court in a declaratory judgment action, or continue in the face of the patent. Licenses can usually be obtained on more favorable terms if they are negotiated early on in the product life cycle, before product success has been demonstrated, and before the company is highly invested in the product and its development and sales. If the company decides to continue in the face of the patent, it should first obtain an opinion of competent patent counsel that the patent is invalid and/or that the company's product does not infringe. An exculpatory opinion of this nature is an important element in a defense against willful infringement and enhanced damages should the company ultimately be sued.

Use the Results of the FTO Review to Enhance the Health of the Company

The results of a strategic FTO review present the company with a wealth of actionable intelligence that can be utilized to the company's advantage in many ways. As mentioned above, potentially vulnerable products or product lines can be re-engineered to steer clear of third-party patents. In addition, the intelligence gained from the FTO review provides potentially valuable information about the technological direction and priorities of key competitors. Sometimes, the FTO reveals technological areas of "white space" where no one has staked out claims, in which case, the target may choose to devote resources to creating and developing innovations in that space. Likewise, the FTO results may reveal that the target has the opportunity to obtain dominant patent claims that would cover niche progressions being made by its competitors. Finally, the results of the FTO study, coupled with the patent portfolio review, may produce actionable business development opportunities. For example, after reviewing a competitor's patents and related products, it may become apparent that the target has patents or patent applications that are not important to the business and are potentially better utilized by the target's competitor. This provides an opportunity to sell or license the assets for revenue, or to flag the assets for potential cross-licensing.

Conclusion

VC-related diligence often takes place at a relatively early stage in the life of a target enterprise when there is still time to fix problems, strengthen IP positions and practices, and enhance the overall value of the target enterprise. For this reason, it is important to employ the following value-driven elements in IP due diligence: (a) use experienced IP attorneys and other professionals to perform the diligence; (b) design a strategy for the investigation that is precisely tailored to the target and the business environment in which it operates; (c) determine whether the patent claims are strong and well aligned with the target's business goals; (d) probe below the surface of recorded patent assignments to scope out hidden ownership conflicts; and (e) strategically assess the prospects for third-party patent infringement (freedom to operate). At the end of such an investigation, there will be many opportunities to use the results and intelligence from the investigation to further strengthen the patent portfolio so that it will remain vigorous and valuable for years to come. Even in the patent world, an ounce of prevention is worth a pound of cure.

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