

IP Due Diligence and the Value Proposition: Developing and Evaluating BioPharma IP Portfolios for Strategic Investment Benefits

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ABSTRACT

INTRODUCTION

“Tell us your value proposition.”—This mantra is repeated to every startup company, biotechnology or otherwise, by every potential investor. Every business plan of every startup must respond to this question.¹ Venture capitalists, aware that a business failing to provide value to its customers cannot succeed, will not invest in a business with a weak value proposition.

Generally, it is only after a potential investor has made a tentative commitment to invest that the question of due diligence arises. Due diligence is a rearguard investigation, designed to assure to the potential investor, among other things, that the target company has not spoiled its ability to carry out its business plan by inattention, miscalculation, or misbehavior. Due diligence investigation of intellectual property (ie., “IP”) is part of the due diligence procedure.

It is the thesis of this article that IP due diligence should be more closely linked to the target company’s value

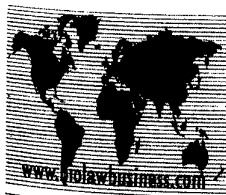
proposition than is commonly supposed—because a company’s IP portfolio should itself be closely linked to the company’s value proposition. This article begins by discussing the “classical” IP due diligence procedures, the ones that are normally followed. It continues with a discussion about how an IP portfolio of a company should be linked to its value proposition. Finally, this article highlights how this linkage changes IP due diligence procedures.

CLASSICAL IP DUE DILIGENCE

“Due diligence” is a term that is in fact derived from federal securities laws provisions, which impose liability on an underwriter for material misrepresentations or omissions in a registration statement or prospectus, unless the underwriter can show a reasonable belief, after “reasonable investigation” and after having exercised “reasonable care,” in accuracy of the material.² The term “due diligence”, was first

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applied to the defense these provisions give to the underwriter and to the obligation, imposed on the underwriter by these provisions, to investigate the company being financed by the underwriter.³ The term has been broadened over time. Today, "due diligence" refers to the investigation into a company made by a potential investor, such as a venture capital firm, prior to an investment in the company, regardless whether a public offering or an underwriter is involved.⁴ IP due diligence is part of the general due diligence investigation.⁵

Classical IP due diligence tends to be practiced by using lengthy checklists to assure that a company is adhering to acceptable minimum standards in handling its intellectual property issues. At bottom, however, classical IP due diligence, being rearguard in nature, can be said to be focused principally on two concerns: 1) Does the company own all its intellectual property? And, 2) Does the company infringe on the intellectual property rights of others in the conduct of its business?

IP Ownership

It is in addressing these two concerns that there arise the lengthy checklists of tasks for the IP due diligence team. To address ownership of intellectual property, it is important to review the procedures that give rise to the intellectual property and the documents that have been created while following such procedures. Agreements with employees and contractors of all sorts often have (and often lack or poorly set forth) critical provisions affecting intellectual property rights of the company, and should be reviewed. Trade secret rights of a company will depend in substantial part on the company's documents and procedures that establish and maintain the confidential nature of its trade secrets. The separate recording statutes of federal laws governing patents,⁶ trademarks,⁷ and copyrights⁸ govern title to these properties, and title searches in the Patent and Trademark Office and the Copyright Office should be undertaken or at the very least considered. Where foreign patents and trademarks are involved, consideration should also be given to evaluating their state of title with the relevant foreign governmental authorities. Documents of assignment should also be reviewed, for wording in these documents can affect rights dramatically; a trademark assignment, for example, is invalid unless it includes an assignment of the goodwill of the business conducted under the trademark.⁹ Development agreements and license agreements should also be reviewed for their impact on title to intellectual property as well as rights to practice technological implementations pertinent to the company's business.

Material transfer agreements, which typically involve a hybrid of rights under trade secrets and patents, also need to be reviewed and evaluated.

Freedom to Operate

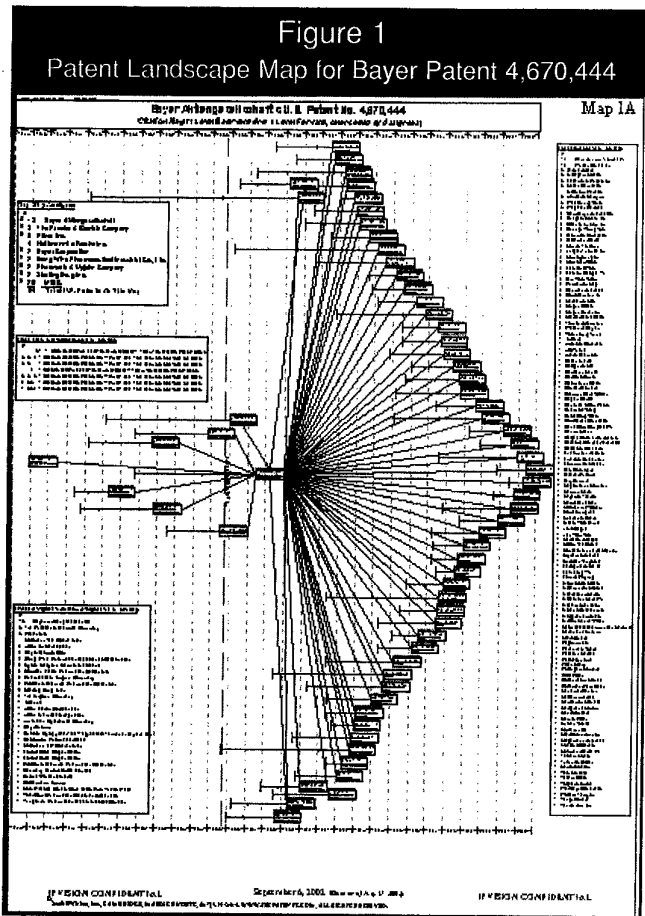
It is one thing to own IP rights; it is another thing to be able to conduct a business without infringing third party IP rights. Thus the fact that a company has a patent for a product does not give it the right to make the product. So, although Transkaryotic Therapies, Inc. holds patent number 6,048,524 for "In Vivo Production and Delivery of Erythropoietin for Gene Therapy," this fact did not prevent Transkaryotic Therapies from being sued by Amgen for infringement of a collection of Amgen's patents for erythropoietin technology.¹⁰

Determining whether a company can conduct its business without running afoul of third party IP rights requires analyzing the company's product and service offerings in relation to third party IP rights of potential relevance. Patents, trademarks, copyrights, and trade secrets each need to be addressed.

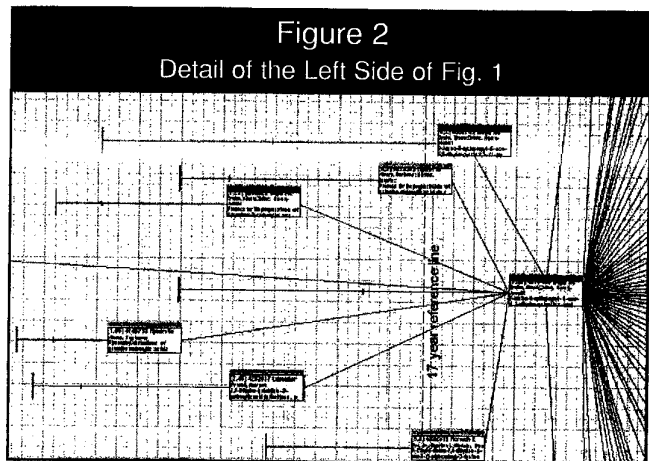
Some instances of IP that will need to be considered for freedom to operate may well arise out of the company's own documents. If patent, trademark, and trade secret rights, for example, have been licensed in from another company, it will be important to look to the license agreement to determine whether the scope of the license is sufficient in relation to the company's business activities. One should not stop at the license agreement, however, because it is also possible that the licensor company obtained additional IP, such as patents, not in the license agreement, which may affect freedom to operate. Thus it is often important to conduct independent IP searches in areas of relevance to the company's business to identify third party patents, trademarks, or copyrights that may be of importance. Additionally, it is important to scrutinize any demand letters, litigation history, and other relationships with competitors to identify potential third party IP risks.

MAKING AN IP PORTFOLIO ADDRESS THE VALUE PROPOSITION

So much for classical IP due diligence. It can tell us whether a company has IP roadblocks to carrying out its business and it can tell us whether the company owns its IP. While these things are indeed important, classical IP due



Source: IPVision, Inc., Cambridge, MA, 2002, custom chart.



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diligence does not tell us how wise the company has been in developing its IP.

The wise company will work to have its IP play a strategic role in the company's business by focusing IP development on enhancing the company's value proposition. Making a company's IP portfolio address its value proposition involves using IP fundamentals purposefully to benefit the company's business. This is based on the principle that intellectual property provides a company with exclusive rights that can be used against potential competitors: patents, the right to exclude competitors from making, using, selling or offering to sell products or services that are patented;¹¹ trademarks, the right to exclude competitors from using trademarks that are the same as or confusingly similar to those of the company;¹² and copyright, the right to exclude competitors from copying or adapting textual and graphic material and software of the company.¹³

The exclusive rights provided by intellectual property can and should be developed in a manner that they are linked to the company's value proposition. Patents should be crafted when possible to prevent a competitor from offering products and services that are equivalent in terms of function

and benefit to those of the company. Trademarks should be registered to protect the key brands of the company from being copied by competitors. Copyrights should be registered to protect key textual and graphic materials.

To develop an IP portfolio that helps to protect the company's value proposition necessarily requires an awareness of alternative offerings in the marketplace—some competitive intelligence. Indeed, the awareness should extend not just to products and services of competitors but also to the competitors' IP and business approaches. With knowledge of this sort, the company can more intelligently craft its own IP to exclude competition from eroding the value proposition offered by the company's products and services.

As an example, let us consider the approach taken by Bayer Aktiengesellschaft¹⁴ with respect to ciprofloxacin, sold by Bayer in the U.S. under the CIPRO trademark; this product is Bayer's leading pharmaceutical patent¹⁵ and is covered by U.S. patent 4,670,444, which is scheduled to expire at the end of 2003. Ciprofloxacin is a synthetic antibiotic used in the treatment of urinary tract infections and severe hospital infections and is also approved for treatment of anthrax.¹⁶ An analysis of the procedural history of Bayer's ciprofloxacin patent and of subsequently issued patents that cite this patent shows that much of the prior art and subsequently issued patents in this area are the result of Bayer's own filing activity.

Although such an analysis can be performed manually, it is also possible to utilize customized patent mapping services. An example of a patent landscape map from Bayer's ciprofloxacin patent is reproduced in Fig. 1. For normal viewing, this map would be printed on a large-format paper, so the high level of detail can be discerned. This map shows citations going back one generation (parents) and going forward one generation (children). The horizontal axis shows time, and each patent is represented by a box placed at its issue date; the line to the left of the box starts at the filing date of the patent. A line that connects one patent to another indicates that the earlier patent was cited by the later

patent. The starting patent 4,670,444 is shown filled in with yellow in the box. Each patent box has band along the top with a color code by assignee (Bayer is red), and the box at the upper left shows the patent count of the top eight assignees; of the 64 patents on the map, the box shows that 8 are assigned to Bayer. (In fact if Bayer Aktiengesellschaft and Bayer Corporation-in pink-are counted as one, then the total is 10 Bayer patents.) It is also apparent, by looking at the distribution over time-the horizontal axis-of the red and pink boxes, that Bayer's patent activities began with earlier prior art references to the subject patent and continue way to the right of the subject patent, being among the latest to have been filed and issued. After Bayer, the next most prolific companies are Proctor & Gamble, Pfizer, and Hoffman-LaRoche, in that order. The box at the lower left provides similar detail for all listed assignees but without color coding. The box at the left between the top and bottom boxes lists the patent classes of the U.S. classification system by the frequency in which patents on the map are placed in those classes; in this instance, 44 of the 64 patents are in class 514. The box at the upper right lists inventors whose patents appear on the map in order of the number of patents for which each inventor is responsible; the inventors at the top of the list are potentially the most valuable to their employer, since they are responsible for the most patent issuances.

In Fig. 2 is shown detail of the map of Fig. 1, looking at the starting patent (the Bayer ciprofloxacin patent, in yellow) and going to the left. The patents to the left are prior art references that were cited in the starting patent.

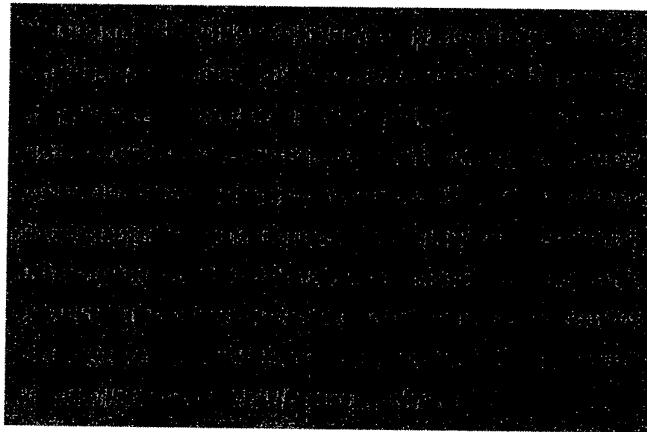
Fig. 3 also shows detail of the map of Fig. 1, but this time ????????? Here a similar detail of the first map exists, but looking to the right of the starting patent. The patents to the right of the starting patent are those that cite the starting patent as prior art.

What is particularly special about maps of this sort is that one can get a reasonable feeling for the competition in this technical area without any substantial technical knowledge. Such maps enable identification of the major competitors are, when they filed for, and when they obtained, patents; collectively where the competitors fit in terms of time and space, who the inventors are and their relative contributions, and so on-all this information in a single visual document. Information in a format like this is powerful because it provides an intelligent synthesis of many complex factors governing the patent positions of competitors. And information such as this can be used in helping to structure a

company's patent portfolio.

More information can in fact be obtained from patent mapping activities. In Fig. 4, a "co-citation" map is shown. This particular map plots all of the references of the previous map, but also the references cited in each of those references. The same graphic conventions apply to this map as to the first map, but the effect of including more generations of patents is significant. Areas of the map reveal where one patent cites a very great number of the prior patents, particularly in the upper right. Such a patent might be important. Of the assignee totals, here 53 of 378 patents are assigned to Bayer Aktiengesellschaft, 18 to Edward Mendell, 16 to Hoffman-LaRoche, and 13 to Warner Lambert, and 12 to Pfizer. A variation of this map, wherein one tabulates the co-citation count of each reference can sometimes identify additional prior art that is pertinent to the starting reference.

In Fig. 5, the detail of the upper right portion of the map of Fig. 4 is seen, and the patent in the upper right cites a very great number of prior patents is U.S. patent 6,261,601. This

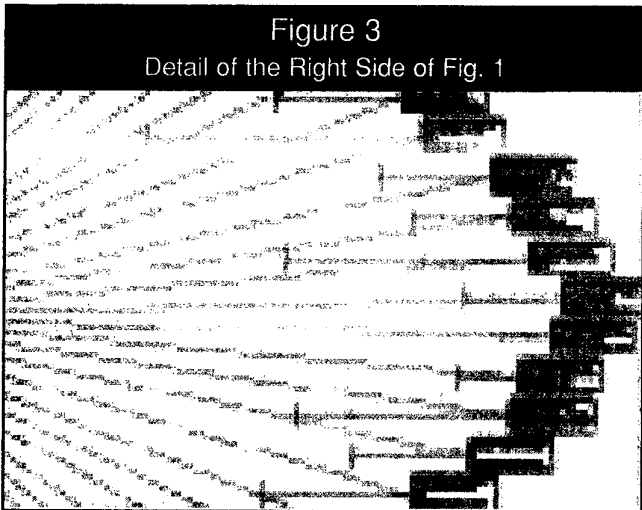


patent was issued to Ranbaxy Laboratories Limited of India for a formulation of a pharmaceutical such as ciprofloxacin permitting its controlled release following oral administration. Bayer licensed in such technology from Ranbaxy, so that even after Bayer's ciprofloxacin patent has expired, Bayer will be able to offer a proprietary version of ciprofloxacin that can be administered once a day rather than twice a day as for conven-

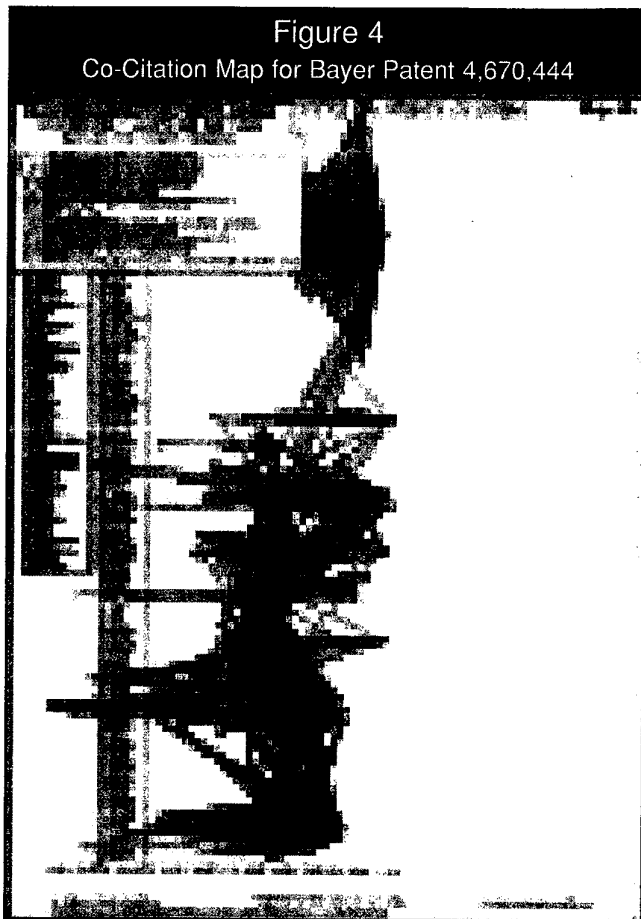
tional ciprofloxacin.¹⁷

Did Bayer find out about the Ranbaxy patent by using patent mapping? The point is that patent mapping and related searching techniques could have provided Bayer with this information. And once it had the information, it could take appropriate steps to augment its portfolio to continue to maintain market advantage and its dominance in the synthetic antibiotic market. In this respect it can be seen that Bayer's patent strategy is linked to its value proposition and serves to enhance and protect it from erosion by the competition.

Such a strategy can best be developed when there are periodic meetings among the company's heads of product development and marketing along with patent counsel. In this way competitive intelligence can be shared and used in shaping both business strategy and IP strategy in a manner that they are congruent and enhance the company's value proposition.



Source: IPVision, Inc., Cambridge, MA, 2002, custom chart.



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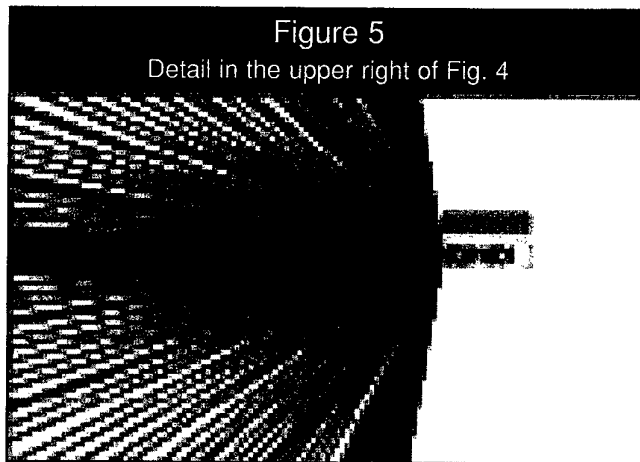
NEW IP DUE DILIGENCE, LINKED TO THE VALUE PROPOSITION

Linking IP due diligence procedures to a company's value proposition does nothing to dispose of classical IP due diligence. A potential investor in a company still wants to know whether the company owns its IP and whether the company can conduct its business without infringing on the IP rights of third parties. But a wise potential investor will also want know the extent to which the company's IP operates in service of its value proposition.

Seeking the answer to this question can beneficially involve use of patent maps of the sort discussed above. It should also involve determining whether the company has patents issued or pending with claims that cover the significant present and planned products and services of the company, the scope of those claims in relation to the prior art, and the patent estates held by competitors in relevant markets. Where appropriate, trademarks and copyrights should also be addressed.

Interestingly, the IP analysis here cannot be wooden and must reflect the realities of the marketplace and the value proposition offered by the company's offerings. What are the benefits of the company's products? It is these benefits that need to be protected by the company's IP from exploitation by competitors, and so the patent analysis must look to ways, if any, that a competitor might try to avoid the company's patents to provide equivalent product offerings.

Our hypothetical investor performing this kind of due diligence would be impressed by a company that could demonstrate immediately to the investor that it had done its homework—patent maps showing its pre-eminent position, patents with claims that cover its products and potential work-



Source: IPVision, Inc., Cambridge, MA, 2002, custom chart.

arounds of its products, and an on-going program to enhance its IP portfolio as it develops new products and refines existing ones. Such a company would be able to tell the investor that it knows its value proposition and also has an IP portfolio that protects the value proposition against incursion by the competition. **JB&B**

ENDNOTES

1. See Kenneth P. Morse, Senior Lecturer and Managing Director MIT Entrepreneurship Center, "Some Suggestions for Writing Business Plans that Raise Money," PowerPoint presentation, 2002, at <http://entrepreneurship.mit.edu/Downloads/ken-morse-businessplans.ppt>: "Entrepreneurs need to have outstanding:
 - Team
 - Technology
 - Value Proposition
 - Market
 - CustomersApplies to Corporate VCs as well..."
2. Sections 11 and 12(a)(2) of the Securities Act of 1933, 15 U.S.C. § 77k and 15 U.S.C. § 77l(a)(2).
3. See, for example, *Glassman v. Computervision Corp.*, 90 F.3d 617, 623 et seq. (1st Cir. 1996) (exercise of "due diligence" as a defense to section 11 and 12(a)(2) liability).
4. "Due Diligence is an intensive investigation of a company undertaken by venture capitalists, investment bankers, investors or others into the details of a potential investment." M&A: Sample Due Diligence Checklist, on website of WR Hambrecht + Co., at <http://www.wrhambrecht.com/comp/ma/process/diligence/index.html>.
5. *Id.*, "Patents, trademarks and other intangible assets" are listed as some of the property and equipment of the company to be investigated.
6. 35 U.S.C. § 261.
7. 15 U.S.C. § 1060.
8. 17 U.S.C. § 205.
9. For example, *Marshak v. Green*, 746 F.2d 927, 929 (2d Cir. 1984).
10. See *Amgen Inc. v. Hoechst Marion Roussel, Inc. et al.*, 314 F.3d 1313 (Fed. Cir. 2003).
11. 35 U.S.C. § 271.
12. 15 U.S.C. § 1114.
13. 17 U.S.C. §§ 106 and 501.
14. The author does not represent Bayer Aktiengesellschaft.
15. Bayer Aktiengesellschaft, Form 20-F, filed with the Securities and Exchange Commission, for fiscal year ending March 31, 2002, p. 17.
16. *Id.*
17. *Economic Times (India)*, August 15, 2002. I have inferred from the article, which mentioned no patent numbers, that the patent licensed involved patent 6,261,601.