

A publication of
The Williamsburg BioProcessing Foundation

September/October 2004

BioProcessingTM JOURNAL

Advances & Trends In Biological Product Development

Vol. 3 No. 5

www.bioprocessingjournal.com

Intellectual Property “Must Dos” For Technology Companies

By DAVID L. PARKER

From an intellectual property (IP) standpoint, probably the two biggest problems I encounter in my practice for early-to-middle stage technology companies are: (1) their failure to fully understand and keep abreast of the competitive intellectual property environment, and (2) their failure to institute procedures that will permit and encourage development of a strategic intellectual property portfolio. By “strategic,” I mean an intellectual property portfolio that focuses on both an offensive and defensive position — a portfolio that not only covers the product and all aspects of its manufacture, production, and applications (defensive portfolio development), but also provides significant blocking positions with respect to competitors’ efforts.

I have frequently met with seemingly well-informed entrepreneurs who informed me that their intellectual property portfolio was in order. When I inquired about what they had done, I was invariably told that they had filed one or more patent applications which they believed adequately covered their product. Entrepreneurs often assume that simply performing a rudimentary search or filing a patent application provides protection for the development of the product in question, much like staking a claim in the gold rush days. Nothing, of course, could



be further from the truth. Rarely do these companies have a good working knowledge of the intellectual property positions that might present obstacles to product development and commercialization, and even more rarely do these companies have procedures for strategic portfolio development.

In this article, I provide a series of straightforward approaches to intellectual property portfolio development and management that I like to refer to as intellectual property “must-dos” for

technology companies. I have found that these “must-dos” provide a strong foundation on which to develop a commanding intellectual property position.

Strategic Portfolio Development

As I mentioned, with strategic portfolio development both offensive and defensive patent filings are emphasized.

To develop a strong defensive portfolio, a company must have a good working knowledge of its product, how

David L. Parker, Ph.D., J.D. (dparker@introgen.com; dparker@fulbright.com) is vice president, intellectual property, Introgen Therapeutics, Inc., Austin, TX, and is also a partner at Fulbright & Jaworski LLP, Austin, TX. The opinions and views expressed in this article are those of the author and in no way reflect the views of Introgen Therapeutics, Inc., Fulbright & Jaworski LLP, or any of its clients.

it is made, how it is to be used and by whom, and, most importantly, an excellent working knowledge of its technology inventory. The latter is not as simple as it sounds.

To lay the groundwork for strategic portfolio development, a company must also have a strong working knowledge of both “direct” and “indirect” competitors and their IP positions. “Direct” competitors are companies that are either competing directly with similar products or vying for the same customers. “Indirect” competitors are not competing against your company *per se*, but are nonetheless “snipers” that are developing intellectual property positions that could block one or more avenues of commercialization, or make those routes more expensive. The key is to be aware of competitors’ positions BEFORE you have committed to a certain product configuration or commercialization strategy.

Why Important?

A patent portfolio that emphasizes both an offensive and defensive position provides much better “room to maneuver” in the market and protects key products much better “around the edges,” so that as your marketing or development plans change, your portfolio is better able to accommodate the change.

Further, a “well-rounded” patent portfolio places you in a strategic position when it comes to any “interactions” with third parties. The more cards you hold that third parties might need, the more willing third parties will be to accommodate your business interests.

Having an understanding of your competitors and their intellectual property gives you an ability to better “connect the dots” and assess competitors’ motivations for their actions. Competitors’ actions will almost always be based on intellectual property considerations. If you know the intellectual property component, you will have valuable insight into your competitors’ strategies.

Lastly, knowledge coupled with strategic portfolio development not only adds significant value to the technology

company, it garners respect in the eyes of analysts, investors, potential partners and suitors, and competitors.

Learn the “Landscape”

As I mentioned, it is critical for technology companies to know about competitors AND know competitors’ IP portfolio. This is done through an in-depth IP “landscape” analysis that typically first involves a detailed and thorough web-based search to identify entities worldwide that are involved in the development of technologies in competing areas. Exemplary web searching should include at the very least both a company and subject matter search of the web in general (a Google-type search), one or more scientific and patent databases (e.g., Dialog/STN, U.S. Patent and Trademark Office, and European Patent Office databases), and interviews with scientists. Through this search, one can develop a good working knowledge of the identity and activities of direct and indirect competitors.

After the first-stage search is reviewed and culled to the most relevant data, this information is then used to enter the second, more indepth stage, which involves the identification, analysis, and review of the companies’ IP positions. This is not always straightforward, as related entities may not be immediately apparent. There may be licensors, collaborators, subsidiaries, etc., contributing intellectual property to an identified company. Nevertheless, relationships, collaborations, and licensing entities can be assessed through searching the web for company web sites, press releases, and SEC filings (10Ks and 10Qs on Edgar).

Once the relevant companies and related entities are identified, you should then analyze their respective IP portfolios to identify those that are most relevant to your current development (tactical) as well as future development (strategic). There are detailed up-to-date and user-friendly web sites that permit you to identify and pull down patents and patent filings based both on the particular company and on the technology itself. (Useful examples include the U.S. Patent and Trademark

Office (USPTO) website at <http://www.uspto.gov>; the European Patent Office (EPO) search website at <http://register.epoline.org/espacenet/ep/en/srch-reg.htm>; and the Canadian Patent Office search website at <http://patents1.ic.gc.ca/intro-e.html>)

In-House Portfolio Assessment and Development

The flip side of knowing competitor companies and their positions is having a good working knowledge of your own technology. Only on rare occasions have I found that company leaders have an adequate knowledge of what their protectable technology includes.

Take this real-life scenario as an example: I was asked to evaluate the technology of an early-stage company with very promising technology involving the development of widgets. They had a large number of patent applications filed that covered the widgets including the various modifications to the widgets that they had instituted over the years. In taking a stroll through their facilities I would ask questions like “What’s that thing over there?” And the answer would invariably be “Oh, that’s the production device for producing the widget,” or “That’s the software that is used to control the widget.” When I would then ask why they have not filed patent applications on the device or software, the answer I would get is something like “Because that’s a standard device or software.” A little digging, though, reveals that these devices or software have never been used for widgets of this sort, and patent protection at these bottlenecks could potentially provide across-the-industry domination.

Technology “Inventory”

It is crucial that technology companies identify all aspects of their technology that could form the basis for a competitive advantage when protected. This requires that you first identify all technology within the company that in any way relates to the “making, using, and selling” of your technology — the rights conveyed by patent protection.

This is done by carrying out a detailed inventory, including an inventory of the technology itself, including all of its subparts or components, how it is made or manufactured, formulated, produced, packaged, etc., including the machines and devices used in manufacture. But don't stop there. Look to how the technology is going to be marketed and used (e.g., clinical therapeutic applications, business methods).

Then, looking at your current IP, determine where the "holes" are in your protection and assess where additional protection should be sought, bearing in mind that overlooked areas of commercially significant patent protection often include protection for software and for so-called business methods.

Internal Systems for IP Management

Particular positions and systems should be set up internally to facilitate a strategic portfolio development.

IP In-House Coordinator

While it is not critical to have an in-house intellectual property attorney, it is very important to have an in-house IP coordinator. The ideal in-house coordinator has a strong technology background and has, or develops, a strong working knowledge of the company's operations and technology development efforts, as well as the particular technology segment's "players." The coordinator should also have, or develop, a strong working knowledge of the patent system. This would include taking and passing the USPTO agent's exam, which permits attorneys and non-attorneys alike to conduct business before the USPTO.

The IP coordinator's functions are critical to developing a strong offensive and defensive IP portfolio. Of course, maintaining the related patent files and formal documents involves administrative tasks such as setting up competitive alert systems, maintaining a notebook library system, overseeing and liaising with outside counsel, advising management, etc. More importantly, perhaps, the coordinator must identify and maintain developing IP positions within the company and also coordinate with

collaborators who have an IP obligation to the company through sponsored research agreements or material transfer agreements. The coordinator must keep abreast of all the developments in technology and recognize the subtleties. An example of a technology development subtlety might be recognizing that an IP opportunity exists in a scientific study showing that a drug exhibits a previously unknown property or that a therapeutic gene is found to work by different mechanisms of action. Further, "maintaining" IP positions requires strict oversight of presentations by the company and its collaborators, such as abstracts and scientific publications, to ensure that appropriate patent applications are filed in a timely fashion.

IP Meetings

A technology company should have regular meetings to review in-house technology developments as well as external, competitive issues. The meetings should be attended by at least one representative from each of the major technology development areas of the company as well as individuals familiar or liaising with outside researchers or collaborators, along with the IP coordinator and, preferably, patent counsel.

Competitive Alert Systems

It is also important that a company set up regular/automated search systems that identify recently published patent applications and newly issued patents of relevance. At Introgen Therapeutics, Inc., ("Introgen"), where I serve as the vice president of intellectual property, we employ the automated search capability of Dialog Information Services to conduct regular searches of both scientific and patent databases using a broad assortment of technology key words and names of direct and indirect competitors. The searches are conducted regularly, typically twice a month or so, and the results are reviewed by the IP coordinator or IP counsel, and circulated through appropriate scientists at the company.

Employment Contracts

A technology company should have appropriate employment contracts

that include IP assignments and post-employment assistance obligations for everyone (including management). I say "for everyone" because in my private IP practice I have seen and been involved in a number of disputes involving senior scientists (often founding scientists) who were not required to execute an employment contract with standard IP provisions. Under most states' laws, the inventor of a technology "owns" the associated intellectual property unless he or she has assigned the ownership right to the employing company. This can be true even when the inventor developed the technology in question while in the employ of a company.

Notebook Maintenance

Appropriately detailed scientific notebooks can be critical in proving a company's rights to a particular intellectual property, most notably to evidence invention dates if challenged during patent prosecution, in litigation, or in a patent interference. A patent interference is an administrative procedure conducted by the USPTO and peculiar to U.S. patent law that determines the "first to invent" an invention in question. Notebooks should be formal, numbered, company notebooks that are distributed in numerical order by the IP coordinator, who is responsible for maintaining a log. Procedures should be put in place for having notebook pages regularly signed and dated by the researcher and witnessed by a third party. A notebook witness should be a company employee familiar with and capable of understanding the technology, but is preferably not a potential co-inventor of the technology. The purpose of this is to provide corroboration of the technology development. Under USPTO interference procedures, co-inventors cannot corroborate their own invention development. Once the notebooks are completed, they should be checked in to the coordinator and maintained both by copying onto a CD using a high-resolution technique, and by storing the actual notebook in a fire-proof safe, to which only one or two individuals in the company have access.

Standard Contracts

Lastly, it is a good idea for companies to develop “standard” contracts such as one- and two-way confidential disclosure agreements (CDAs), material transfer agreements (MTAs), sponsored research agreements (SRAs), cooperative research agreements (CRAs), and the like. These are important documents that can at least provide a reasonable “company-preapproved” starting point for negotiations with third parties.

Strategic Portfolio Development

At the risk of sounding like a patent attorney, I can state unequivocally that a technology company should never be satisfied with one or two approaches to protecting its lead product candidates. One reason for this is that while U.S. patents enjoy a presumption of validity, they are nevertheless held invalid or unenforceable 20 to 40 percent of the time. Furthermore, patent scope is defined by the wording of a patent's claims — the numbered sentences at the end of the patent — and the meaning of these claims is both a major battleground of patent litigation and a major focus of design-around engineers and lawyers. Having multiple approaches to patent coverage can greatly minimize the risk of market control loss due to the possible invalidity or design-around with respect to any one patent. For example, at Introgen we currently have 14 U.S. patents that cover our lead product candidate, Advexin® adenoviral p53. It is not by happenstance that we have patents that cover:

- adenoviral p53
- the core DNA of the adenoviral p53
- pharmaceutical compositions
- cancer therapy in general using adenoviral p53
- specific cancer therapies using adenoviral p53
- specific routes of administration (intratumoral, intravenous, regional, etc.)
- combination therapy using p53 with conventional chemotherapy and radiation

- purified adenoviruses, including various aspects of production
- commercial scale production/quantities of adenoviruses
- commercial pharmaceutical formulations of adenoviruses

This portfolio was developed with a specific strategy in mind. We envisioned the complete development and use of the product from beginning to end, including clearly identifying the product and all of its parts as well as pharmaceutical formulations and compositions, how it would be made in commercial-scale quantities, and how the product was going to be used in the clinic.

This formula will work well for any technology company. Step back and look at every aspect of the related technology and ask these questions. At the same time, ask how competitors are going to develop competing technologies. Your own IP portfolio development should not only focus on your product(s), but should also anticipate how the industry as a whole will develop and commercialize competing products.

If possible, patent expenses should not be a major concern or focus of a company. Every dollar spent in strategic portfolio development is worth many times the investment. Thus, companies should file on both major and incremental advances in each area of product production, product composition, and product use and distribution.

A detailed consideration of foreign-filing strategy, due to its intricacies and multi-faceted nature, is beyond the scope of this article. However, an effective strategy includes filing international applications so that your company can control at least 80 percent of the potential consumers of the product (in dollar terms) as well as at least 80 percent of the potential producing countries, where possible. Of course, the funds available to a technology company for patent filing and prosecution will necessarily impact the scope of international filing.

Conclusion

Management, key scientific personnel, and non-IP counsel must be proactive. You must learn and understand your IP positions and the IP-related issues facing your company and your competitors. This includes learning to read and understand your patents as well as those of your competitors, or at least having a working knowledge of what the applicable IPs cover, and where their strengths and weaknesses lie. For any new product, you must know in advance where the IP landmines are and what the plan is for avoiding them. Systems must be put in place that will promote the development, maintenance, and timely capture of IP. You should file on all aspects of a product's production, how it will be formulated and used, and all aspects of the product itself. Having a day-to-day strategic IP mindset and structure will give a company an enormous competitive advantage and may well keep you in the market and out of court.



CALL FOR PAPERS

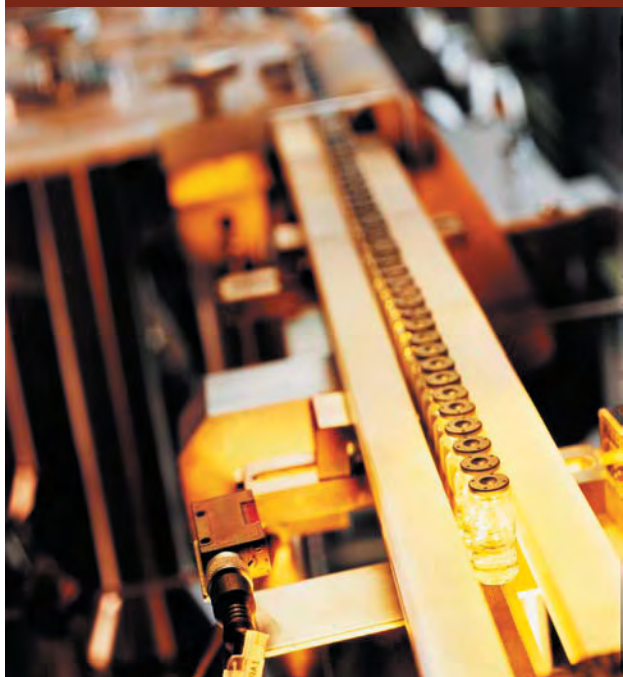
BioProcessing[™]
JOURNAL

**Advances & Trends In
Biological Product Development**

www.bioprocessingjournal.com

ph: (757) 963-1409
fx: (757) 423-2065

Your Product Our Experience



CELL GENESYS...

has extensive experience developing cellular, viral and gene therapies. We have established significant manufacturing, quality, regulatory and logistics capabilities for development, production, testing and distribution of products for all clinical phases.

As part of a long-term commitment to these technologies, **CELL GENESYS** is offering its facilities and expertise on a contract basis.

Manufacture

- Autologous and allogeneic cell-based vaccines
- Somatic cell products
- Viral products
- Viral vectors for gene therapy

Production

- All phases of clinical drug development
- Facilities for cell culture, purification, and fill/finish

Expertise

- Process Development, Engineering and Technology Transfer
- Quality Control laboratories for in-process & release testing



CELL GENESYS

CONTACT

Mike Ramsay
Sr. VP Operations
Cell Genesys, Inc.
650-266-2928

mike.ramsay@cellgenesys.com