The Metropolitan Corporate Counsel®

www.metrocorpcounsel.com

October 2013 Volume 21, No. 10

Funding Biotech Innovation: The Ins And Outs Of Collaboration Arrangements And Licensing Agreements

The Editor interviews ***Lori M. Waldron,*** *Member, Life Sciences Practice Group, Sills Cummis & Gross P.C.*

Editor: Please describe your background and practice.

Waldron: I am a transactional lawyer and a member of my firm's Life Sciences Practice Group. My practice focuses on the representation of both emerging and well-established companies in business transactions, with a particular emphasis on the life sciences industries. I represent my clients through all phases of their business cycles, including start-up, financings, license and collaborative agreements, supply and distribution agreements, and M&A.

Editor: What are some of the biggest challenges that smaller and medium-sized biotech companies face today?

Waldron: For many years, "biotech" was a hot word, with the prevalence of emerging technology and cutting-edge research and development such as the Human Genome Project. The technology and R&D are still there. However, with a tough economic climate, the market and industry have changed substantially over the last decade, with a large drop-off in large venture capital (VC) funding for early and middle-stage biotechnology companies with novel but unproven ideas. In the past, VC firms and other funding sources pursued earlier-stage innovation more aggressively. More recently, however, it has become very difficult for an early or middle-stage company without good clinical data to obtain enough financing to pursue their programs. More and more of these companies now are dependent on smaller seed financing and government grant money and find themselves operating on a shoestring budget.

Lori M. Waldron

Editor: What if the biotech company has a novel idea, and has submitted a patent application, but does not have an issued patent or patents? I imagine this makes it even tougher.

Waldron: A company can still obtain solid financing if its patent or patents are not yet issued, as long as the likelihood that the U.S. Patent and Trademark Office will ultimately issue the patents covering the core technology is high. It is difficult to obtain financing if the company's patent portfolio is not strong and if the likelihood that pending applications will be approved by the USPTO is not clear. The patent approval process at the USPTO is a very long one. It typically takes four to five years to obtain approval of a patent application. The long approval process is a big problem for many of these companies – particularly if the survival of the company is reliant upon the success of one or two key patent applications. The USPTO has instituted some improvements recently, with increased staff and slightly shorter timelines, but it is still an arduous process.

Editor: How about Big Pharma? With so much competition out there, what are some of the challenges?

Waldron: Yes, the competition is fierce. With more and more blockbuster products going off-patent, big pharmaceutical companies are under continual pressure to introduce new, novel products into their pipelines. It costs millions and millions of dollars to bring a product to market. These large pharmaceutical companies may engage in initial research and development activities for a whole host of potential products, but only a scarce few of these programs will lead to the next stage of more intense internal clinical and related activities. Once the compound, formula or other composition is internally developed, the company must then take it through the rigorous approval process of the FDA, which takes many years to complete. Again, many of the pipeline products never make it through the entire FDA process and fail before ever hitting the market – all at a huge expense to the pharmaceutical company.

Editor: How do the biotech and big pharmaceutical companies handle some of these issues?

Waldron: In light of the fact that it is so difficult and expensive to bring a new product to market, pharmaceutical companies often look for ways to minimize the risk and expense. A common approach is the formation of a collaborative arrangement or other strategic alliance between a larger pharmaceutical company and a smaller biotech company. The pharmaceutical company typically contributes research and other funding. The biotech company typically contributes its proprietary platform. This type of arrangement is a win-win for both parties. The pharmaceutical company obtains access to cutting-edge technology and potential new products. The smaller company obtains needed financing and access to the big pharmaceutical company's R&D, regulatory and marketing expertise and distribution channels. Often, scientists from the biotech company and the pharmaceutical company will work side by side, in the

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same laboratory, and leverage off of each other's knowledge.

Editor: How is this "collaborative arrangement or other strategic alliance" between the two companies typically structured?

Waldron: The most common type of collaborative arrangement takes the form of a license agreement. The biotech company grants the pharmaceutical company a license to proprietary technology and patent rights in exchange for funding. The funding may take various forms, including an initial up-front payment, milestone payments and royalties. The initial up-front payment often provides the biotech company with a quick infusion of much-needed capital. Milestone payments are often triggered by the completion of one or more stages in the R&D or commercialization process – and thus if the milestone is not achieved, the milestone payment does not become due by the pharmaceutical company. Royalty payments are generally calculated as a percentage of net sales of the final product. Also, the pharmaceutical company may receive equity in the biotech company.

Editor: I am sure that these collaboration arrangements include many complicated concepts.

Waldron: Royalty payment provisions, in particular, can become very intricate. Of course, the definition of "net sales" is important, as this is the amount that is the base for the royalty payments. However, there are many other royalty-related considerations. These issues include royalty floors and ceilings, the treatment of sales made by sub-licensees, whether or not royalties are due before a patent issues (that is, if the patent is still at the application stage with the USPTO), and "combination product" and "royalty stacking" matters (the potential reduction in royalties because the licensee also needs or desires to incorporate third-party technology into the product, thus raising the cost of the product for the licensee). Likewise, many similar issues arise with respect to milestone payments.

Editor: You also mention that scientists from the biotech company and the pharmaceutical company may work side by side in the same laboratory. Can this become problematic?

Waldron: Absolutely. Each party to the collaboration will continue to own all of its "background" technology and information – the information and technology that it owns before the start of the collaboration and that it brings to the relationship. That point is rarely disputed. The difficult issues arise when a new invention is discovered or created during the course of the joint collaboration by scientists from both companies. Both parties want to own the invention, with competing interests as to whether or not the licensee (usually the pharmaceutical company) should pay a royalty to the licensor (usually the biotech company) and whether or not this new invention may be used by either party outside of or after the collaboration. There are many resolutions to these issues, including assignment provisions with an exclusive grant-back license and non-competition provisions.

Editor: What happens if the collaboration ends?

Waldron: That is a very good question. Collaborations do sometimes terminate prematurely. The collaboration can terminate either in its entirety or only in part (for example, only with respect to a particular product, patent right or territory). The consequences of termination vary based on the cause of the termination. If a party breaches the agreement, it typically has fewer post-termination rights. If the pharmaceutical company terminates because it determines that the program is technically or commercially infeasible, then post-termination rights may favor the biotech company. Other important issues to consider are whether the licensee has ongoing post-termination license rights of any sort and, if so, whether an exclusive license converts to a non-exclusive license. Also, do royalty and other payment obligations survive? If there is a related manufacturing or supply agreement, does that agreement also terminate? Of course, it is also important to consider whether or not to include a post-termination non-compete.

Editor: I know that many novel inventions are discovered at major universities. How does a company obtain access to those inventions?

Waldron: Universities can be a significant resource for life sciences companies. Many companies routinely scour the academic journals and other publications looking for innovation. Most major universities have a formal technology transfer office. These tech transfer offices are in the business of licensing out technology in the hopes of commercialization in exchange for payment.

Editor: Are these license agreements with universities similar to other license agreements?

Waldron: Yes and no. The license agreement will often include similar types of financial terms. However, the university usually has a unique interest and mission to preserve academic freedom and increase its reputation in the academic community. This is in disparity to the company's interest to maximize profit. This disparity manifests itself in many ways. For example, the university and the life sciences company often have competing interests with respect to the publication of results of academic research activities related to licensed technology. The university inevitably desires to publicize (for example, by publishing a report in an academic journal or presenting a report orally in a conference setting) explicit results of the research and specific details regarding the underlying laboratory testing, data and intellectual property. The life sciences company, by contrast, inevitably desires to preserve the confidentiality of these activities. There are solutions to these issues, including the university's agreement to delay publication in order to provide the life sciences company with the opportunity to obtain appropriate patent or other intellectual property protection.

Editor: The attorneys in your firm include many lawyers who formerly worked in government. It must be an enormous benefit to have such expertise and resources in-house.

Waldron: Without question. Our lawyers include a former New Jersey Supreme Court Justice and Attorney General, a former Chief of the New Jersey Office of Economic Growth and a former member of the U.S. House of Representatives. In addition to their legal knowledge, these attorneys give us a unique insight into many levels of state and federal government. In fact, a ranking of "politically influential law firms" in New Jersey ranked Sills Cummis & Gross number one among Am Law 200 law firms in the state.

The views and opinions expressed in this interview are those of the interviewee and do not necessarily reflect those of Sills Cummis & Gross P.C.