Portfolio Media. Inc. | 860 Broadway, 6th Floor | New York, NY 10003 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Q&A With Morgan Lewis' Randall Sunberg

Law360, New York (April 25, 2012, 1:58 PM ET) -- Randall B. Sunberg is a partner in Morgan Lewis & Bockius LLP's business and finance practice, vice chairman of the firm's life sciences interdisciplinary group, co-chairman of the firm's life sciences transactions practice and managing partner of the Princeton, N.J., office.

Sunberg's clients range from early-stage biotechnology start-ups to global pharmaceutical companies. He also advises private equity, venture capital and investment banking firms focused on the life sciences industry.

Sunberg's background includes a variety of transactions, including negotiating and structuring complex collaborations, mergers and acquisitions, divestitures, joint ventures, corporate partnering and licensing, and the equity investments that often accompany such transactions.

Q: What is the most challenging case you have worked on and what made it challenging?

A: One of the most challenging deals I have worked on was a complex collaboration between two large, global pharmaceutical companies involving a novel area of platform technology and product candidates that neither company had the financial capacity or expertise to develop and commercialize on its own.

The technology was in an emerging area of intellectual property and regulatory law, which necessitated seeking advice from the U.S. Food and Drug Administration and European Medicines Agency with respect to the regulatory pathway, and then reflecting that advice in the collaboration agreement with caveats appropriate to regulations that had not yet issued and were expected to evolve over time.

The transaction also included ancillary process formulation, drug delivery and device collaborations with several biotech companies that had advanced technologies in those areas. In addition to coordinating the timing of the execution of these ancillary collaborations with the main deal, we had to ensure that the inventions and other rights under those agreements were available to both of the global pharmaceutical companies, even though technically only one might have been a party to the ancillary biotech collaboration.

Finally, the parties also committed to the establishment of a large manufacturing site that would be jointly financed and owned, which raised a host of regulatory, real estate, environmental, tax and accounting issues.

Due to the parties' close working relationship and sizeable commitment in funding and other resources, the transaction included "puts" and "calls" in the event either underwent a change in control. Interestingly, one of the parties was later acquired and the other party wound up buying out its interest in the collaboration.

Q: What aspects of your practice area are in need of reform and why?

A: The model for biotech funding is in need of an overhaul in order to preserve the robust nature of this source of innovation. Many biotech companies are struggling to attract investors and to raise the funds necessary to continue their drug development programs.

The familiar sources of funding, such as venture capital firms, are seeking lower-risk investments and are leaning generally toward later-stage opportunities. Earlier-stage investing has been taken up, to some degree, by in-house venture arms of global pharmaceutical and big biotech companies.

However, the overall level of funds available is far from the capital needs of these companies. As a result, biotech companies are pushed toward licensing out their intellectual property for fees, milestones and royalties, or toward being acquired.

The pharmaceutical industry needs a strong base of biotech companies that can move new science from the lab to pre-clinical development and beyond. In the absence of well-funded biotech companies, the big biotech and pharmaceutical companies will need to find new ways to access novel technologies.

As a result, we are seeing the emergence of a new model of collaboration arrangements between industry and academia, as well as an increase in the traditional types of sponsored research agreements with universities and institutes.

Q: What is an important issue or case relevant to your practice area and why?

A: An important issue affecting life sciences companies relates to funding crisis among biotech companies, referenced above. Big biotech and pharmaceutical companies are often wary of the financial condition of biotech licensors, and this concern is impacting deal structures.

In a collaboration transaction, the licensee will typically depend on the licensor to maintain and perhaps improve the intellectual property that is being licensed, as well as perform certain functions or conduct certain aspects of product development.

However, if the licensee is concerned about the biotech licensor's financial health, it may require that the intellectual property related to their deal be assigned rather than licensed. This change in structure from license to assignment may potentially deprive the biotech company of the ability to further exploit that technology.

Although such structures can be worked around, for example by granting back rights to the assignor, it is a major shift in dynamics between the parties. The assignment, rather than license, of intellectual property can further marginalize the biotech company, exacerbating its problems in obtaining new funding from investors.

In addition to this shift toward assignments, concerns about the financial health of licensors have led pharmaceutical company licensees to also design financial terms that de-risk the deal for them with low up-fronts in lieu of larger downstream payments. Licensees are able to obtain such terms, in part, because they have increased negotiation leverage resulting from there being fewer funding alternatives than in the past.

I recently worked on a deal where the biotech licensor got just enough funding in the upfront payment to cover the Phase IIb activities that it was obligated to conduct, at the end of which the pharmaceutical company licensee would pay the large milestone, thereby effectively electing to continue with the collaboration and assume the Phase III activities.

Unfortunately, the study results did not meet endpoints, giving the pharmaceutical company the right to terminate. Essentially, the licensee got a very low-cost option on the program, and the licensor just got its costs covered for the study.

With the rare exception, pharmaceutical companies are not willing to compete and pay large amounts for licensing opportunities, but rather are willing only to make incremental bets with escape routes if the product candidate fails.

Q: Outside your own firm, name an attorney in your field who has impressed you and explain why.

A: In addition to life sciences collaborations and mergers and acquisitions, I have worked on a number of royalty monetization transactions. These deals require expertise in structured finance and secured lending, as well as in licensing and intellectual property.

I have been impressed by Dale Osadchuk of Davies Ward Phillips & Vineberg LLP for his precision in this specialized area of life sciences financing.

Q: What is a mistake you made early in your career and what did you learn from it?

A: One mistake that I made early in my career was to accept the directions given to me from the more senior lawyer on the transaction and to proceed to perform the drafting-related skills that I was developing as a junior lawyer, without sufficiently questioning the overall deal structure.

Although drafting and negotiation skills can make you a valued lawyer, understanding the client's business goals and the big picture of the transaction will make you an even more valued member of the client's team. I learned that these skills are essential to bringing creativity to the table.

Fortunately, in my area of practice in life sciences collaborations and partnering deals, there is a tremendous opportunity to contribute new ideas on structures and on ways to resolve issues, and it makes working on these deals that much more fun. I try to instill in the junior associates with whom I work this sense of embracing the entire deal, as well as the context for the deal in the client's overall business.

The opinions expressed are those of the author and do not necessarily reflect the views of the firm, its clients, or Portfolio Media Inc., or any of its or their respective affiliates. This article is for general information purposes and is not intended to be and should not be taken as legal advice.