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Life Sciences MVP: Morgan Lewis' Randall Sunberg

By **Rachel Slajda**

Law360, New York (December 05, 2012, 4:53 PM ET) -- Randall Sunberg of Morgan Lewis & Bockius LLP spent the last year facilitating collaborations among pharmaceutical companies, including a nearly $2 billion multidrug deal between H. Lundbeck A/S and Otsuka Pharmaceutical Co. Ltd., earning him a spot among Law360's Life Sciences MVPs.

Sunberg, co-chair of Morgan Lewis' life sciences transaction practice, represented Lundbeck, a Denmark-based company, in negotiations to collaborate with Otsuka on up to five psychiatric drugs.

The resulting agreement, signed in November 2011 and worth up to $1.8 billion for Otsuka, granted Lundbeck commercialization rights to two Otsuka drugs that are in the late stages of development. The two companies will collaborate on up to three Lundbeck drugs that are still in the early research stages.

Sunberg told Law360 that, besides the sheer size of the deal, the agreement was unusual in bringing back a product rights structure that has not been in much use over the past decade. Under the quid product structure, one party has the right to pick multiple products from the other party's pipeline in the future — a risky but potentially lucrative trade-off, Sunberg said.

“It's certainly something you need to define as clearly as possible,” he said. “There are elements of it that are still unknown, and that's the value: there might be things of value in the pipeline in the future.”

Another major deal led by Sunberg was the collaboration between Merck Serono SA and Dr. Reddy's Laboratories Ltd. to work together to develop biosimilars, or the generic version of biologic drugs, for oncology treatment. Under the agreement, Dr. Reddy's will hand early product development, handing off to Merck after Phase I trials. Merck will manufacture and finish development, sell the final product in most parts of the world and pay Dr. Reddy's royalties.

Sunberg said the negotiations were a milestone for Morgan Lewis. There are only a handful of similar agreements between major innovator companies and generics makers like this one, he said.

“It's a large dollar commitment by the innovator pharmaceutical company and a large commitment of technology and speed to market by the biosimilar company, and putting together their expertise to do the clinical development,” he said.

The negotiations dealt with a slew of thorny issues, Sunberg said, including regulatory uncertainties for biosimilars in much of the world, intellectual property rights and collaboration over vast distances, with Merck based in Germany and Dr. Reddy's in India.

Sunberg, who started out in more traditional merger and acquisition deals, said he appreciated the constructive nature of such collaborations.

“The nice thing about the collaborative work we do, which I spend most of my time on, you have two parties coming together to build an ongoing relationship on how they're going to take on a particular project, how to take it from early research to commercialization,” a relationship that requires a lot of coordination, meetings and information exchange, he said.

Sunberg said that in addition to biosimilar deals, which are growing in popularity now that Europe is approving biosimilars and the U.S. is establishing a pathway to do so, he is spending much of his time on research collaborations between universities and pharmaceutical companies.

The universities have taken the place of startup biotech firms, to which large pharmaceutical companies have often turned to handle the early-stage research and development of promising products, he said. But with such startups struggling to get financing, big pharma is increasingly turning to academia to pick up the slack, he said.

Now, the relationships between universities and drug makers are increasingly collaborative, with universities demanding a greater say in what happens to their research, rather than the old model wherein pharmaceutical companies paid universities for the research, he said.

Bridging the sometimes competing interests of academic researchers and drug makers can be a tricky matter, he said.

“There's a fundamental tension because the pharmaceutical company wants to have all the rights to what they're paying for. But the university wants to have the research go out to other labs, have other people do things with it. It's part of their academic mission,” he said.

“Bringing those two different starting points together can be a challenge, but it lends itself to creative results, creative solutions, really hearing what each side is trying to achieve and trying to find some compromise,” he said. “That's a challenge and that's exciting.”

Sunberg and Morgan Lewis have also represented GlaxoSmithKline PLC in a global licensing and co-development agreement with Janssen Pharmaceuticals, Inc., for Janssen's antibody Sirukumab; Enzon Pharmaceuticals, Inc. in its research, development and licensing collaboration with Zhejiang Hisun Pharmaceutical Co. Ltd.; and Concordia Pharmaceuticals Inc. in the sale of its assets to Kadmon Corp. LLC.

--Editing by Eydie Cubarrubia.