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Thomas "Tom" Duley of King & Spalding

KING & SPALDING

BIOTECH AND PHARMACEUTICAL

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KING & SPALDING

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King & Spalding's Thomas "Tom" Duley has forged his place as a go-to lawyer in the life sciences, particularly for biotech and pharmaceutical companies looking to hash out cooperation agreements to get cutting-edge products to market. This past year, it was SciClone Pharmaceuticals Inc. in an exclusive licensing deal with Soligenix Inc. to develop, promote and market an oral mucositis treatment in patients with head and neck cancer in China, Taiwan, South Korea and Vietnam. Duley told *The Recorder* about the past year's highlights, how he developed his unique practice and his approach to client service.

What were your professional highlights of the past year? What made that deal or those deals stand out?

In August, we advised the biopharma company Dermira in a licensing agreement with Roche and Genentech worth up to $1.4 billion. Dermira acquired rights to a drug called lebrikizumab, an antibody currently being tested as a potential treatment for certain lung diseases. Dermira hopes to develop the drug for atopic dermatitis, one of the most common skin diseases in the world.

What made the Dermira transaction significant for us was not only the dollar value, but also that we represented the smaller company as the acquirer of rights from a larger company; and, in this case, the program being acquired was an antibody in late clinical-stage development, with substantial clinical, regulatory and manufacturing responsibilities being transferred to our client. The biotech companies that I represent are typically the seller of their technologies to larger pharmaceutical companies, but for this deal, the proverbial shoe was on the other foot.

And earlier this year, we advised Incyte Corp. on two clinical collaboration deals with pharmaceutical companies Merck and BMS. One was a clinical trial collaboration and supply agreement with Merck where an existing collaboration was expanded. Under this deal, both companies will look at combining Merck's antibody Keytruda with Incyte's drug epacadostat to treat a number of different cancers. For the second Incyte deal, with BMS, the parties would be combining epacadostat with BMS's antibody Opdivo in clinical trials for the treatment of head and neck cancer and nonsmall cell lung cancer. We also represented Incyte in its expanded clinical collaboration with AstraZeneca and its global biologics research and development arm, MedImmune. This deal was just announced Oct. 31. The parties will combine Incyte's drug, Epacadostat, with AstraZeneca's drug, Imfinzi (durvalumab), in a phase III trial in patients with certain types of nonsmall cell lung cancer.

What makes these Incyte deals stand out is that a large, publicly traded biopharma company, Incyte Corp. turned to me and my firm repeatedly to craft successful collaborations with other large pharmaceutical companies in their efforts to better treat cancer by developing therapies that combine two or more drugs owned by different companies. This "combination therapy" approach to cancer is at the cutting edge of clinical oncology. And these collaboration deals are complex because they involve regulatory and intellectual property issues for valuable products.

In September 2016 we advised one of our longtime clients, SciClone Pharmaceuticals, on a licensing agreement with Soligenix, granting SciClone the right to develop, promote, market, distribute and sell a drug treatment called SGX942 (dusquetide), which is being investigated as a treatment for oral mucositis in patients with head and neck cancer, in the People's Republic of China, including Hong Kong and Macau, as well as Taiwan, South Korea and Vietnam. This deal included the purchase by SciClone of $3 million of Soligenix's stock. Earlier, SciClone also engaged us on a transaction with Ability Pharmaceuticals SL of Barcelona, Spain, under which SciClone in-licensed Greater China rights to the solid tumor drug candidate ABTL0812 in a deal worth potentially $20 million.

(Again,) these SciClone deals demonstrate how a U.S.-based specialty biopharma firm turned to us repeatedly to craft successful licensing agreements to enable the client to develop and commercialize western pharmaceutical products in China and other Asian countries.

In July 2016 we announced that we had advised Jounce Therapeutics Inc., in a strategic

collaboration with Celgene Corp. to develop and commercialize immuno-oncology products. Jounce received $225 million upfront and is eligible to receive up to $2.3 billion in development, regulatory and commercial milestones across all programs reaching commercialization, plus profit-sharing in the United States and tiered royalties on ex-U.S. sales. This deal is worth up to $2.6 billion. The New England VC Association named this matter its Transaction Deal of the Year.

What makes this deal stand out is that it's an example of a well-funded, but very early stage biotechnology company located in Cambridge, Massachusetts, coming to me and my colleagues at King & Spalding in San Francisco to handle one of the largest biotech partnering deals of its type.

All of the above deals also demonstrate a key sweet spot for King & Spalding in the life sciences area here in California: With substantial in-house biopharma experience in my own background and my colleagues' backgrounds as well, we excel at structuring deals to get drugs developed and commercialized. This operational savvy is what sets us apart.

With which clients do you have the longest relationships? How far back do those relationships go?

Biotech is a small world. I trace many client relationships back to my time as senior corporate counsel for PDL BioPharma over a decade ago. My former PDL colleagues became clients at companies like Five Prime Therapeutics and Jounce Therapeutics. Most recently, for example, in representing Dermira, I was once again working with CFO Andrew Guggenhime, another former PDL executive.

Why do you think clients come back to you? What can they get from you that they don't get from someone else?

King & Spalding's Life Sciences team in California, though not as large as those of other firms out here, regularly notch significant, high-value deals—such as the Dermira deal in August and my colleague Geoff Leonard's recent $300 million deal for Apama Medical—that are on par with deals by those other firms. And as I mentioned earlier, King & Spalding is particularly skilled in commercialization work, which is complex and requires expertise across disciplines on things like patent prosecution, government relations, licensing and collaboration deals, clinical trial design, and FDA regulatory and enforcement issues. Not a lot of firms can call on the level of expertise on FDA regulatory issues that King & Spalding can. And personally speaking, I think clients appreciate that I've served as senior corporate counsel of a life sciences company myself, because I know the kinds of issues that are of concern to growing life sciences companies. Similarly, my corporate colleague Stephen Abreu spent several years in-house as an industry contracts officer at UCSF, and one of my FDA/regulatory partners, Gary Messplay, spent five years at Eli Lilly and Co. We understand the pressures, goals and timelines our clients are under because we've experienced them ourselves.

What's more important in the current market and why: offering bespoke services or being efficient?

Can I say both? I think our clients want—deservedly—to receive guidance that is fully tailored to their needs, and they want it delivered on a swift timetable. We try to use templates and model agreements when possible, but every deal is different and there are almost always bespoke solutions that we have to come up with. I think the key deliverables of quality and efficiency that we strive to provide can be summed up in one word: value. If our knowledge, skills and experience add value to a client's business, then I feel we have delivered on our core promise as corporate lawyers.

Outside your partners, who is another corporate lawyer you admire and why? Howard Clowes, of DLA Piper. Howard, who I worked closely with when I was in-house at PDL Biopharma and since, is the consummate professional. He is knowledgeable, dedicated and cares deeply about his clients. But beyond that, and what makes Howard special is that he is a gentleman through and through.

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