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R&D – Lifeblood Of The Life Sciences Industry

*The Editor interviews **Jonn R. Beeson** and **Kevin B. Espinola**, Jones Day. Both attorneys counsel a broad range of companies on corporate and transactional matters. They are currently engaged by SAP to complete a merger with Sybase valued at $5.8 billion.*

Editor: Please describe your backgrounds for our readers.

Beeson: During my 14-year practice I have had a significant focus on mergers and acquisitions, but that focus has been supplemented by corporate finance, SEC compliance, corporate governance and counseling representation. I have a broad background in representing companies generally and understanding the issues that companies face. In the area of mergers and acquisitions, I have practiced across a broad range of industries, but my most significant deal concentration has been in the life sciences industry. In that area, I have represented a wide range of companies such as Amgen, Allergan, Abbott Laboratories, Avanir Pharmaceuticals, Biomarin, Beckman-Coulter, Celgene, MedImmune, VNUS Medical Technologies and many others.

Espinola: Like Jonn, my practice focuses on representing a wide range of public and private companies in mergers and acquisitions. As part of my practice, I also represent public and private companies on day-to-day corporate matters, including SEC compliance and providing corporate governance advice. On the M&A side, my 13 years of practice have focused heavily in the life sciences area. Over the years, I've represented Amgen, Celgene, CIMA Labs, ICOS, K-V Pharmaceutical, Medicis Pharmaceutical, MedImmune, Biomarin, Watson Pharmaceuticals and others. We are attracted to life sciences M&A work because of the complexity of the issues involved and the overall activity and excitement in the industry itself.

Editor: Describe Jones Day's capabilities and experience in the field of life sciences M&A. How does your firm's approach differ from that of others?

Jonn R. Beeson

Kevin B. Espinola

Espinola: Jones Day has a widespread M&A group, from California to Japan. Every office has M&A specialists and a subset of that group has life sciences expertise. Life sciences expertise reaches beyond M&A, penetrating all areas of focus and practice. For example, our tax group is very experienced in helping our life science companies in structuring and advising on tax matters. One of the things that makes Jones Day unique within our profession is our guiding principle – "one firm worldwide." This is more than a slogan for us at Jones Day – it is a way of life. What it means for our clients is that we will bring the best to bear for every client in terms of the right resources anywhere in the world and at a moment's notice. All of our offices are happy to help on any transaction because of the way our firm is structured. Our people are recognized and rewarded for providing great client service, rather than rewarding the person who brings in the deal or placing the individual's interests above the client's or the firm's interests. The focus at Jones Day is on who are the right people to manage the deal for the client; who will generate the best result for the client.

Beeson: In response to your question about both life sciences and M&A, when completing transactions, clients are looking first and foremost for outstanding M&A counsel. Jones Day has counseled clients on more M&A transactions than any other firm in every quarterly period during the last ten years. That is a statistic that we are very proud of. Because of this experience, we have huge resources within the firm to tap into. In the life sciences area we also have great support functions. Kevin mentioned tax. Also, our IP counsel are routinely involved in licensing transactions, patent prosecutions and joint ventures. In performing due diligence on a transaction, they can assess issues from the perspective of a counselor that has been preparing those same types of agreements and is concerned about the same types of IP issues, whether there is freedom to operate under a particular patent or whether a particular patent's claims would be valid. On the antitrust side we have a world-renowned antitrust department. Our antitrust lawyers are routinely hired on matters to provide antitrust counsel, even if we are not principal corporate counsel on a transaction. We also work with our private equity and venture folks who are on the ground floor when evaluating IP. Bringing all these resources to the table allows us to provide significant value to our life sciences, and other, clients.

Editor: What has the "batting average" been over recent years in getting mergers approved – with and without divestitures?

Espinola: From my perspective, on matters that we have worked on the batting average has been extremely high in getting approval from the antitrust regulators. Antitrust is a unique animal in that it is very field and fact specific. Before we can answer a client who wants a ballpark answer as to its prospects for antitrust approval of a transaction, we ask him to educate us about his business and that of the target company. It is key that everyone understands any overlaps between the products of prospective acquirer and the target. Typically, we gather the facts about the companies first, and then we help them assess the antitrust risks and whether we think the trans-

Please email the interviewees at jbeeson@jonesday.com or kespinola@jonesday.com with questions about this interview.

action poses the need for any divesture requirements in order to obtain antitrust approval. Fortunately for M&A lawyers at Jones Day, we have the best antitrust practice in the world, with a significant amount of experience in the life sciences area.

Beeson: That is why it is really important to have antitrust counsel familiar with the subject area in current deals. Antitrust counsel needs to be able to dig in and understand what the products are and, in some cases, what the science behind them is and how they are going to be used in the marketplace so that we can then appropriately communicate with the antitrust regulators, whether in the U.S., the E.U. or some other jurisdiction, in order to educate them on why this isn't a problem from an antitrust perspective or where the potential areas of overlap are and what the market concentrations are in those areas of overlap.

Editor: What are the special concerns in these deals regarding IP valuations and licensing relationships?

Espinola: While I am not a financial expert**,** for those transactions involving acquiring or licensing intellectual property rights, what acquirers will look for in intellectual property rights is an understanding of the profile of the patent portfolio of the company with respect to each product, the length of patent life associated with those products, the ability of the buyer to take its existing patents and combine them with the products and patents of a target entity. The stronger the patent portfolio and the protections stemming from that, the more likely a buyer is going to be willing to pay full value for the assets.

Beeson: One of the things that we're seeing is a significant uptick in transactions where the acquirer is buying pipeline, i.e., products that are in very early stages of FDA approval or still in the clinical phase pre-FDA review. The potential for these products is not fully known and must be assessed and evaluated by the buyer. For example, Kevin and I earlier this year represented Celgene in connection with it's acquisition of Gloucester Pharmaceuticals, and in that transaction Celgene was buying pipeline products. That transaction is structured with earn-outs and contingent payments into the future to help bridge the valuation gap. If a product doesn't perform as expected, the buyer doesn't end up completely overpaying for the product while if the product does perform as expected, the seller can then get full value.

Espinola: It's a little more difficult not to pay full value for products in the pipeline of a public company, whereas if a company is acquiring a private company, the acquiring company can be much more creative in the consideration that it's offering, including offering milestone payments and other forms of contingent consideration.

Editor: How is a target company's pipeline portfolio assessed in terms of its valuation?

Beeson: Usually the client has a sense of intrinsic value based on its internal business models and similar transactions in the marketplace. It comes down to looking at the quality of the R&D functions the target company performs, the breadth of the portfolio or just the particular profile of a specific product and how it fits into the buyer's portfolio or R&D function. From a financial perspective we're seeing a lot of contingent payments being made because of the uncertainty in many evaluations. As potential buyers assess the target and the products or the devices that a target may have, the buyers agree to share upside when they are able to see its success in the market. Buyers who have cash available today can pick and choose the best portfolio products on very favorable terms.

Espinola: Another interesting aspect of life sciences transactions is the R&D capability of a target. It is one important and sometimes overlooked element in these deals. Companies want to continue growing, and one way to grow is through acquisition and the other is through internal product development. If you have a talented R&D group that comes with the products you're acquiring, that's a significant bonus. Companies like Amgen, Celgene and Allergan are strongly motivated to serve their patient population and have a strong desire to acquire and internally develop products that will enhance lives of their patents. The life sciences industry is driven not only by the bottom line, but also by meeting patients' needs and making patients' lives better.

Editor: Why is it that the pharma, biotech and medical device industries are more actively in the merger business then other industries?

Espinola: One of the obvious reasons for the urgency is the product life cycle and the time to market. If a pharma company can find another company that has a head start in developing a product that would meet patient needs, then at the right price it makes sense to acquire that company as opposed to investing internally in R&D. Like any industry, management of life sciences companies are under constant pressure to produce results on a quarterly basis, and acquiring products and companies is often a component of their growth strategy.

Beeson: Life sciences mergers have definitely been on the rise, being one of the most active areas even during the recession. The re-advent of blockbuster mergers such as Pfizer and Wyeth and Merck and Schering-Plough are recent examples. On the biotech side there has been a lot of activity as well. Now that financing is freeing up, we should see a continuation of merger activity.

I would add that on a macro level the industry has been affected by developing prescription trends and intensifying generic competition and a limited number of pipeline products. As a result, pharma companies are going outside their internal R&D efforts to fill those pipelines. In other cases their R&D efforts may have been focused on a particular area, and they have now understood that complementary products, which they can acquire, might allow them to develop synergies with their product portfolio.

Editor: What special concerns under the Obama administration have come about in this space regarding antitrust enforcement?

Beeson: It really comes down to the unique aspects of the companies that are involved in the transaction – what the overlap has been. I am hearing from our antitrust counterparts that they have some concern over increased enforcement and regulation on the antitrust side, but that is not unique to life sciences.

Editor: Do you see greater consolidation in these industries as a result of the recently enacted health-care legislation? What about the need to effect economies of scale as more barriers arise and there is greater price competition from abroad?

Beeson: We haven't seen the full effect of health-care legislation. Again it goes back to pricing pressures, which have been placed on health-care companies and particularly the pharma companies for some time now. Those pressures are only going to increase. If companies wish to continue to maintain the significant growth they have experienced over the past 15 years, they will need to broaden their existing product portfolios, tucking more products into their sales force's bags that are complementary.

Espinola: I agree with Jonn. I think that M&A in the life sciences is more global than ever before. There are some advantages to acquiring companies overseas. Often the regulatory regimes, the FDA's counterparts, are a little more flexible, granting quicker approvals. Products that have not been approved in the U.S. can be reviewed prior to their introduction for FDA approval here.