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WATCHING BIOTECH GROW UP

BY DAVID MARCUS

Alan Mendelson has seen almost the entire development of the biotechnology sector. As a young lawyer at Cooley LLP in 1980, he worked on the incorporation papers for AmGen Inc. (AMGN) which went on to become one of the dominant players in the industry. By the time Mendelson, now 67, moved to Latham & Watkins LLP in 2000, he was working almost exclusively for biotech companies and had become one of the leading lawyers in the area.

Mendelson continues to draw upon the network of entrepreneurs he began building in the 1980s. Earlier this year, he advised Kythera Biopharmaceuticals Inc. (KYTH) on its $2.1 billion agreement to sell to Allergan plc (AGN). Mendelson first met Kythera CEO Keith Leonard Jr. when he was AmGen's vice president-Europe. Mendelson also knows Dennis Lanfear, the CEO of biosimilars company Coherus Biosciences Inc. (CHRS), from his time at AmGen.

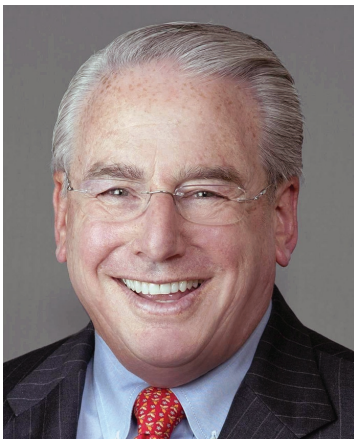
One of the client companies Mendelson is most excited about is OncoMed Pharmaceuticals Inc. (OMED), whose CEO Paul Hastings Mendelson met when he advised Axys Pharmaceuticals Inc. on its 2001 sale to Celera Corp. Hastings was the CEO of Axys at the time.

Despite his deep network of connections in the industry, Mendelson says he began to worry about the future of his practice during a long lull in IPOs after 2007. But thanks in part to the JOBS Act, the biotech IPO market has come back, and Mendelson has worked on at least eight IPOs since the law's passage, including those of Kythera and OncoMed, as well as on a range of other transactions, including two venture capital financings for Coherus and a deal in which OncoMed agreed with Celgene Corp. (CELG) to co-develop and commercialize as many as six anti-cancer stem cell product candidates.

Mendelson, who graduated from the University of California at Berkeley in 1969 and Harvard Law School four years later, is on the boards of the California Healthcare Institute, a public policy and lobbying organization for the state's biotech industry; the Scripps Research Institute; the UC Berkeley Foundation and the UC Berkeley Department of Chemistry. He's also a member of the UC Innovation Council, which UC system President Janet Napolitano formed last year to advise her on technology and entrepreneurship initiatives.

The Deal sat down with Mendelson in his Menlo Park, Calif., office in July to discuss his career, the impact of the JOBS Act on the IPO market, and the implications of the Affordable Care Act for the sector. Excerpts from the conversation follow.

The Deal: How did you get into biotech?



ALAN MENDELSON LATHAM & WATKINS LLP

Alan Mendelson: Total luck. I was a first-year partner at Cooley, and a senior partner at the firm, a guy named Edward Huddleson, had been on the board of Raychem Corp. with a guy named Bill Bowes for 20 years. Bill was transitioning from being an investment banker to being a venture capitalist, and he and another guy came to see Ed. And Bill said, "We think there's room for one more biotech company." This was at a time when there was Genentech, Biogen, and about three others. Ed was looking for someone to do the organizational documents. I joke that I was the only young partner who didn't go out to lunch that day, and so I got what turned out to be Amgen.

I did the incorporation of Amgen in April 1980. About eight months later, Ed had a second startup company, Acuson, which was going to go into the ultrasound diagnostic business. For many years, Acuson was the leading radiology ultrasound company in the world, and was ultimately sold to Siemens in 2000. Within eight months, Ed gave me two companies that were major drivers in the life sciences industry.

At Amgen, I hit it off with George Rathmann, the founding CEO, who was without a doubt one of the most important people in my life. AmGen's initial general counsel, a guy named Robert Weist, was a patent lawyer by training, and he recognized he needed help doing deals, and so I did every major deal that AmGen did in the first 10 years of its existence. When Bob stepped down as general counsel in 1989, I served as general counsel for a year. Gordon Binder, the CEO at that point, asked me to do it for a month or two, and then kept stalling me, hoping that I would leave the law firm and move down. For a variety of reasons, I didn't think that was appropriate to do.

Some people don't like being lawyers in a law firm; they struggle with the pressures -you have to produce business and keep active. But I was lucky because I recognized what I was good at. So while becoming the general counsel of Amgen could have been more significant financially, I knew who I was and what I liked doing, and I knew if I took the job at AmGen I would have to give up all of my other smaller biotech clients, and I didn't feel comfortable doing that. I liked being the outside lawyer.

What was the effect of the JOBS Act on biotech?

In my self-evaluation in 2009 or 2010, I was lamenting that my practice was going away, because all these companies I had taken to a certain point were being sold. There weren't so many new ones, and there weren't many IPOs.

One of my partners, Joel Trotter, was on the task force that wrote the JOBS Act. As Joel would brief me about things, I kept saying to him, "This is not going to have much impact." But it did for a variety of reasons. One, the ability to file confidentially was incredibly important to an industry where success at getting deals out was not assured. The JOBS Act was signed in April 2012. If you look at the number of life sciences IPOs in the few years before that, it was very small. Even for companies that people agreed were quality companies, there was the risk that you would file and you wouldn't be able to get the deal done. Filing confidentially was a big deal because failing publicly is something that venture capitalists and the management team don't like to see.

The JOBS Act also allowed companies for the first time to test the waters. This is what turned out to be the most significant thing. The ability to test the waters allowed the company that was on file to go out and meet with institutional investors multiple times. It gave them a sense of the management team and the science explained multiple times, and if you met with them within a few weeks or months after your initial meeting, it allowed them to ask if you'd hit the milestones you told them about. It gave people more comfort in deciding to invest in the space. The JOBS Act also made some of the disclosure obligations and whether you have to comply with some of the Dodd-Frank obligations as quickly a little easier.

That legislation was a significant factor in contributing to a lot of capital raising in the industry over the last three years. Capital is critical, more than in perhaps any other industry, because it costs so much to bring a single drug to market. If you can't raise that capital, the dream ends. I think it ensures that the U.S. will continue to be the leader in biotechnology, which I was really worried about five years ago.

What's the relationship at this point between academia and the business of biotech?

The Cohen/Boyer patent [for recombinant DNA technology] came out of the University of California-San Francisco, and that was the first of many developments that have translated into commercial products, both at universities and at private institutions like the Gladstone Institute or the Scripps Research Institute. They do incredible, cutting-edge basic research. They're not very good at taking it to the next step. Taking that basic research and translating it into products is something that companies are typically better at doing.

That core research that universities and private institutions like Gladstone and Scripps do has to be the continuing driver for the industry. We'll see whether Congress ultimately passes this 21st century initiative that the Republicans have pushed, because one of the elements of it is more funding for NIH, whose funding levels have declined over the years. NIH funding is critical to those institutions. If you don't fund that basic research, on the back end you won't get as many new products.

We're in a period of extraordinary transaction ferment in healthcare generally, much of which is driven by Obamacare. What has the effect on biotech and pharma been and how has it affected even which companies are funded and which drugs are developed?

In health insurance, in hospital management, the Affordable Care Act has had a major impact and is driving consolidation, certain kinds of investment and practices that could be harmful to the pharmaceutical industry. You see that in the controversy over Gilead Sciences' hepatitis C products and the $1,000 pill, and the refusal of Express Scripts to pay for it. Is that the ACA, or is it people who manage access to drugs having the economic power to say no?

There's no question the impetus of the ACA is to put cost

pressures on companies that are selling products. Certainly, with the classic therapeutic [drug] that's going to be reimbursed, companies have to worry about getting out of formulary, about reimbursement, about how to market the drug and not run afoul of fraud and abuse legislation. Those are real issues.

For the clients that I work with, for the most part, it hasn't caused them not to be funded, it hasn't caused them to not pursue significant diseases, particularly in the cancer area. My personal view is that the ACA hasn't had that significant an impact on therapeutics. In the device space, I think that the combination of the device tax that was part of the ACA and the inclination of the FDA to force device companies to more classic clinical trials has extended the timeline for getting approval of those products, and I think it's clear that the device area has been less than robust over the last few years.

There have been fewer companies being formed, and I keep hearing stories about venture capitalists who are focused on devices getting out of the business. Even my most successful [device] company Intuitive Surgica-which makes the Da Vinci robotic surgical system-even for them getting a particular accessory approved today takes at least a year longer than it did in the early years of the company, and that's a reflection of the FDA processes.

One of the things they face, and I think all the companies that have major capital equipment products in the device space face, if you look at where hospitals are spending their money, yes, they'd like another Da Vinci system, but they need to put billions of dollars into IT products and systems to better manage the delivery of healthcare services. Where the ACA has had some impact is on driving healthcare IT development much more so than was true five or 10 years ago. And that in turn will impact how many Da Vinci systems hospitals can buy.

One way or another, we're going to get a new administration in January 2017. How do you think that will affect the FDA?

Notwithstanding what one might have expected, and not withstanding what the Republicans will always say about Barack Obama, my personal view is that the FDA has been much better under the last seven years than it was under George W. Bush. Part of that was that there was some stability in the leadership of the FDA. Margaret Hamburg came from the congressional side. She worked for a congressman who was a pariah to the industry, and yet she, I believe, set the right tone. Absent some right-wing crazy or maybe a left-wing crazy becoming president, which I don't think is likely to happen, I think the agency will be constructive. I don't think it's likely to change dramatically.

You mentioned earlier a huge demand for healthcare IT, but are there other areas where you're seeing VCs focus?

Tools. I've got a new tools company helping the industry much like Applied Biosystems in the early days of AmGen and others that helped provide the sequencing machines that really were a step forward. Getting the full potential out of CRISPR technology- [Editor's Note: CRISPR technology allows for the editing of genetic sequences and can, in theory, cure genetic diseases if applied to tissue]-is going to take additional scientific development, and there are risks associated with it in terms of ethical issues, because if you take the technology associated with it to its perhaps logical extreme, you could have designer babies. That scares a lot of people, and it should. But, putting aside how scientific institutions and companies should self-regulate, capturing that potential is going to take sophisticated tools.

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