KAYE SCHOLER

Emerging Trends: Maintaining the Competitive Advantage in Human Genome Technology

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When it comes to DNA analysis technology, accept the fact that you are going to be sued. But if your primary strategy is to protect your commercial position through litigation, as opposed to innovation, you are going to face a rough road.

Q. Can you tell us a little bit about your background and some of the work you are currently doing?

I started life as a general commercial litigator and as a prosecutor in the US Attorney's office. But I morphed into a patent litigator when my mentor, Barbara Caulfield, hired me to run an in-house trial team at Affymetrix. At Affymetrix, I really enjoyed being inside a company and close to the scientists, people who were so well-known in the nucleic acid field, on a day–to- day basis. It was an exciting time to be there. The company was on the cover of *Science* in 2007! I have certainly litigated more than just patent cases in my career, but at Affymetrix, I was able to immerse myself in the patent technology field and gain a real familiarity not only with the law but with the economics of that industry, which continues to be helpful.

Since coming back to private practice at Kaye Scholer, I have had the pleasure of continuing to work with many of the leaders in the nucleic acid analysis field, including many old friends and colleagues from what I fondly refer to as the "Affymetrix Diaspora." For example, we have enjoyed working with former Affymetrix colleagues at Raindance and Pacific Biosciences.

We, of course, continue to represent Affymetrix and recently won two important victories for them in long-pending cases. In a case Enzo filed against Affymetrix back in 2003 in New York, we won summary judgment of non-infringement. And in a case against Affymetrix in Boston, the Court recently issued its claim construction which resulted in the plaintiff stipulating to non-infringement of its patent.

We have also expanded on our knowledge to work for other industry leaders in the nucleic acid field. We represent Sequenom and Complete Genomics. Recently, we achieved a victory for our client Complete Genomics. In a well-reasoned 44-page opinion, the Court found that the alleged inventor of the patent in suit had not exercised diligence in reducing his invention to practice and that, therefore, a prior art publication invalidated all of the asserted method claims in the patent.

Q. What do you enjoy most about practicing in this field?

I love having the opportunity regularly to interact with my client's scientists, who are such masters in their fields, to learn and get into the details of the latest technology. I continue to be amazed by the innovation that my clients and others in this field are driving. For example, my client Complete Genomics has dramatically reduced the cost of sequencing whole human genomes. Or there's our client, Sequenom, which in the fall of 2011 announced the commercialization of the first test to detect Down Syndrome using only the cell-free fetal DNA present in a mother's routine blood sample, which will replace the more invasive and risky invasive procedures such as amniocentesis.

When I think about the fact that the first draft of the human genome – delivered in 2001 by an extensive public-private partnership after about a decade of work – cost an estimated $3 billion, and that today the price for a whole human genome sequencing is under $5,000 (and plunging rapidly), not to mention the potential medical uses to which such information can be put, I feel like I am witnessing – and at least indirectly participating in – something truly profound.

Q. How has your practice in this area changed in the last ten, five, one year(s)?

Ten years ago, researchers were still mapping the human genome, and many of the ideas our clients are working on now were not even viable. The technology innovation cycles have sped up. The volume of IP litigation continues to increase.

Q. In your opinion, what are some of the biggest regulatory challenges facing DNA research today?

For starters, I think as the ability to acquire genetic information increases, and cost decreases, and it becomes almost routine for all of us to have access to that information, some controversy over how that information is to be used will occur. Privacy, certainly, is another issue that always arises and that continues to raise red flags for biotech and lawmakers. But the thing that I find the most compelling is that these huge, profound developments represent—objectively, relatively speaking—only a small shift in what's possible. Knowing whether your baby might have Down Syndrome or other genetic issues is not new. The thing that's changing is simply the scope, the cost, the ability for more people to get the information, more quickly, more cheaply, etc. Previously, only pregnant women over 35 thought it worth the cost to get tested for the Down Syndrome gene; testing costs have declined so much that perhaps soon pregnant women of all ages will be able to affordably and safely obtain this knowledge. In perhaps just a few years' time, all fetuses will have their entire genome sequenced. We have been living in an age where the ability to access information has become enormously easier and cheaper. Biology/genomics is just joining that party now.

The uncertainty of the regulatory environment also makes it difficult to raise money, fund new business and have confidence in your business plan. The recent *Prometheus* Supreme Court decision regarding the patentability of genes didn't fully address the situation. The unfortunate reality for everyone is that we are going to be litigating these issues for at least another three to five years. Any court decision you get, whether a loss or a victory, on either side of a *Prometheus* issue, is just going to be a step in the road. It will be a while until there is some stability on the issue of the patentability of genes and what that means for researchers and the companies/institutions that fund such research and any relevant medical applications of that research.

Q. What are some of the technological and financial challenges facing DNA analytic technologies?

The dramatic reduction in cost and time to access a very high volume of information is creating a couple of challenges. On the tech front, there is as much of an interpretation challenge as there is an access challenge. We're speeding toward Big Data, but so what? The issue is no longer so much being able to *get* the data as being able to understand what the data *means,* and then figure out what to do with that understanding. You may have genetic information, and that's great, but the next step – the interaction between genetics and disease, is still very complex uncharted territory. In this way, the technical problem marries up with the regulatory problem.

You want to sell directly to patients so they know they have a slightly higher risk of X, but then what? There is also the problem of perception. People don't really know how to measure statistical risk. People still fear flying more than driving, in spite of statistical evidence that the former is exponentially safer than the latter. The regulatory agencies are struggling with specific issues, but also the broader spectrum of: What does it mean to tell someone you have a slightly higher risk? What's next? And how should we be regulating this?

And perhaps the final challenge I'll mention today (though, of course, there are many more) arises in getting past the pure science and out into the real world where, for example, you face such issues as what the reimbursement scheme will ultimately be. A company can develop this knock-out new test, but will insurance pay for that test? Maybe not, or maybe not right away. It takes a couple of years to reach equilibrium as to price and reimbursement. It makes for an environment where there is interest on the part of larger companies to add new tests – or possibly new smaller companies who have created these tests – to their portfolios, but there is also a lot of wait and see.

Q. What would be your top advice for a fledgling – or even established – company or its in-house counsel in the biotech sector making its way through the complex legal landscape? What does it take to succeed and maintain a strong position?

Great question. As I was in-house, I would probably start by saying, "Look, I've sat in your chair." My first piece of advice would be to stake out your initial position. You need to think about the big picture and craft a long term five or ten-year plan. During this step, a lot of executives are thinking only about attracting initial investment and just getting their biotech company off the ground, but they need to do more, think ahead. You only get to do this once, so

you need to be very thoughtful about those early patent applications. Doing (and spending) too little is the wrong answer. But doing (and spending) too much is the wrong answer, too. It's a delicate balance.

Next piece of important advice: accept the fact that you are going to be sued. If you are developing any DNA analysis technology of interest that has real market potential, litigation is almost impossible to avoid. There are just too many people who have demonstrated that they are willing to assert their IP to protect their market position to realistically expect that you won't at some point be sued. One key to getting through it, however, is considering costs. As I think any good attorney should do, I routinely sit down with my clients and discuss this very practical issue with them at every step. You need to understand where the moving parts of the litigation are, the risk profile associated with those choices, and then make decisions that match your risk profile with the expense. Do we absolutely need to take ten depositions or will we limit to five? Do we need to file three dispositive motions or stick to our best one?

Finally, any companies that have been through the litigation mill more than once are probably starting to adopt the use of internal resources and their own vendor relationships to control litigation costs around the commodity aspects of litigation, e.g., document collection, production, and review. This may technically take money out of the law firm's pocket, but I'm a big fan of this trend and would encourage companies to consider these options as well.

Q. Interesting. So you've told me I (as a young and growing company in this space) can and should basically expect to get sued. Do I have to sue other people?

A. Maybe. But I'll tell you, in my opinion, if your primary strategy is to protect your commercial position through litigation, as opposed to innovation, you are going to face a rough road. You need to succeed in the lab and in the marketplace. Success in the courtroom can only be a secondary tool.

About Kaye Scholer LLP
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