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JUNE 2017

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FOCUS: LIFE SCIENCES

MCC INTERVIEW: Steven Maslowski / Akin Gump Strauss Hauer & Feld LLP

Changes in the Law Leave Litigators Dancing as Fast as They Can

Lawyers also await guidance from the FDA

Steven Maslowski, an IP litigator at Akin Gump Strauss Hauer & Feld LLP, handles cases on the cutting edge of life sciences. It's a complicated place to be these days, as the courts are sorting through changes in the law and litigators are waiting for guidance from the Food and Drug Administration. And it's all playing to the tune of something called "the patent dance." The interview has been edited for style and length.

MCC: In 2010, the Biologics Price Competition and Innovation Act (BPCIA), introduced as part of the Affordable Care Act, created an abbreviated pathway for the licensing of biosimilars. The so-called patent dance involves a complicated set of disclosures between branded biologic drug makers and companies seeking to market cheaper, biosimilar versions. How does the dance play out in practice, and what impact does the current uncertainty about it have on the strategic patent advice you give clients?

Maslowski: As to how it plays out in practice, I think the second part of your question sort of nails it. It's uncertain how the patent dance is really going to play out in any individual case. What we're seeing is that it plays out differently, case by case. It seems like, along the spectrum, we have essentially biosimilar applicants not complying with the patent dance at all, some companies seeking to introduce biosimilars that comply with some portions of the patent dance, and then at least some entities that have attempted to do what I'll call "full compliance" with the patent dance.

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In terms of how it's playing out, obviously it still remains to be seen what exactly must be done, and I know we're going to talk about the Supreme Court's input on that. But in terms of the strategic advice we give to clients, to be honest we represent companies on the innovator side of this issue, and the strategic advice that is really appropriate there is to just continue to seek enforcement, consistent with the statute and the provisions as written. Until there's more guidance, whether it comes from the court or the FDA through regulations, the innovator side is obviously seeking to have the BPCIA interpreted according to its plain language and the mechanisms that are defined there.

MCC: It sounds like what you're saying is that so far the BPCIA has led to an extended litigation dance that is still in process.

Maslowski: Yeah, I think that's fair. I'm not sure it's any different than any other congressional act that's passed that implements an entirely new statutory scheme. But your statement is correct in the sense of yes, it has certainly spawned litigation in terms of trying to understand the procedures that have been defined by Congress and it seeks to get more certainty there.

MCC: Various commentators have talked about "first wave" BPCIA litigation and what is seen as an impending "second wave." One commentator predicted that new first wave litigation and any second wave litigation will likely spin off a range of legal and regulatory issues that will keep litigators like you very busy for years to come. What is this all about, and how do you see biosimilar litigation unfolding in the next few years?

Maslowski: This whole process starts when the FDA accepts an application from a biosimilar applicant, which then opens the 20-day window for an exchange of information. Then, over the next six months or so, the parties exchange a number of things, ultimately arriving at a list of patents that will be included in this so-called first wave of

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litigation. Then the second wave comes via the 180-day commercial marketing notice that the applicant is required to provide that then provokes the second wave of patent litigation. This allows the innovator (the patent holder) to seek, for example, a preliminary injunction based on patents that had not been litigated in the first wave.

So, in terms of litigation unfolding in the next few years, I think a lot of the focus has been on the first wave and the initial issues there. There's a lot to be learned in the second wave, I think, and there will be a lot of unique legal issues that come out of that, including the question about injunctions, and the appropriateness of an injunction in that second wave will certainly be an interesting issue.

MCC: To clarify one thing: What you just described is really the patent dance we referred to earlier, correct?

Maslowski: Yes, I understand the patent dance to generally refer to the first and second waves, including the exchange of information that occurs there.

MCC: Now this year is expected to be extremely busy for biosimilar litigation. What cases are you watching at the trial and appellate levels, and what are their implications?

Maslowski: The one that everybody is watching is the U.S. Supreme Court case *Amgen v. Sandoz*. That really is going to provide a lot of guidance to everyone, as soon as we hear from the court. After that, my firm is involved in one of the earliest cases, I think the second case: *Janssen v. Celltrion*. For obvious reasons, we're watching that one. There are a couple of cases that are going to trial later this year that will be interesting. As we turn from some of the mechanisms, and the disputes about what the regulations really mean, and we turn to actually litigating these cases on the merits, in front of a jury, and see how they actually come out, that will be interesting. Amgen has a couple of cases that are scheduled for trial this year, including *Amgen v. Hospira*. Amgen's an interesting entity because they're on both sides of this equation. They are both a patent holder and an innovator, on the branded side. Then they're also seeking to introduce their own biosimilars, so Amgen has a unique perspective as it charts a course down this path.

MCC: You already mentioned the Supreme Court case: The April 26 Supreme Court argument in the consolidated cases of* Sandoz v. Amgen *and* Amgen v. Sandoz. *The court seemed to struggle with the complexity of the patent provisions of Obamacare and the procedural complexities underlying the litigation, at least according to SCOTUSblog. Where do you see the court going on those two key issues?

Maslowski: I'll start by saying that people a lot smarter than me have a hard time predicting this stuff, so I'm not sure I have any particular insight into where the court's going. But with respect to what I understood from the arguments, it's the same thing that the industry is faced with, which is trying to understand what the provisions mean, and what guidance is out there, in terms of how to properly interpret this act. As I understand it, for example, Justice Breyer had numerous questions and indicated that, in one way or another, there was a need for agency guidance on where the agency saw these provisions going. So I think, sort of like with the implementation of IPRs (inter partes reviews) and PGRs (post-grant reviews), having guidance from the agency itself, in this case the FDA, I think would be helpful.

I don't like to characterize the Supreme Court as struggling with anything. I think they are hard to read from oral argument, and at least I haven't seen anything that indicated that folks felt like this case was clearly going to come out one way or another. At the end of the day, they will do their best to interpret the plain meaning and the plain terms that are in the BPCIA and go from there.

MCC: You mentioned IPRs. As an alternative or supplement to patent litigation, biosimilar developers are turning to post-grant proceedings, such as IPR, at the U.S. Patent and Trademark Office. How do you evaluate the strategic considerations for clients in the use of such post-grant proceedings.

Maslowski: Being on the side of the innovator companies most of the time, it's usually a question of the reaction, from their perspective. Bringing an IPR or PGR, you're seeking to invalidate someone else's patent. So in terms of the broader strategic considerations for clients, it's really on a case-by-case basis, but at the end of the day we are certainly seeing an increase in the use of those procedures in an attempt to invalidate patents. And the use of the procedures comes down to a balance of the strength of, or purported strength of, your defenses – whether you think your prior art defense is your strongest, or whether it's a written description or enablement defense that you believe is your strongest, and whether you feel that there are benefits to taking a shot first in the patent office.

But at the end of the day, from a branded side, an innovator side, it's not a secret that those companies are not big fans of the proceedings at the patent office right now, in the sense that we're seeing some patents that cover multibillion dollar drugs go down in front of the PTAB [Patent Trial and Appeal Board] on a somewhat limited record with limited testimony. That's certainly a concern from the innovator's side of the equation. But we'll see how it plays out. The patent office is continuing to attempt to refine the proceedings and to improve what I'll call "the perception of fairness," the proper balancing of both the interests of the challenger and the interests of the patent holder, which I think is still a work in progress.

MCC: When President Trump chose Dr. Scott Gottlieb as his nominee for FDA commissioner, he turned to a long-time advocate of faster pharmaceutical innovation in general, and biosimilar development in particular. What impact would Dr. Gottlieb's approval have on your clients and their litigation strategies involving biosimilars?

Maslowski: I can't speak for any of my clients, and my comments shouldn't be interpreted or attributable to any of my clients, but I think everyone, regardless of the type of company, is in favor of faster pharmaceutical innovation. I do think the focus has to remain on that last word: innovation. Of course patient access to drugs is the top priority, and I know from reading a number of pieces about Dr. Gottlieb that that's one of his big priorities: getting patients access to drugs as quickly and as expansively as possible, and seeking to bring that innovation to patients faster.

With that in mind, however, we do need to continue to incentivize the stakeholders, who invest billions of dollars to try to bring these drugs to market in the first place. And let's be clear: A lot of money is spent on drugs that never come to market. So while the public seems to focus on approved drugs, biosimilar drugs and generic drugs – we need to keep in mind that the process needs to

remain such that companies, big and small, are incentivized to try to bring new and novel compounds and biologics to patients.

MCC: You recently settled a complex biologics dispute against Merck over PD1 antibodies used to treat cancer. You represented Bristol-Myers Squibb and Ono Pharmaceutical Company. Tell us about this case and what it means for immunotherapies for cancer, which once-weary pharmaceutical companies are now jumping into with both feet.

Maslowski: I can't talk about the case itself, but I can certainly say that this case, and the fact that it involved such a revolutionary area of technology – the idea of using immunotherapy to treat cancer, and the wildly successful results that have been seen from these therapies – was both exciting and humbling, quite frankly, to be involved with. The stories of patients who have been treated, who then continue to be able to lead a normal and full life, like I said, it's amazing to see, and it's a real privilege to be a part of.

MCC: I think that may be a good note to end on, because sometimes we observers see these cases as all about strategy and evidence and complex trials. But you're dealing not just with evidence but also with patients – with people – and I'm glad you brought them into the picture here.

Maslowski: I agree completely.